

**RISK REGULATION, MANAGEMENT
AND COMPLIANCE**

A report to the BRI Inquiry

by

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Executive Summary

1. Risk controls can be operated within organisations or imposed by external regulators. Controls can be applied at various stages in the development of risks and the realisation of harms – they can operate formally or informally, by means of rules or through other mechanisms such as accountability and review.
2. A variety of general regulatory methods can be used to control risks. These include: command and control; self-regulation; incentives; franchising; contracting or licensing; disclosure; state actions; liability laws; insurance mechanisms (Section 2.2.).
3. Different philosophies of risk control can be contrasted (Section 2.3). These include: technical and economic approaches as well as psychological, sociological and cultural perspectives. An important divide lies between those who think risks can be identified, assessed and predicted accurately and those who argue that this is often not possible and that risks have to be negotiated and constructed.
4. Within UK Government a wide variety of approaches to risk is adopted within and between institutions (Section 2.4). The Health and Safety Executive (HSE) has played a leading role in developing Tolerability of Risk strategies (which combine qualitative and quantitative aspects) but strongly quantitative approaches are encountered in some sectors (e.g. transport).
5. Risk assessment procedures are encountered across UK government but in some sectors (e.g. health and welfare) commentators have criticised regimes as being too strongly committed to anticipatory endeavours (Sections 2.5.10-16). Emphasis on assessing potential hazards, argue the critics, can prove expensive, infringe civil rights and lead to inflexibility and a lack of responsiveness (Section 2.5).

6. The use of blaming similarly gives rise to contention, with critics suggesting that systemic failures are often not picked up when risks are attributed to responsible individuals and blame is attached to these persons when things go wrong (Section 2.5.28).
7. Rules and guidelines that are designed to control risks may have little effect in some circumstances – particularly where professionals are committed to the exercise of judgement and the application of discretion in relation to specific issues (Sections 2.5.21-25).
8. The precautionary principle has been endorsed by a number of governmental bodies but has yet to be developed into a rigorous approach (Section 3.1). As indicated (in para 5, above) critics of precautionary or anticipatory strategies are quick to point to the limitations of such approaches.
9. Commentators and policy-makers debate whether risk controls should be 'rational' or 'social' – where the former approaches tend to found regimes on Cost-Benefit analyses and the latter normally emphasise participation and negotiation between lay persons and experts. In UK government it has been accepted in many circles that risk controls cannot be designed on a purely rational basis (Section 3.2.3). A number of participatory models are in the course of development (Section 3.2.4) but there is some tension between 'social' approaches and the rationalities involved in the Cabinet Office's current approach to regulatory risk assessment (Section 3.2.7).
10. Self-regulation by the professions is an important constraining mechanism in UK risk control but it is a mechanism often viewed with suspicion in spite of its frequently cited strengths (Section 3.3). Those strengths include the expertise of self-regulators; their knowledge of what the regulated will see as reasonable; the low costs of information gathering and the ability of self-regulators to act informally. Perceived weaknesses include: self regulators'; limited accountability; exposure to ministerial interference; vulnerability to capture; lack of independence and bias in favour of membership interests (Section 5.3.3.9-12).

11. In the health sector criticisms of professional self-regulation have led to increasing structuring with rules and greater bureaucratisation. There is some evidence, however, that professionals who are trained in, and used to, making judgements on the spot find it easy to exercise those judgements with freedom in spite of any relevant rules (Section 2.5.25).
12. Critics of professional self-regulation point to the need for external involvement in the governance of self-regulatory mechanisms and the NCC advocates a presumption against self-regulation (Section 3.3.13).
13. A number of factors affect a regulator's ability to secure compliance and these include: the regulatee's propensity to comply willingly; the strength of enforcement powers and sanctions available; the seriousness of the risks at issue; the visibility of breaches of the rules; the frequency of contacts between regulators and regulated and a variety of political influences (Section 3.4).
14. Compliance is measured with reference to such factors as: commitment to regulatory objectives, attitudes to compliance; record; quality of management; organisational ability to comply and treatment of staff (Section 3.4.4.3).
15. The inclination to comply may be affected by costs; self-interest (or self-preservation); the profitability of breaking the rules and running risks; a corporation's feeling of responsibility; a firm's aspiring to 'good citizenship'; reputation factors; perceived likelihood of detection; level of knowledge or risks; intra-organisational pressures; and competing organisational objectives (Section 3.4).
16. Achieving compliance may not produce the results that policy-makers desire. Those regulated may side-step the rules by 'creative compliance' strategies and defeat the policy objectives of rulemakers; the rules, moreover, may be ill-targeted and over or under-inclusive (Section 3.4.5).
17. Self regulation can be combined with external regulation to achieve strong accountability and independent complaints resolution processes. In such hybrid

forms the difference between self-regulatory and regulatory regimes may not be dramatic.

18. Good risk regulation regimes should be efficient and effective, accountable, open and fair. They must allow proper access to democratic, consumer and lay voices. Astute risk regulators intervene at the point in the development of a risk that offers the best balance of the above desiderata (Section 4.1).
19. Areas of professional judgement present special problems of risk management and special problems for 'command' or rule-based, regimes of control. Professionals often make decisions and policies that are of high importance, low visibility and high discretion. Professionals, moreover, tend to cherish their domains of judgement and will offer resistance to various control devices such as rules (Sections 2.5.23-25; 4.7).
20. This suggests that, in relation to risks from professional judgements, controls should emphasise openness, peer group scrutiny, incentive structures, training, cultural contexts and collective as well as self-appraisal approaches, rather than reliance on external rules and blame-based regimes. There may also be a case for emphasis on resilience, learning from mistakes and adjusting procedures rather than efforts to identify in advance the individuals and situations that are liable to produce risks.

1. **Introduction**

This report reviews current knowledge concerning the control of risks through regulatory and managerial devices. It outlines leading approaches to the control of risk in the UK, considers the factors that affect the securing of compliance with controls and pays particular attention to the role of the professions in limiting risks.

2. **Approaches to Risk Regulation**

2.1 **Risk Control Regimes**

Risk control devices are multi-dimensional and encompass a mixture of institutions, practices and ideas that are best characterised as risk control regimes.¹ Regimes, be they managerial or regulatory, tend to break down into components: first, the methods of collecting information concerning issues to be controlled; second, the means of policy or rule-making so that targets or goals can be set, and third, the systems for enforcing and securing compliance.

2.2 **General Control Strategies**

Risks can be controlled within organisations through techniques of management or they can be regulated by the imposition of constraints from outside the institution performing the primary function. (As will be seen below, the distinction between internal and external controls maybe clouded by hybrid or combined techniques.) We outline here the main risk regulatory strategies that are employed in modern government.² The main strategies are:

¹ See Hood et al (1999).

² For a review see Baldwin and Cave, 1999, chapter 4. Devices aimed at controlling competition are not reviewed here.

2.2.1 *Command and Control Regulation*

Traditional command and control regulation is characterised by the use of rules reinforced by legal sanctions. Required behaviour is stipulated, standards are fixed, unacceptable actions are defined and outlawed and penalties for non-compliance are set out. Command and Control regulation's strength derives from the use of law to designate what is acceptable. Its alleged weaknesses are that it involves high levels of intervention in management; it is marked by complex rules and 'red tape;' it conduces to capture of the regulator (insofar as the regulator relies on the regulated for the information needed to write and apply the rules); it is expensive to enforce and administer; it involves high standard and rule-setting costs; and it only demands compliance with a stipulated standard rather than the best level of risk avoidance that is reasonable in the particular context.

2.2.2 *Self-Regulation*

The State allows many professions to self-regulate. Proponents of self-regulation argue that it is marked by a high commitment to compliance on the part of those who are governed; that rulemakers and enforcers are well-informed (concerning inter alia the tricks of the trade); that informal and formal controls are easily combined and that such regimes involve low public costs. Critics urge that self-regulation tends to be seen as, and often is, secretive, unaccountable and poorly enforced. Critics also suggest that rigorous governmental oversight of self-regulation can lead to bureaucratic and cost duplications as well as policy confusions.

2.2.3 *Incentives*

Governments may control risks by adjusting economic incentives – as where hazards from leaded petrol are responded to with differential taxes for leaded and unleaded fuels. Such regimes are welcomed as involving low interference with managerial freedoms, as involving incentives to reduce risks to zero (not to a given standard only) and as requiring low cost enforcement. They are criticised

on the grounds that complex rules may not easily be avoided; that they assume a high degree of rationality from the regulated (whereas many risks flow from irrational, ill-informed actions) that predicting outcomes from given incentives is very difficult; that large regulatory lags (time delays) can be involved, and because they are politically contentious in allowing risk creators a free hand provided that they can afford to pay the relevant costs.

2.2.4 *Franchising, Contracting and Licensing*

Risks can be controlled by allowing risk creators to operate subject to stipulated conditions and by limiting the periods for which permissions are given. The advantages of such regimes are that potential practitioners can be screened to allow only suitably qualified parties to enter the sector. Sanctioning, moreover, is said to be strong because excessive risk creators or under-performers can be disciplined by the non-renewal of franchises, contracts and licences. The limitation of such controls is that those given permissions or licences may enjoy incumbency advantages (informational and operational) so that monitoring their activities and replacing them maybe expensive and/or difficult. The costs of such controls may also be high because those drafting the initial terms and conditions will require extensive bodies of information. There may, moreover, be problems of inflexibility insofar as the tight rules needed for effective control may not conduce to the development of new ways to control risks or meet markets. Where, on the other hand, terms and conditions are phrased openly, the attendant uncertainties may produce high costs to the state or to consumers.

2.2.5 *Disclosure*

Risk controls can be imposed by requirements that operators or service providers, supply information to the public concerning their products and businesses. Consumers or state institutions may then decide whether to purchase high risk/low cost or low risk/high cost products. Such controls involve low levels of intervention, can be said to be highly democratic and may be useful where risks are low and more strongly preventative measures are not called for. Their weaknesses are that information users may make mistakes and undue risks may

be run; price may prevail over rational risk assessments; and the information produced may be sparse, unreliable or unintelligible.

2.2.6 *State Action*

Where the State does not trust the private sector to limit risks it can take direct action – for example by building industrial premises with good ventilation systems and renting these to manufacturers whose processes are known to involve the emission of harmful dust particles. Such actions may ensure that risks are properly controlled but there are potential problems. The public sector may not prove conspicuously good at maintaining and operating such premises. Public expenditure is involved, the incentive to innovate may be low and access to such premises may distort competition in the marketplace.

2.2.7 *Rights and Liabilities Laws*

If the State gives certain parties the right not to be exposed to stipulated risks, and the right to sue risk creators or harm causers, this may control risks in a manner that involves low public expenditure. As a risk limitation system, however, it encounters a number of difficulties. Enforcing such rights may be expensive and establishing who created which risks may be difficult. Victims may be unwilling to go to law and risk creators may, accordingly, be under-deterred. Where risk creators are insured, their own incentives to control risks may be limited and, as an overall strategy, such laws may be inappropriate where risks are high and preventative measures are called for. If, moreover, the risks at issue tend to be caused by irrational, ill-informed behaviour, the deterrence mechanism will not operate as an effective restriction on the creation of risks.

2.2.8 *Insurance Mechanisms*

Private or public insurers may operate to control risks by imposing conditions on the supply of insurance cover and by using economic incentives, such as deductibles, to encourage proper risk-reducing behaviour. (Fire risks, for example, are controlled by insistence on the fitting of sprinkler systems).

Insurance controls operate effectively, however, only if risk discrimination is possible and in some sectors there may be a paucity of incident statistics available. Where risks are spread by insurance there may be an excessively low level of deterrence of risk creators. Insurers may not be attuned to the inspection procedures necessary to make such controls operate well, but where they are, such regimes may come to resemble command and control systems with all their familiar problems plus lower levels of public accountability.

2.2.9 Often multiple strategies are used to regulate risks. For example, state regulation may attempt to co-opt corporate risk management systems through enforced self-regulatory regimes or the state may delegate regulation to third parties. Examples of the former would include the HSW Act and the latter strategy is seen in the duties imposed on airlines to check passports.

2.3 **Philosophies of Risk Control**

2.3.1 In order to control risks it is necessary to understand how risks are, or should be, perceived, assessed, quantified and responded to.³ A number of broad approaches can be distinguished.

2.3.2 *Technical perspectives*, as seen in actuarial approaches, look to the relative frequencies of events amenable to 'objective' observation (e.g. numbers of deaths) and assess probabilities by extrapolating from statistics on past events. Similarly, in epidemiological studies, populations exposed to a risk are compared to control populations and attempts are made to quantify relationships between risks and harms. Engineering approaches attempt to assess the probabilities of failures in complex systems even where there is insufficient data on the given system as a whole. Fault-tree or event-tree analyses are used and the failure probabilities for each component in the tree are evaluated before all such probabilities are sought to be synthesized.

³ See generally, Royal Society, 1992; Krimsky and Golding 1992, Baldwin and Cave, 1999, Slovic *et al* 1978.

2.3.3 Technical approaches, in general, seek to anticipate harms, average events over time and space, and use relative frequencies to specify probabilities. They are associated with the view that decisions on risks can be made on the basis of objective evidence that can be treated mathematically to produce a numerical result. This perspective has been used not merely to assess the quantum of risks but also their social acceptability. This latter application has, however, been much criticised by social scientists⁴ on the grounds that what persons perceive as undesirable depends on their values and preferences and that technical strategies tend to undervalue objectives such as equity, fairness, public participation and resilience.⁵ Objectors have also contended that judgements are involved in selecting, defining, and structuring the 'risk problem' and that these influence subsequent conclusions.⁶ Such criticisms have eroded not only the idea of objectivity in risk assessment but also the presumed difference between expert and lay public views of risk – the critics of technical approaches hold that both technical and lay assessments of risks involve human interpretation, judgement, and subjectivity.⁷

2.3.4 The *economic perspective* on risk transforms undesired effects into subjective utilities so that comparisons between different risks and benefits can be made using the currency of personal satisfaction. This provides a means of integrating risk analyses into decision processes in which various costs and benefits are assessed in pursuit of the allocation of resources in a way that maximise their utility for society.

2.3.5 Central difficulties for the economic approach⁸ are how individuals' subjective utilities can be aggregated; how costs imposed on parties beyond the immediate transaction can be taken on board; how future risks are accounted for; how monetary units can be placed on risks of health losses or deaths; and how utilitarian, wealth-maximisation or contractarian ethics can be justified. The

⁴ See e.g. Douglas, 1985; Renn, 1992; Mazur, 1985; Beck, 1992 Clarke, 1989.

⁵ Short, 1984. For official acceptance that risk regulation 'cannot be reduced to a set of rules based on universal formulae for quantifying and valuing costs and benefits' but involves ethical and perceptual problems see HM Treasury 1996.

⁶ See Vlek and Stollen, 1980; Cranor, 1993.

⁷ Royal Society, 1992; Fischhoff, 1989.

⁸ See e.g. Slovic, Fischhoff, and Lichtenstein, 1979; Baram, 1980.

economic approach thus begs serious distributional questions and makes contestable assumptions both about the rationality of market decisions and concerning the freedom of choice and quality of information encountered in the market place. It is said to involve a range of judgements and modelling assumptions and to be highly prone to manipulation.⁹ It, moreover, involves a bias towards the wealthy since all methods of placing a monetary value on life (e.g. making reference to willingness to pay, insurance, calculations, or court awards) are in some way based on the wealth of the victim and impliedly encourage saving the lives of the wealthy and imposing risks on the poor.¹⁰

2.3.6 The *psychological approach* to the definition and measurement of risk focuses upon individual cognition and such questions as how probabilities are perceived; how preferences relating to risk can be accounted for and how contexts shape individuals' risk estimations and evaluations. Thus, several factors, have been said to impinge on perceptions of seriousness of risks.¹¹ These include:

- catastrophic potential;
- degree of personal control over the size or probability of the risk;
- familiarity with the risk;
- degree of perceived equity in sharing risks and benefits;
- visibility of the benefits of risk taking;
- potential to impose blame on risk creators;
- delay in the manifestation of harm;
- voluntariness with which the risk is undertaken.

2.3.7 Risk, within such an approach, is seen as a multidimensional concept that cannot be reduced to a mere product of probability and consequences. Such a focus on the individual is, however, said to underplay the extent to which perceptions are affected by group, social, institutional, and cultural factors.¹²

⁹ Self, 1975.

¹⁰ Otway, 1992.

¹¹ See Royal Society, Risk, 1992, ch.5; Renn, 1992; Slovic, Fischhoff, and Lichtenstein, 1981; Gould et.al., 1988.

¹² See Royal Society, 11, 108.

- 2.3.8 *Sociologists* have addressed this under-emphasis by attending to social relations and institutions as influences on risk perception and by examining the ways that moral positions and valuations affect responses to risk. They have tended to stress the limitations of technical approaches and to argue that expert knowledge is not value free but conditioned by social contexts; that public attitudes to risk are affected by a wide range of variables and that public tolerance of risk is a political issue in which the degree of public involvement in risk management processes may play an important role.¹³
- 2.3.9 At a more general level, Ulrich Beck and other sociologists have talked of the 'risk society' in which we now live. This begins 'where nature ends' in the sense that risks are no longer imposed from outside and suffered as a matter of fate but are 'manufactured' – they are the products of mankind's decisions, options, science, politics, industries, markets, and capital.¹⁴ In this risk society we increasingly struggle to negotiate the future, science can no longer be looked to for answers, and conventional political mechanisms do little to assure us. The challenge is said to be to develop political processes that will come to grips with these new risk-related issues.¹⁵
- 2.3.10 *Cultural theorists*, in turn, have contended that attitudes to risk vary according to cultural biases – attitudes and beliefs shared by a group – and that risk is a plastic concept allowing the development of no single measure by which different cultural biases towards risk can be compared.¹⁶
- 2.3.11 Such cultural approaches to risk have been linked with psychological and sociological treatments in the work of 'social amplification theorists' who suggest that signals concerning risks are filtered through social amplification stations (e.g. groups of scientists; the media; pressure groups and politicians) and that this filtering intensifies or minimises certain aspects of risks.¹⁷ Other social scientists have focussed on risk communication and have attended to the ways that

¹³ See Krimsky and Golding in Krimsky and Golding; Giddens, 1994.

¹⁴ See Beck, 1992; Giddens, 1994; Franklin, 1998.

¹⁵ See Giddens, 1994.

¹⁶ See Douglas, 1992;

¹⁷ See e.g. Kaspersen et al., 1988.

messages about risks are conveyed and the institutional and cultural contexts under which risk messages are formulated and conveyed.¹⁸

2.3.12 In 1999 the Health and Safety Executive (HSE) discussed the criteria employed by regulators in the health, safety and environmental field in decisions on risk control.¹⁹ The Executive suggested that three 'pure' criteria are used either on their own or to develop new criteria. They are, first, an equity-based criterion, holding that all individuals have unconditional rights to certain levels of protection (a criterion used to fix maximum risk levels above which no one should be exposed); second, a utility-based criterion which applies to the comparison of incremental benefits of measures to reduce risks and the costs of the measures; and, third, a technology-based criterion that reflects the idea that a satisfactory level of risk prevention is attained when "state of the art" technology is employed to control risks.

2.4 **UK Government: Leading Approaches to Risk Control**

In the departments and agencies of UK government, questions of how risks are to be controlled are closely related to issues concerning the assessing of risks, and the setting of standards.²⁰

2.4.1 *Generally: The Cabinet Office*

2.4.1.1 Since 1996 the Cabinet Office has insisted that all regulatory proposals put forward by government officials be supported by a Compliance Cost Assessment (CCA) accompanied by a risk assessment.²¹ The latter must identify the potential benefits associated with various options and must place a value on those benefits so that they may be compared to the costs imposed on consumers, businesses and the Government. The post 1996 risk assessments seek to: identify the problem and the harm involved; estimate the risk associated with the harm (this involves

¹⁸ See Royal Society, 1992, 5.5; Otway and Wynne, 1989.

¹⁹ See HSE, 1999 p.41.

²⁰ The leading review is that published in 1996 by the Interdepartmental Liaison Group on Risk Assessment (ILGRA, 1996) and see also ILGRA, 1998.

²¹ See Cabinet Office, 1998.

assessing the probability or frequency of the harm arising as well as its likely magnitude); identify regulatory options; estimate the impact of the options on the risk; place a monetary value on the expected benefits of each option; compare the costs with the benefits; and identify any important issues of equity or other political considerations.

2.4.1.2 Within government, approaches to risk assessment and control have evolved individually rather than according to a general blueprint and wide variations are encountered. A number of reports have urged that more consistent approaches should be developed²² and a 1996 report published by HM Treasury on the Setting of Safety Standards²³ recommended, first, that, though a general rule-based, cost-benefit analysis (CBA) approach was unrealistic, common frameworks should be developed for all safety standard policy judgements: second, that, although a considered balancing of costs and benefits should be an objective of all regulation, this had sometimes to take into account important ethical constraints and, third, that there was a need for greater consistency in the extent to which costs of risk reduction and the examination of public values and preferences were taken into account.²⁴

2.4.2 *Health and Safety*

2.4.2.1 The Health and Safety Executive (HSE) has maintained a pioneering role in the use of risk assessments in regulation. The HSE employs a mixture of quantitative, and qualitative, cost-benefit-based and equity-based, criteria in determining whether a risk is so great as to be unacceptable; whether it is so small that no further precautions are called for; or, where the risk falls between the two states, whether it has to be reduced as low as is reasonably practicable (ALARP). The broad framework for considering these issues is known as ToR – the Tolerability of Risk approach.²⁵

²² See e.g. ILGRA, 1998, p.12.

²³ H.M. Treasury, 1996.

²⁴ H.M Treasury, 1996, p.12.

²⁵ See HSE, 1998, 1999.

- 2.4.2.2 ToR thus involves the making of decisions concerning acceptable and unacceptable risks. For risks above the limits of acceptability, remedial actions are called for irrespective of costs. Where risks are acceptable they are borne as ordinary background risks of life.
- 2.4.2.3 In between these categories – in the 'tolerability region' – risks are accommodated in order to secure social and economic benefits and efforts are made to balance the costs of risk reductions versus the associated benefits. The HSE has suggested that, for workers, a 1 in 1,000 risk of death per annum is at the threshold of tolerability and, at the other end of the spectrum, a risk of 1 in 1,000,000 per annum for the public is broadly acceptable.²⁶
- 2.4.2.4 In controlling risks in the tolerability region the HSE often uses existing standards or what is regarded as good practice as a guide to deciding appropriate risk levels. Where no standards or good practices exist, use is made of cost-benefit analyses (CBAs). The value of life figures used for CBAs are those employed by the Department of Transport for appraising new road schemes.
- 2.4.2.5 HSE deals with uncertainty in risk calculations by adopting the view that ALARP calculations should be biased in favour of greater safety where risks are considerable. Its procedure in assessing risks is generally open and consultative. As a rule, the HSE states,²⁷ its risk assessment procedures require that: assumptions to fill gaps in knowledge be tested (e.g. by sensitivity analyses); more weight is attached to consequences for hazards giving rise to irreversible or potentially severe detriment (e.g. cancer); the greater the uncertainty concerning the likelihood of a risk being realised, the more weight is given to its consequences; the greater the uncertainty on consequences, the more emphasis is placed on worst case scenarios and comparative risk assessments shall be used in relation to novel hazards.

²⁶ ILGRA, 1996, p.18.

²⁷ HSE, 1999, p.31.

- 2.4.2.6 The HSE has made it clear²⁸ that it sees ToR as "inherently precautionary"; that both individual and societal risks should be taken into account in risk control regimes; that HSE proposes numerical criteria for informing decisions on tolerability only for a very limited category of risk – namely those involving fatalities (individual or multiple).
- 2.4.2.7 In looking at measures to be taken to reduce risks, the HSE sometimes carries out formal CBA analyses of various regulatory options but where CBAs are not possible, quantitative or qualitative estimates are used. Explicit valuations are always carried out where proposals would require duty holders to make major investments or where new regulations are introduced. When conducting CBAs, HSE uses the value of a statistical life at £902,500 (1998 prices).²⁹
- 2.4.2.8 The HSE's approach to the securing of compliance with risk-reducing measures is marked by the (generally consensual) use of a wide variety of techniques.³⁰ Statutory duties, regulations, approved codes of practice and guidance notes are applied through prosecutions, the issue of prohibition or improvement notices, persuasion, negotiation, education, bluff, advice, information-giving and promotional work. Within the rules and standards a key concept is "reasonable practicability" as exemplified in the expressions "so far as is reasonably practicable" (SFAIRP) and "as low as reasonably practicable" (ALARP). Central to this approach is the requirement that duties have to be carried out in a matter that is proportional and where compliance does not involve unreasonable difficulty or cost. Whatever the regulatory tool or enforcement strategy, the HSE describes³¹ its general approach as one designed to manage risks by: enlisting the co-operation of those affected; fostering a culture disposing those involved to give of their best; planning and setting priorities for ensuring that risks requiring most attention are tackled first; setting up a system for monitoring and evaluation progress; and applying sound engineering practice.

²⁸ HSE, 1999, p.3.

²⁹ HSE, 1999, p.35.

³⁰ See generally Baldwin, 1995; Dawson *et al.*, 1988; Genn, 1993; Gunningham, 1984, Hutter, 1997.

³¹ See HSE, 1999 p.39.

2.4.2.9 The EU has a large influence on UK health and safety regulation but, in general, safety standards in the EU are based on political judgements supported by little analysis of risks. The Commission and most EU countries reject suggestions that risks be weighed against costs.

2.4.3 *Transport*

2.4.3.1 In the transport sector, risk assessment is central to the regulatory approaches adopted in developing legislation and enforcement and also in education, training and publicity. Risk assessments are also used in deciding on investments in road safety. This is a sector marked by the availability of a considerable body of statistics and quantitative calculations of probabilities of accidents and their severity play an important role in policy-making. Where practicable, proposals are evaluated using a consistent set of explicit values and the use of CBA is well-established.

2.4.3.2 In aviation, both domestically and internationally, bodies such as the Civil Aviation Authority (CAA) and International Civil Aviation Organisation (ICAO) have used risk assessment techniques in design and standard evaluation for over 30 years. In shipping and rail the Department is promoting the use of risk assessments.

2.4.4 *Health*

2.4.4.1 Risk assessment has a role in many departmental standard setting procedures but the broad approach in this sector is equity-based. Weight is accordingly given to questions of fairness and the need to protect those weakest in society. Qualitative methods are used in relation to the safety of medicines, food safety, air and water quality standards, emergency planning, vaccination and immunisation strategy, assessment of medical devices and health promotion. Uncertainty is dealt with by the introduction of safety factors plus, in some areas, reference to the precautionary principle.³²

³² ILGRA, 1996, p.21.

- 2.4.4.2 The Department has developed well-defined methodologies for assessing exposure to certain hazards. In relation to chemical products, for instance, laboratory studies identify "no observable effects levels" (NOAELs) and appropriate safety factors are taken on board in setting standards. If no such threshold is identified, exposure is reduced as low as reasonably practicable.
- 2.4.4.3 In 1996 the Clinical Negligence Scheme for Trusts was introduced and is effectively an insurance arrangement for trusts. Premium levels are based in part on levels of risk so that risk reductions bring premiums down. Jones, 1996, suggests that this has had a "positive effect" in inducing hospitals and individuals to scrutinise safety levels.
- 2.4.4.4 The introduction of clinical procedures and guidelines to structure practice is one of a range of risk management strategies used in the NHS,³³ and there have been suggestions that recommended methods are more likely to be followed if part of a hospital's policy than if not – though, almost half of the time, the guidelines are not followed.³⁴
- 2.4.4.5 In judging risk-taking behaviour by colleagues there is evidence that NHS staff take into account both the outcome of the behaviour and whether it follows a protocol.³⁵ Different groups varied in their attitude to rule-breaking, however, with doctors more tolerant of rule-breaking than midwives. Researchers have suggested that those trained in the use of clinical judgement are more tolerant of protocol breaches than those, such as nurses, who have been trained in the regulation of behaviour by rules and guidelines.³⁶
- 2.4.4.6 Studies of welfare professionals have suggested that informal structures and relations are highly important in controlling risks.³⁷ Groups may control their own work and pursue goals that are different from those of the organisation. Front line workers know how the job is done and are often difficult to observe

³³ Grimshaw *et al*, 1995.

³⁴ Glynn *et al*, 1997; Lomas, *et al*, 1989.

³⁵ Parker and Lawton, 2000.

³⁶ *Ibid*.

³⁷ See Harrison, L., Alaszewski, A., and Walsh, M., 1998.

and control. Within welfare agencies, researchers found a wide discrepancy between staff perceptions and official policy accounts.³⁸ Discrepancies tended to be highest where the agency possessed an explicit risk management policy that was participatory, non-punitive and anticipatory. Staff tended to think that this was not how the organisation operated in practice.

2.4.4.7 Studies of informal constraints in the welfare sector suggest that staff treat official policy as one source of guidance to be used with other aids to decision-making, such as local and professional guidance, with the emphasis on staff exercising professional judgement. In interviews, staff were oriented to the pursuit of users' interests, not their own careers or protections of the agency.³⁹ Even where formal policies were well-developed, interpretation and judgement played considerable roles – risk policies would be used or discarded as perceived client benefits demanded. Professionalisation increased this flexible approach to rules.⁴⁰

2.4.5 *Environment*

2.4.5.1 The Department makes use wherever possible of the HSE's ToR framework and, within the ALARP area, uses a technology-based criterion known as BATNEEC (best available technology not entailing excessive cost) and BPM (best practical means). Qualitative and quantitative methods are used in risk assessments concerning radio active waste disposal, control of chemicals, pollution prevention and control, global atmospheric changes, land use planning, contaminated land control, and habitat protection. An area in which emphasis rests on quantitative risk assessment is waste management. Uncertainties are accommodated through informed scientific judgements and the use of safety factors.

2.4.5.2 In relation to water quality the EU is the main driver of standards and the EU does not usually undertake a sustained CBA of its standards. There is, accordingly, little scope for the application of risk assessment.

³⁸ Ibid p.73.

³⁹ Harrison et al., 1998, p.85.

⁴⁰ Ibid.

- 2.4.5.3 The DoE took the lead in the UK's responses to the UN Sustainable Development Initiative and risk assessment features significantly in ensuing proposals. DoE, moreover, publishes guidance on risk assessment and management issues and sets out how approaches such as BATNEEC and ALARP can be used. In practice the approach is similar to the HSE's ALARP.
- 2.4.5.4 In 1976 the Royal Commission on Environmental Pollution (RCEP) introduced the concept of integrated pollution control (IPC) where it proposed that pollution should be controlled so that damage to the environment as a whole can be minimised.⁴¹ The Environment Protection Act 1990 implemented IPC. Within this regime risk assessments inform standard setting, and a primary objective is to prevent harmful releases or reduce unpreventable releases to a minimum. IPC requires that release processes represent the Best Practicable Environmental Option (BPEO) using BATNEEC methods. To this end BATNEEC does not rely only on technical solutions but includes other techniques such as operating environmental management systems and ensuring adequate staff training.
- 2.4.5.5 Overall, most environmental risks are assessed within governmental control regimes and a strong emphasis has been placed on quantitative approaches to the identification of tolerable levels of risk. Social aspects, such as risk perception and communication, have been largely secondary issues.⁴²
- 2.4.5.6 In June 1995, the DoE published a guide to risk assessment and management for environmental protection.⁴³ The guide notes the uncertainties involved in formal risk assessments. It sets out the five stages of risk estimation (describing the intention; identifying the hazard; identifying the consequences; estimating the magnitude of consequences; and estimating the probability of consequences) and discusses how factors such as perceptions, confidence and quality of life should be incorporated into risk evaluations. The guide stresses a number of points, including: in areas of great uncertainty the precautionary principle should only be used where hazards have long environmental lifetimes or accumulative or

⁴¹ See Royal Commission on Environmental Pollution 1976, 1988.

⁴² Parliamentary Office of Science and Technology, 1996, p.36.

⁴³ Department of the Environment, 1995.

irreversible consequences; risk perceptions depend on a wide variety of factors (dread, control, familiarity etc) and independent assessors may, accordingly, be useful in evaluations; it may not be easy to decide where an environmental risk assessment should start; and, irrespective of the risk assessment or CBA, any proposal may be subject to the overriding requirements of ALARP, BPEO or BATNEEC.

2.4.6 *Agriculture, Fisheries and Food*

2.4.6.1 The regulation of pesticides, flood defences, fisheries, food quality, composition and labelling and hygiene aspects of some specific foods include both qualitative and quantitative risk assessment approaches. Food standards generally are covered by internationally agreed presumptions and are set in terms of tolerability limits based on scientific judgements. Microbiological organisms are mainly controlled by ALARP – based risk management strategies.

2.4.6.2 Risks from animal diseases are managed with reference to precautionary principles where uncertainties are encountered in the scientific evidence. (ILGRA noted such an approach in relation to BSE.⁴⁴)

2.4.6.3 MAFF has, in the 1990s, developed a systematic, 'decision framework' approach to risk management. This seeks to evaluate the effectiveness of risk management actions in the light of intended objectives and any indirect regulatory effects. Food safety issues are, moreover, treated with a good deal of attention to subjective factors and issues such as: public expectations; questions of confidence and reputation; consumers' perceptions and a host of factors beyond experts' judgements on safety. There is a departure from 'rational economic' approaches to risk control insofar as: safety is a main objective of regulation but other factors, such as fair competition within the EU, come into play; safety benefits are difficult to quantify; and regulatory regimes are complex and seen to interact with each other.

⁴⁴ ILGRA p.23.

2.4.7 *Trade and Industry*

2.4.7.1 Risk assessment is generally informal within DTI and used in a variety of ways in different divisions. It is used in particular in relation to the development or adjusting of legislation or standard-setting and in evaluation project failures. Emphasis rests on qualitative rather than quantitative approaches with the object of ensuring that risks are tolerable - that is, suitably low as measured by qualitative guidelines. Since risk assessment is not formalised, little consideration is given to uncertainty and residual risk.⁴⁵ Qualitative and quantitative approaches are used in relation to consumer safety, oil and gas and decision-making of facilities.

2.4.8 *Defence*

2.4.8.1 The Department uses detailed quantitative models within the nuclear and radiation safety areas and has developed criteria on tolerable protection levels in particular situations.

2.5 **Managerial Responses to Risk**

2.5.1 Risks, as noted, can be controlled not merely by external regulators (governmental, agency or professional organisation) but by managers and workers within organisations. (The Turnbull Committee placed risk management at the heart of good corporate governance). Focussing on managers, there are a number of reasons for controlling risks: risks may physically destroy businesses or produce economic losses (e.g. through lawsuits); they may damage production levels and profits and share values; they may harm reputations, they may lower quality of service and products; they may produce personal liabilities and diminish personal rewards and prospects.

2.5.2 Professional managers, it should be noted, face a number of difficulties in controlling risks within their organisations. They may, for instance, lack full

⁴⁵ ILGRA, p.24.

information on operations within their own sphere and in the spheres of colleagues. Where there is a movement from line management to project or team management, it may become increasingly difficult to exert control across the organisation. If increasing specialisation is called for, a manager may lack the expertise to control a host of risks and where risks arise principally 'out in the field' it may be hard for head office managers to exert influence. Resource constraints and demarcations of responsibility may further hinder the would be controller. The causes of risks, moreover, may be diffused through organisations and systemic, rather than the easily identifiable actions of individuals.

2.5.3 Managers, nevertheless, can adopt a variety of approaches designed to reduce risks. The CBI's 1990 study of controlling health and safety risks⁴⁶ argued in favour of a "safety culture" approach to risk management and stated that the ability of companies to control risks was related to three themes: the leadership and commitment of the Chief Executive; line management and the involvement of all employees through openness of communications; and the company demonstrating care and concern for those affected by its business. More particularly, control of such risks was seen to require proper training and resourcing, the setting of achievable targets, the proper investigation of incidents, the monitoring and auditing of safety behaviour, the swift remedying of deficiencies, and the flow of up-to-date information to managers. Such a strategy is consistent with the Total Quality Management (TQM) approach which seeks to generate: a highly motivated workforce, committed to producing high quality products and preventing failure;⁴⁷ participatory corporate cultures; and 'corporate learning'.

2.5.4 There is some evidence that TQM techniques do improve risk management performance, particularly in areas of high consequence risk. As one commentator has stated: 'Industries involved in managing risk associated with nuclear reactors, software, process hazards and oil transportation are benefiting from the

⁴⁶ CBI, 1990, p.53.

⁴⁷ See Horlick-Jones 1996.

advantages of management processes that seek to achieve accident free operations rather than accepting a "tolerable" level of failures'.⁴⁸

2.5.5 A further aspect of managing risks involves incorporating public perceptions into managerial decisions. An "engagement" approach was exemplified by Shell's communications strategy over the disposal of the Brent Spar oil storage and loading buoy in the Atlantic in 1995.⁴⁹ Following strong resistance to its first disposal proposals, Shell engaged in a sustained programme of consultations, seminars and communications with interested parties and pressure groups – a process of responding to concerns rather than defending on initial stated position.

2.5.6 Approaches such as TQM and engaged risk management are not, however, difficulty free.⁵⁰ Problems may be encountered where there is a need to identify high-level, high-consequence problems such as the complex latent failure pathways that can lead to disaster. A second pitfall is that the process of auditing and managing risks may become an end in itself, one seen organisationally as more important than generating quality practices.⁵¹ Third, it may be difficult to change corporate cultures "from above" or to take good risk management cultures and "bolt them on" to an organisation. Finally, TQM systems may require levels of resourcing that cause problems for new, small or medium-sized enterprises that lack the requisite in-house expertise.⁵²

2.5.7 Within the public service there is evidence of both 'engagement' and 'decide-announce -defend' approaches to risk management. Looking at the probation service, Kemshall⁵³ has contrasted recent central and metropolitan 'top-down' approaches to staff training in risk management (in which headquarters have circulated risk policy to staff via pigeon holes and circulars) with practice in a minority of probation services which had used a working party and consultative

⁴⁸ *Ibid* p.151. Horlick-Jones notes that Shell achieved a thirty fold decrease in injuries involving lost time on its tanker fleet when, over 15 years, it introduced a safety management system on TQ in lines.

⁴⁹ Kemshall, H., 1998 pp.223-5, Wilkinson 1997.

⁵⁰ See Horlick-Jones, 1996, p.151; Fortune and Peters, 1995.

⁵¹ Power, 1994.

⁵² Horlick-Jones, 1996, p.151.

⁵³ Kemshall, 1998, pp.225-7.

approach to the development of risk policies, one involving planned communications with staff prior to implementation of the policy.

2.5.8 The decide-announce-defend process is associated with services that are "closed with low participation and low empowerment."⁵⁴ Kemshall comments:

"In the absence of totally reliable predictive methods the primary organisational response is to substitute the prioritisation of actions or areas requiring attention for predictive tools; or to devolve the choice of tool to local managers. Responses to risk errors are usually characterised by hindsight, bias and allocation of blame in an effort to encourage staff to take more care in future, and a lack of emphasis on a learning culture. Ultimately this can result in inefficiency in risk management strategies, policies which quickly fall into disrepute, and, of course, disaster".

2.5.9 Within managerial approaches to risk a distinction can thus be drawn between 'anticipatory' and 'resilience' approaches. Anticipatory systems place emphasis on identifying potential risks in advance and implementing preventative strategies on a precautionary basis. 'Resilience' approaches stress the value of a 'wait and see' procedure characterised by greater flexibility, trial and error, learning and decision-making on the basis of options that are kept open.⁵⁵

2.5.10 Some problems with anticipatory approaches are that they can prove expensive to implement and, where there is a predictive failure, the system's ability to respond to new dangers may be limited. This, however, is said to be the approach now prevalent in the criminal justice and the probation areas – with a recent example in the development of registers and surveillance nets for sex offenders. Her Majesty's Inspectorate of Probation (HMIP) issued guidance on risk in 1997⁵⁶ which was anticipatory, focussing on the proactive identification and prevention of risks. This approach responded to the uncertainties faced by probation staff by listing points of guidance to inform practice – rather than by providing risk

⁵⁴ *Ibid.*, p.225.

⁵⁵ See Collingridge, 1996, Wildavsky, 1998.

⁵⁶ HMIP, 1997.

assessment methods. Responsibility (and, in turn, blame) was devolved to individual managers and assessors for decision-making.⁵⁷

2.5.11 A further difficulty with such anticipatory approaches is that they require risks to be clear cut. Where risks are complex and demand highly situation-specific trade-offs to be made between rights, risks and protections, guidance of the HMIP's type offers little assistance to decision-makers. This approach encourages a focus on defensive decision-making and blaming looms large in the decision-making and evaluating processes.

2.5.12 Other problems with anticipatory approaches are that they presuppose that a consensus on risks to be avoided can actually be arrived at⁵⁸ and that excessively wide monitoring of potentially errant risk causers can not only prove costly to the state but can interfere with liberties and prevent proper consideration of the trade-offs between risk and benefits.

2.5.13 Again with reference to the probation sector, Kemshall's Home Office Review⁵⁹ concluded that 'best practice' guidance on risk management should acknowledge the limits of prediction in all assessment methods and capitalise on the possible. An holistic approach combining clinical and actuarial methods was advocated so as to cover:

- specification of the risks staff respond to and how they are to be prioritised and balanced;
- specification of an appropriate knowledge base and empirically grounded risk factors based on clinical and actuarial studies;
- a framework for staff to use this knowledge and utilise the risk factors systematically (including a proper secretarial grounding in the use of risk factors);
- a mechanism for staff to reflect on their risk judgements.

⁵⁷ Ibid, pp.2; 15; Kemshall, 1998, p.227.

⁵⁸ Hood and Jones 1996.

⁵⁹ Kemshall, 1996.

- 2.5.14 In pursuit of the above approach, staff would have to be trained in and learn the appropriate actuarial knowledge prior to conducting in depth interviews aimed at clinically assessing patterns of behaviour and motivations. A distinction might, thus, be drawn between 'general predictive hazards' based on actuarial knowledge and 'specific hazards' based on clinical knowledge.⁶⁰ Staff would also have to be trained in definitions of risk, risk assessment, risk management and risk control monitoring procedures.⁶¹ Lists of questions for assessors to explore might be developed but it was important to keep a "constantly alert response to the dynamic nature of risk".⁶²
- 2.5.15 In managing high risk persons in the community it was necessary to ensure: risks were appropriately identified by staff; interventions were matched to risks; and interventions were focussed. In risk minimisation activities it was essential that: the effectiveness of interventions was reviewed actively; and that Services could learn from both effective risk management as well as from 'serious incident' failures and reapply this knowledge to practice.
- 2.5.16 Registers, as used in relation to discharged mentally ill patients could be misused, argued Kemshall: "leading to escalation of false positives and unwarranted labelling, intrusion and restriction".⁶³ They were labour intensive, with a potential for misallocating resources. Registers of Serious Risk Offenders should, accordingly, be developed and used with caution. Systems of registration could be confused with actually acting on risk. Conferencing procedures in probation could lead to higher levels of tolerated risks – case conferences and group decision-making should, again, be used with care.⁶⁴

⁶⁰ See Kemshall, 1995.

⁶¹ For details of training methods see Kemshall, 1998.

⁶² Kemshall, 1996, p.32.

⁶³ Kemshall, 1996, p.33.

⁶⁴ Ibid.

- 2.5.17 In the social welfare and social services sector the literature on risk management is thin.⁶⁵ In practice, however, notions of risk are becoming embedded in organisational rationales – marked by the development of a Risk Literature by the Social Services Inspectorate in 1994/5. In the criminal justice field, the Association of Chief Officers of Probation (ACOP) published a "position statement on risk" in 1994 acknowledging the need for a more active approach to risk assessment and management⁶⁶ - this gave central place to actuarial calculations of risks, efficient and systematised management of criminal justice agencies, and the targeting of offenders for the efficient use of resources.
- 2.5.18 In relation to children in need, the notion of risk is central in determining case priority. This was revealed in Giller's 1993 study⁶⁷ of practices in four local authorities. Work under the Children Act 1989 was found to be prioritised with reference to a list of risk factors and risk considerations loomed larger in areas where concerns about accountability were high.⁶⁸
- 2.5.19 In the child protection area under the Children Act 1989, risk controls are subject to guidance from the Home Office (see Home Office, Working Together, 1991) but the task of establishing local procedures for dealing with suspected and confirmed cases of maltreatment is delegated to Area Child Protection Committee (ACPCs).⁶⁹ The guidance offered to welfare professionals contains little specific instruction on how tensions between competing policy objectives should or can be managed. Professionals are expected to use their judgement, but are held to account through the law, professional controls, public inquiries and the media.
- 2.5.20 In child protection there has been a shift away from preventative work (based on high predictive confidence) which had sought to identify at risk children and towards the development of rapid responses to risk. The latter strategies focus on possible or actual harms and presuppose a lower level of predictive ability.⁷⁰ A

⁶⁵ See Kemshall, Paton, Walsh and Waterson, 1997; Alaszewski and Manthorpe, 1991.

⁶⁶ ACOP, 1994.

⁶⁷ Giller, 1993.

⁶⁸ See Varlon, 1996.

⁶⁹ See Tindall, L., and Alaszewski, A., 1998.

⁷⁰ See Parton, 1996.

problem for social workers is, however, that they may be exposed to media criticism for lack of prevention.

- 2.5.21 In recent years a number of risk management strategies have been introduced in the NHS⁷¹ as already noted, there has been increasing use of guidelines and clinical protocols. This movement has been driven by perceived needs not merely to control risks but also to integrate research into practice speedily and to standardise practice costs effectively.
- 2.5.22 Most clinical guidelines and protocols have been developed locally at ward or speciality level. In, for example, obstetrics, a team of one or two obstetricians and a similar number of midwives will develop the protocol and this will be reviewed by the rest of the team for approval and adoption. Large variations are, however, encountered in the extent to which such protocols are used – administrative burdens and the difficulties of obtaining agreements may hinder their production.
- 2.5.23 In general protocols are not expected to be learned by rote or applied rigidly and research has revealed disparities of use between nursing and medical staff, with the medics thought to be far more inclined to 'do their own thing'.⁷² This creates tension between professional groups with nurses occasionally resenting the 'bending of the rules' by senior surgeons.
- 2.5.24 Focus groups discussions have pointed to a number of special problems in using protocols to control medical professionals. The idea of professional autonomy is considered by many to be at tension with the use of protocols. Many, moreover, consider that protocols stifle the development of innovations and are detrimental to patient care. Researchers have concluded that effective risk control through protocols depends on achieving the right balance between standardising practice and freedom for clinical judgement. It also demands that the culture of the health

⁷¹ See Lawton and Parker, 1998, 1999.

⁷² Lawton and Parker, 1998, p.5.

service and the beliefs, attitude and norms of its employees are taken into account.⁷³

2.5.25 In the health sector, criticisms of professional self-regulation have led to restrictions. In the British NHS greater lay managerial control over medical practice followed the Griffith report and NHS reforms.⁷⁴ In post-war social work, bureaucratisation reduced levels of professionalisation and in the child abuse area, public inquiries and departmental responses have been said to have produced legalistic and bureaucratic 'solutions' that turned professionals into passive agents.⁷⁵ Contrary to this account, it can be contended that professionals can easily exercise judgements in bureaucratic contexts.⁷⁶ NHS studies have suggested that GPs have not found the role of the Family Health Services Authority (FHSA) to be a threat to clinical autonomy.⁷⁷ Other studies suggest that bureaucracy has little effect on physicians.⁷⁸ It has been argued in relation to most health and welfare workers, that staff use agency policies and professional guidelines actively to achieve client-oriented goals rather than react to judicial or bureaucratic procedures as passive agents.⁷⁹

2.5.26 The NHS Executive places strong emphasis on assessing potential hazards. An NHS Hospital Trust risk policy document that uses NHS guidelines as a basis will seek to ensure that there is an environment that poses the minimum of risk possible. The limitation of this approach is that it can lead to an excessive sense of security and a diminution of the ability to deal with accidents when they occur.⁸⁰ Public inquiries into child abuse cases illustrate that many disasters are predictable only with hindsight, that actions to prevent harms to children could have been taken but that the information that would have allowed prediction and action was dispersed between a number of organisations.⁸¹

⁷³ Lawton and Parker, 1998.

⁷⁴ Alaszewski, A, Alaszewski, H., and Harrison, L., 1998; Moran, 1999, Chapter 4.

⁷⁵ Howe, 1992.

⁷⁶ Alaszewski, Alaszewski, and Harrison, 1998, p.91.

⁷⁷ Weiss and Fitzpatrick, 1997.

⁷⁸ Prechel and Gupman, 1995 and Moran, 1999. For a similar argument re social workers see Anleu, 1992.

⁷⁹ See Alaszewski and Alaszewski, 1998.

⁸⁰ Alaszewski and Manthorpe, 1998, p.52.

⁸¹ Wildavsky, 1998, DHSS, 1982.

- 2.5.27 The case for resilient approaches to the management of risk urges that best practice develops more effectively from the resolution of risk problems rather than from efforts to anticipate. Flexible procedures, it is contended, produce greater risk responsiveness even though they involve high levels of front-line managerial discretion. A reservation concerning resilient strategies may, however, be that some risks may be so severe that society may be unwilling to 'wait and see' and may demand that high levels of effort and money be devoted to prevention.⁸²
- 2.5.28 In looking at managerial controls over risks, a further contrast should be drawn between 'blame-based' and systemic approaches. Critics of blame-based regimes⁸³ urge that to seek to blame individuals underplays the role of collectivities and organisations in the creation of risks. A study of health care risks by Vincent and others⁸⁴ found that health care workers often inherit latent failures (faulty policies, poor communications, and poor management decisions) and that, although individuals are often blamed, a full analysis of risks would reveal the systemic nature of the risks at issue. Systemic approaches focus attention on the broad institutional contexts within which individuals make decisions⁸⁵ and, compared to blame-based regimes, allow more forward looking and efficient feedback on the systemic deficiencies that lead to risks. They, accordingly, produce more effective mechanisms for redressing faults than are associated with blame-based structures. That said, however, the public's appetite for blame should not be under-estimated or written off as irrelevant.
- 2.5.29 Within welfare agencies generally, commentators have noted that strong allocations of responsibility or blame may give professions an incentive to cover-up and there is a case for confidential systems of reporting. An example is the UK's Confidential Human Factors Incident Reporting Programme (CHIRP).⁸⁶ In welfare agencies a key process is the investigation of incidents and accidents and

⁸² See Collingridge, 1996.

⁸³ See e.g. Horlick-Jones 1996 (a); Johnson 1996 and, for a discussion of 'Collibrationalist' approaches, Kemshall, 1998, pp.236-9.

⁸⁴ Vincent, 1993.

⁸⁵ See the debate on whether corporations should be treated holistically for the purposes of criminal liability – reviewed by Wells, 1996.

⁸⁶ See Alaszewski and Manthorpe, 1998.

the level of trust placed in professionals tends to vary according to professional status. Thus, social workers have not been allowed to self-regulate – errors are subject to external review by inquiries and the media. This contrasts with the medical profession which has traditionally been allowed a high level of self-regulation. Accidents and incidents tend to be investigated by the profession itself. Studies of whistle-blowing in the NHS suggest that there is considerable room for developing further confidential, no-blame reporting systems.⁸⁷

3. **Risk Control and Management: Specific Issues**

3.1 **When to Control**

3.1.1 Regulators or risk managers can intervene at different stages in the processes that lead to harms. Action can be taken to prevent a dangerous situation arising (as where hotels are fire inspected before admitting guests); action can be taken in response to the act of creating a dangerous situation (e.g. operating a hotel without fire doors); or actions can be prompted on the realisation of harms (fire injuries to hotel guests).

3.1.2 The standards used in regulation may reflect the above stages. Specification or design standards seek to prevent; performance (or output) standards look to the seriousness of the acts involved in a process, and target standards look to the harms that result.

3.1.3 A number of factors are relevant in judging the best stage in a process at which to intervene.⁸⁸ Preventive measures may be appropriate where the costs of rectifying a dangerous state of affairs may be high, or where risks are large. Act-based interventions tend to be useful where the costs of prevention are high, or where large numbers of prior approvals cannot be processed, or where enforcement is significantly lower cost at the act stage (because, for instance, identifying errant behaviour has become easier). Harm-based interventions may, in turn, prove the most effective control options where, again, enforcement costs are low. It may,

⁸⁷ See Hunt, 1995, Public Concern At Work, 1997.

for instance, be cheaper for the state to punish 'small' numbers of harm causers than for it to pursue those who cause huge numbers of dangerous acts to occur, especially where only a small percentage of such acts result in harms.

3.1.4 Where there are considerable uncertainties concerning the risks that arise from a process, an important issue is whether the risk controllers should aim to err on the safe side by taking precautionary steps – whether it is better to go wrong (if at all) by over rather than under intervening.⁸⁹

3.1.5 The precautionary principle has been defined by the United Nations Conference on the Environment and Development (UNED) as:

"Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent degradation".

3.1.6 The precautionary principle is incorporated in the European Economic Treaty and other international treaties and conventions on environmental issues. The principle extends beyond the environmental field but "its adoption is far from universal".⁹⁰

3.1.7 The form the precautionary principle should take is controversial. To some it means that potential risk creators should have to justify benefits in advance. At the other extreme, some would only allow regulation when risks are clearly shown to be unacceptable.

3.1.8 Within UK government departments, the general approach is to base decisions on risk assessments and to take a precautionary approach in the absence of full evidence, and in particular, where risks are serious. This approach, as noted, is seen in the HSE's general regulatory philosophy and was endorsed by the

⁸⁸ See Shavell, 1993.

⁸⁹ See Shrader-Frechette, 1991, for an argument in favour of precautionary actions.

⁹⁰ ILGRA, 1998, p.25.

Government in 1995/6.⁹¹ It has yet to be developed into a rigorous system for policy analysis⁹² but has been said to reflect three important considerations:⁹³ first, that the role of science in decision-making is subject to challenge; second, that appraisal methods are increasingly recognised as having their own limitations; and, third, that there is an important place for public participation in decisions on risks, with a role for dialogue between experts, governments and the public to create consensus on inherent uncertainties and tolerabilities of risk.

3.1.9 It has been suggested that there are three basic options in dealing with uncertainties relating to risks: to make the uncertainties explicit; to calculate how changes in the assumptions used will affect calculations; and to identify a range of conditions that could exist in the future and examine what might happen of those conditions occurred.⁹⁴

3.2 **Processes for Risk Control: Rational versus Social**

3.2.1 Standard-setting for risk control purposes can be associated with very different models of process. 'Economic' or 'rational' philosophies may suggest that standards be driven by CBAs and that 'illogical' lay perceptions of risk are left out of account. Stephen Breyer has, along these lines, argued that risk control regimes should be 'depoliticised' and that small groups of specialists should be established in government with the mission of producing a set of rational priorities for risk regulatory programmes.⁹⁵ The group would act rationally and, to this end would be insulated from political pressures.

3.2.2 Critics of unbridled rationality have urged that experts are no more rational than lay persons; that scientists and experts create as many uncertainties as they dispel; and that risk priorities are perceptual, distributional matters that must be negotiated through exchanges of views rather than trusted to experts making

⁹¹ See House of Lords, 1995, Department of Environment, 1996.

⁹² Parliamentary Office of Science and Technology 1996, p.47.

⁹³ See Adams, 1995.

⁹⁴ See Parliamentary Office of Science and Technology, 1996, p.48.

⁹⁵ Breyer, 1993.

hidden value judgements.⁹⁶ Suggestions for setting rational risk assessments within 'social', 'democratic' or 'participatory', processes have involved proposals that such assessments be 'ethically weighted' to reflect public perceptions and preferences concerning risks; that alternative risk analyses and evaluations should routinely be carried out in policy-making and that 'weighted expert opinions' be used to incorporate forecasts by experts in areas of uncertainty.⁹⁷

3.2.3 In UK government it has been accepted in some circles that risk controls cannot be designed on a purely rational, technical, or 'natural science' basis and that subjective, perceptual elements must be taken on board in policy-making. Thus, the HSE has for some years consulted on different perceptions of risks from chemical exposure and the 1987 Layfield report on the proposed construction of the Sizewell B nuclear power station involved a risk evaluation taking account of public opinion.⁹⁸ The DoE's 1995 Guidance on Risk Assessment and Management also accepted that subjective elements were relevant to risk assessments and had to be incorporated in management processes.⁹⁹ The Environment Agency has also accepted that 'sound science' can only inform rather than dictate decisions.¹⁰⁰

3.2.4 Recently, UK government has seen the development of a number of models for combining rational and social, quantitative and qualitative, methods into risk assessments and controls.¹⁰¹ These models aim to make decision-making open, accountable, credible and inclusive (of non-experts as well as experts). They aim also to build consensus around proposals for risk control.¹⁰²

3.2.5 In 1996-8 ILGRA embarked on an inter-departmental project to provide guidance to Departments on good practice in risk communications.¹⁰³ The aims were: to produce an informed debate on risk; to produce a "constructive interaction" at all

⁹⁶ Giddens, 1994; Beck, 1992; Wynne, 1989.

⁹⁷ Shrader-Frechette, 1991.

⁹⁸ Layfield, 1987.

⁹⁹ DOE 1995; Parliamentary Office of Science and Technology, 1996, pp.37-46. See also Cabinet Office, 1996, DoE 1995; Her Majesty's Inspectorate of Pollution, 1995; HM Treasury, 1996, p.23, Department of Health, 1998, p.7.

¹⁰⁰ Parliamentary Office of Science and Technology, 1996, p.47.

¹⁰¹ Parliamentary Office of Science and Technology, 1996, p.19; Department of Health, 1998.

¹⁰² Ibid and see Soby, B.A. et al, 1993; Environmental Council, 1994. For Hampshire County Council's use of such processes see Parliamentary Office of Sciences and Technology, 1996, p.20.

stages of decision-making; to improve understandings between public and Government on policy-making about health, safety and environment; and to influence behaviour positively.

3.2.6 The results of ILGRA work have been a short guide for officials on communications about risk¹⁰⁴ and a report on research results.¹⁰⁵ ILGRA's research found that much good practice on risk communication (as well as a wide variety of practices) was encountered in UK government but that: it was exceptional for communication to be treated as an integral part of risk management policy; risk communication was too often seen as a one-way operation; risk debates were often technical in nature, presenting barriers to public inclusion and not inspiring confidence or trust; and that in certain fields the provision of independent advice via expert committees was widely distrusted.¹⁰⁶ ILGRA's 1998 Guidance aimed to respond to these shortcomings by encouraging wider and more constructive risk communication practices.

3.2.7 It has been noted already that the Cabinet Office demands that risk assessments accompany the compliance cost assessments that have to be submitted to ministers when decisions are taken on whether and how to control risks. The Cabinet Office's guidance on risk assessment tends, however, to restrict rather than broaden considerations involved in risk assessments.¹⁰⁷ The guidance demands that benefits be valued in monetary terms and compared to costs imposed on a business. This ties the process to 'objective' risk assessment and leaves issues of perception to Ministers. Critics urge that this allows the CBA to drive policy-making and runs counter to the participatory direction favoured by much risk research.¹⁰⁸

¹⁰³ ILGRA, 1998, pp.15-18.

¹⁰⁴ ILGRA, 1998 (a).

¹⁰⁵ ILGRA, 1998 (b).

¹⁰⁶ ILGRA, 1998 p.16.

¹⁰⁷ A point made by the Parliamentary Office of Science and Technology, 1996, p.42.

3.3 **Institutions for Risk Control: the Professions and Others**

3.3.1 The task of controlling risks may fall to a number of institutions, notably: central government departments, regulatory agencies, self-regulatory bodies, such as the professions, and private companies. This section notes the relative strengths and weaknesses of insurers, independent agencies and self-regulating professions.

3.3.2 Insurers are limited as risk managers in a number of well known ways.¹⁰⁹ Private insurance companies will not always find it profitable to match premiums narrowly to individual risks; competition may prevent the pooling of information on risks; problems of solvency may distort the market and private insurers may not offer cover on a number of risk types.

3.3.3 Regulatory agencies have proliferated in the UK since the fifties¹¹⁰ and are exemplified by bodies such as the Civil Aviation Authority, Health and Safety Commission/Executive and Independent Television Commission. The acknowledged strengths of such institutions are that they offer independence from central government (which is of special value if quasi-judicial decisions have to be taken); they offer their staff a sustained career structure; they allow continuity of expert policy-making across changes of government (they can accordingly plan in the long term); and they can carry out a variety of functions ranging from adjudication and enforcement to specialist policy-making.

3.3.4 The weakness of agencies is often said to be that: they offer only limited accountability; they are vulnerable to ministerial interference; their combining functions may produce the worst of a number of worlds; they may produce policies that conflict with those of the Government; and they may be liable to capture by business interests.

¹⁰⁸ Ibid.

¹⁰⁹ Royal Society, 1992, p.139.

¹¹⁰ See Baldwin and McCrudden, 1987, Baldwin and Cave, 1999, chapter 5.

- 3.3.5 Self-regulation, as commonly encountered in the UK professions tends to be associated in the literature with a number of strengths.¹¹¹ First, a familiar claim is that self-regulatory bodies can usually command higher levels of relevant expertise than outside bodies. The controllers, thus, know the shortcuts and tricks of the trade and can control the risks of errant membership behaviour very efficiently. Such expertise might be 'bought-in' by outside regulators, but proponents of self-regulation contend that it is their ongoing contact with operational affairs that keeps self-regulators more up-to-date and effective than outsiders.
- 3.3.6 A second, oft-cited virtue of self-regulation is that the professional body will have a special knowledge of what regulated parties will see as reasonable in terms of obligations. This allows standards to be set in a realistic manner – one that produces 'identification' with the rules and higher levels of voluntary compliance than is possible with outside-driven rules.¹¹² Misjudging levels of rule accountability leads, say proponents of self-regulation, to low levels of voluntary compliance, high state enforcement costs and inefficient controls.
- 3.3.7 A third strength of self-regulation, especially claimed in the professions, is that there are low costs of securing information. Self-regulators have low monitoring and enforcement costs because they are in close contact with practitioners and such costs are borne by members not the State.
- 3.3.8 The ability of self-regulators to act informally and independently of rules is a fourth claimed strength. Bodies such as the Law Society, it is said, can control risks of errant conduct by peer group influence, informal advice and discussion, training, codes, charters, guidance notes and reference to the cultural understandings shared by professionals. Such informal controls can reduce risks in ways that formal rules cannot and they mean that disputes can often be resolved informally without reference to expensive legal processes. When professionals exercise judgements, control through rules may, as noted, prove

¹¹¹ On self-regulation generally see NCC, 1999; Black, 1996; Ogus, 1995; Baldwin and Cave, 1999; Baggott and Harrison, 1986; Graham, 1994.

¹¹² For this point see Baldwin and Cave, 1999, p.127.

difficult and non-rule-based controls are especially useful. In relation to the self-regulation of press complaints, it has been argued that a move away from informality brings legalism and defensiveness and high expense in the place of co-operative processes for complaints resolution.¹¹³

3.3.9 Self-regulation has been viewed with suspicion, however, for a number of reasons. A first difficulty arises where membership of the body or profession is voluntary. If membership is not compulsory, risks may be ill-controlled because risk creators are likely to be found disproportionately in the body of maverick non-members. The 'regulatory paradox' is that those who are regulated tend to be those 'responsible' parties least in need of regulation.¹¹⁴ It is arguable that in all self-regulatory regimes there should be appropriate incentives (legal, operational or economic) to 'join the association.'

3.3.10 A second concern with self-regulation is that in some areas professional status is used for market-enhancing purposes and there maybe few formal obligations to meet any particular level of standards or training requirements. (In the health sector a report to the Department of Health from the University of Exeter made this point in 1997 in relation to proponents of alternative and complementary medicine.)¹¹⁵ Where, moreover, a number of self-regulatory bodies compete for members, this may lead to a competitive lowering of standards or to confirmation of the lowest standards encountered in the field.

3.3.11 A particular worry in relation to the professions is that changes may occur so that the common understandings that justified and underpinned professional self-regulation may disappear – the gentlemen may be joined by players. This, it has been argued, took place in the financial services sphere in the eighties and nineties where new entrants upset 'the common community of understanding, where shared norms, culture, and practices enabled business to be conducted on

¹¹³ See Lord Wakeham in the House of Lords, 5 February 1998, (discussed Baldwin and Cave, 1999, pp.127-8); Black, 1997, pp.30-7.

¹¹⁴ See Baldwin and McCrudden, 1987, pp.151-3 and National Consumer Council (NCC) 1999.

¹¹⁵ See NCC, 1999, p.13.

the basis of trust with the collective norm being reinforced by representatives of the group'.¹¹⁶

- 3.3.12 Critics of self-regulation may also see such regimes as making manifest the capture of power by groups who are unaccountable through normal democratic channels. They may add that self-regulation can act in a manner that is unfair to outsiders because non-members have poor levels of access to decision and policy-making processes. Past UK experience, indeed, suggests that self-regulators have a sporadic, unstructured and patchy record of consultation.¹¹⁷ Self-regulators may also be poor enforcers of standards against members because they fear a loss of members and a lowering of their income base.
- 3.3.13 The NCC¹¹⁸ has addressed issues of public confidence in self-regulation, urging that such frameworks must involve, *inter alia*: strong external involvement in design and operation; a separation of the scheme from industry institutions; full representation of consumers and other outsiders on the governing body of the scheme (with a majority of lay members); clear statements of principles and standards (to be published); adequate sanctions for those breaching codes and a majority of lay members within the system for redressing complaints. The NCC has argued¹¹⁹ that if there is not a majority of lay persons on the governing body for rule-making in a professional self-regulatory regime, there should be regular outside scrutiny from a competition authority to ensure that entry standards are not anti-competitive; and from government to impose statutory rules where the profession does not protect the public interest. The NCC suggests, furthermore, that there should be a presumption against self as opposed to external, regulation.¹²⁰
- 3.3.14 The NCC reported in 1998 on a number of particular aspects of trade association self-regulatory regimes that had caused concern. Among the points highlighted were the following.

¹¹⁶ Black, 1999, p.52.

¹¹⁷ Graham, 1994, p.198.

¹¹⁸ NCC, 1998.

¹¹⁹ NCC, 1999, p.64.

¹²⁰ Ibid pp.67-8.

- 3.3.15 The trade associations surveyed in 1996 by the Consumer Congress showed an 'alarming picture of inactivity and complacency'. Only two out of twenty-seven associations had researched consumer awareness or attitudes concerning their codes. Lay involvement was rare.¹²¹
- 3.3.16 Trade associations had difficulty in reconciling their roles of protecting members' interests and regulating standards of service.¹²² They faced 'disciplinary conflicts' especially when faced with expulsion as a main sanction.
- 3.3.17 The numbers using redress schemes were 'disappointingly low' and codes of practice were generally of low visibility.
- 3.3.18 Studies of particular self-regulated sectors by the NCC revealed a series of further problems. In the insurance industry the regime was flawed in relation to: complaints handling and claims; the competence required for selling insurance; the lack of flexible sanctions; the weakness of monitoring; the misleading guidance relating to disclosure of status (as tied agent or independent intermediary); and redress.
- 3.3.19 In the advertising industry self-regulation was generally thought to be successful but the NCC put much of this down to the 'underlying threat of legislation and the availability of special sanctions' as well as the independence of the Advertising Standards Authority (9 out of 13 members were lay). Reservations concerned the length of time the ASA took to process complaints and the resulting limitation of deterrence; the weak regime of sanctions and the regime's poor accessibility.
- 3.3.20 In relation to the Law Society and the Office for the Supervision of Solicitors (OSS) the NCC noted the looming threat of legislation to create an independent body to replace the self-regulatory OSS. Concerns were whether the lay membership had much influence on regulation and complaints handling: 'The chief influence on regulation and complaints handling is the Law Society's

¹²¹ NCC, 1998, pp.34-5.

¹²² See OFT, 1998.

Council.¹²³ The complaints mechanism had 'never commanded public confidence' and delays and questions about the OSS's independence remained as worries. Sanctions for dishonesty and serious misconduct were 'arguably not well enough used'. Penalties for inadequate service and minor misconduct were not adequate.

- 3.3.21 In the building profession the NCC encountered no less than seventy associations and doubted whether consumers could identify a reliable association. Particular problems in this industry were: the lack of rigorous membership controls in associations; the poor frequency of inspections and the exposure of the industry to unregulated 'cowboys'.
- 3.3.22 In the health sector the NCC examined the regulatory bodies for professionals including those for General Practitioners, Nurses, Midwives, Chiropodists, Dentists and Opticians. A number of problems were identified in the health profession's self-regulatory systems, including the following.¹²⁴
- 3.3.22.1 The primary aim of professional regulation was to protect the public but it had other, contradictory functions. It limited access to professions, promoted the profession's own interests and involved a tension between the public interest and professional protectionism.
- 3.3.22.2 There was no over-arching body to monitor and evaluate the extent to which professional self-regulation served the needs of patients in the context of increasing use of multi-disciplinary care.
- 3.3.22.3 People were poorly protected when using private sector services (which may be publicly funded) where, for instance: doctors do not have to have specialist training to practice a speciality; the professions allied to medicine do not have to be state registered; and anyone can set up a cosmetic surgery clinic and advertise for patients.

¹²³ NCC, 1998, p.49.

- 3.3.22.4 Unregistered professionals could be used in NHS services, for instance in general practice, or through nursing or locum agencies.
- 3.3.22.5 Consumers did not understand which 'titles' were protected and which were not – for instance the use of the terms 'nurse', 'physiotherapist' or 'psychologist'.
- 3.3.22.6 There was no clarity about what it meant to be 'on the register' with variation between bodies in the extent to which extra qualifications, current practising status (active or not), re-validation or recertification, and previous actions taken against the practitioner, were included.
- 3.3.22.7 There was a lack of openness in the various procedures employed by the bodies (e.g. relating to criteria used in screening complaints; reasons for rejecting complaints; information about the complaints).
- 3.3.22.8 Lay and consumer participation varied in extent on self-regulatory councils and in committees and in the local audit and other processes which were an integral part of self regulation.
- 3.3.23 *Self regulation versus regulation*

The contrast between self-regulatory and regulatory mechanisms can be drawn too starkly.¹²⁵ Nearly all regulatory systems involve elements of self-regulation (e.g. where firms monitor their own compliance) and nearly all self-regulatory mechanisms are subject to some degree of external oversight – even if this is merely the 'shadow' of potential government regulation. Nor should it be assumed that controls over risks always take the form of body A controlling regulatee B's conduct. Regimes of control often involve a host of institutions and pressures that relate to different or common aspects of the activity regulated. To take an example: the risk of sub-standard legal services being supplied by a lawyer is not controlled wholly by a single body such as the Law Society or Bar Council – up to twenty institutions have rules or operate procedure that impinge

¹²⁴ See NCC, 1999, pp.54-5.

on the quality of legal provision (e.g. Law Society, Bar Council, Inns of Court, Specialist Bar Associations, Chambers, Lord Chancellor's Department, Parliament, Judiciary, Court Officials, Solicitors Firms, Barristers' Clerks, Legal Aid Providers, Insurers, Universities, Ombudsman, Pressure Groups etc, etc.).¹²⁶

3.3.24 *Appraisal and Feedback*

Within the public sector there are numerous examples of routinised risk control appraisal mechanisms. As noted already, the HSE's general approach is to encourage policy-makers to set up systems for monitoring and evaluating the performance of risk control measures.¹²⁷ Follow-up procedures as encountered in the HSE, aim to establish: whether risk controls have achieved intended results; whether modifications of approach are demanded because of changes in, for example, technologies or public concerns; whether the information gathering or risk assessment methodologies used, or the assumptions, or the CBA that underpinned the relevant policy, needs to be reconsidered; whether improved knowledge or data would have improved the relevant decisions or policies at issue; what lessons can be learned to guide future regulatory decisions, to improve decision-making processes, or to create greater trust between regulators and those affected by risks. Bodies such as the HSE and Home Office have an established record of commissioning outside research on the effectiveness of risk control systems in operation.

3.4 **Enforcement and compliance**

3.4.1 There is a fairly substantial UK and overseas literature on enforcement and the ways in which enforcement officials regard compliance but the literature on how those subject to regulation consider compliance is relatively underdeveloped. This section is largely drawn from the literature on compliance with state regulatory regimes or regimes where there is a mix of state and other regulatory

¹²⁵ Baldwin and Cave, 1999, p.136-7.

¹²⁶ See Baldwin, 1997.

¹²⁷ For discussion see HSE, 1999, pp.39-40 and HSE 1999(a).

structures – as, for example, where the state co-opts and guides organizational risk management systems.

3.4.2 *The Concept of Compliance*

Regulation aims to control, but not to eliminate, risk. This is not straightforward since definitions of risk and the tolerability of risk vary over time and according to circumstances. Often they are contested. What constitutes compliance is thus often subject to negotiation and change.¹²⁸ This in turn has implications for securing compliance.

3.4.3 *Securing Compliance*

3.4.3.1 A variety of factors has been found to influence the ability of enforcement officials to secure compliance. The primary factors are:

3.4.3.2 Legal frameworks – which are often vague incorporating broad legal standards and involving the exercise of discretion. The literature suggests that specific legal standards are more readily prosecuted than those which are more broadly framed. Specific, detailed standards may, however, prove inflexible and less capable than more general rules of taking into account changing understandings and approaches to the tolerability of risk.¹²⁹ Detailed rules may also fall foul of criticisms that they tie up operations in red tape and do not encourage risk creators to think creatively.¹³⁰ Some commentators have argued that different types of rule have to be linked to different compliance-seeking strategies in order to achieve effective risk control. Detailed rules, for instance, may be usefully employed where there is a need to prosecute recalcitrants, but more general rules may be appropriate where the regulator is promoting a message to parties who are well-disposed to comply.¹³¹

¹²⁸ Di Mento, 1986[Aalders, 1993]; Hutter, 1997.

¹²⁹ Baldwin, 1995.

¹³⁰ Baldwin, 1995.

¹³¹ See Baldwin, 1995, chapter 6.

- 3.4.3.3 Enforcement is influenced by the legal powers available to enforcement officials, for example, powers to access private space and confidential information; powers to collect evidence and interview persons; and powers to sanction. The legal rights of the protected are also relevant (e.g. rights to information disclosure; the right to know¹³²).
- 3.4.3.4 The potency and immediacy of sanctions for non-compliance influences enforcement. Where officials regard the sanctions as derisory they may be reluctant to resort to law. Some argue that weak sanctions are ineffective and do not deter,¹³³ others can find no evidence that the level of penalty influences deterrence.¹³⁴
- 3.4.3.5 The seriousness of the risks to be prevented, affects compliance and widely-varying levels of risks may be encountered, ranging from high probability to low probability risks, and from catastrophic consequences to low levels of harm. Generally compliance is most readily secured where the risks consequences are serious and probability of harm high. In these circumstances the evidential demands of law may be more readily satisfied and there may be less public tolerance of non-compliance.¹³⁵
- 3.4.3.6 Securing compliance is generally more easily achieved in reactive as opposed to proactive situations, most particularly in circumstances where there is highly visible evidence of non-compliance, such as an accident or where the non-compliance is visible to complainants. Important here may be public accountability - where non-compliance is visible, the agency may be exposed to high levels of scrutiny and thus maybe more inclined than otherwise to secure compliance formally and speedily.¹³⁶
- 3.4.3.7 Frequency of interaction between the regulators and the regulated is a factor that has been identified by a variety of studies as an influence on the ways in which

¹³² Cohen, 1991; Knegt, 1989.

¹³³ Carson, 1982; Clinard and Yeager, 1980; Croall, 1992; Richardson et al, 1993.

¹³⁴ Gray and Scholz, 1991.

¹³⁵ Hutter, 1997; Jasanoff, 1986; Short and Clarke, 1992.

¹³⁶ Black, 1971; Hawkins, 1984; Hutter, 1997.

compliance is secured. Where interaction is frequent there is a tendency to use informal, persuasive enforcement techniques to secure compliance.¹³⁷ One point of caution here is that high levels of interaction can lead to leniency, even capture.¹³⁸

3.4.3.8 The regulated's willingness and capacity to comply is a matter often related to the size of the regulated organization. Regulatory capacity refers to technical, informational and economic ability to comply and often larger companies fall into this category more readily than smaller companies. The influence is two-fold. On the one hand, there may be a greater willingness to comply. This may, for instance, be related to intra-organizational pressures such as the employment of in-house experts such as compliance officers. On the other hand, greater regulatory capacity affords greater ability to challenge regulatory demands.¹³⁹ It should also be noted that large organizations can pose problems of their own because the risk management problems encountered by them may be complex and even generated by their very size. The potential for non-compliance is thus much greater.¹⁴⁰ Some commentators divide regulatees into the well-informed, well-intentioned; well informed, ill-intentioned; ill informed, well-intentioned; ill-informed, ill intentioned, and argue that different techniques should be deployed in relation to these groupings when compliance is sought.¹⁴¹

3.4.3.9 The political influences that impinge on efforts to secure compliance are various, ranging from the general political environment (eg. the strength of pro-regulation interests) to the preferences of political authorities, recent disasters, and budgetary constraints. Such factors may influence the strength of the regulatory mission and tolerability of risks. Again, the nature of the precise influence is complicated and likely to vary across time and place.¹⁴²

3.4.3.10 A variety of factors relating to the nature of the regulatory institution will also influence the ways in which compliance is secured. Such factors include the

¹³⁷ Aalders, 1993; Grabosky and Braithwaite, 1986; Hutter, 1997; Scholz, 1984.

¹³⁸ Ayres and Braithwaite, 1991.

¹³⁹ Bardach and Kagan, 1982; Braithwaite and Fisse, 1987.

¹⁴⁰ Di Mento, 1986; Hutter, 1997; forthcoming; Vaughan, 1982.

¹⁴¹ Baldwin, 1995, Chapter 6.

leader's policy approaches; beliefs about enforcement style; and degrees of staff professionalism. The regulatory capacity of the agency and its staff are important and especially significant may be the technical and professional ability of inspectors to understand regulatory problems.¹⁴³

3.4.4 *The Inclination to Comply*

3.4.4.1 It is important to distinguish between the compliance of the organization and the compliance of individuals within the organization. There is no straightforward explanation of compliance. Organisations and individuals vary in their abilities and motivations to comply and they differ over time and across issues. Moreover it needs to be understood that compliance varies between organizations and also within organizations.

3.4.4.2 Enforcement officials' assessments of compliance focus on both levels. At the organizational level, they focus upon systems and, at the micro level, upon different categories of people (eg. employers and employees; specialists and generalists; the skilled and unskilled; the experienced and inexperienced).

3.4.4.3 Compliance is judged according to a variety of criteria which may vary between organisational compliance and individual compliance.¹⁴⁴ These include:

- the organization's / individual's commitment to regulatory objectives;
- their attitude towards compliance;
- the record of compliance;
- the quality of management;
- an organization's ability to comply;
- an organization's treatment of its staff;
- the size of an organization - relating to complexity and potential for non-compliance.

¹⁴² Bardach and Kagan, 1982'; Carson, 1982; Dwyer, 1990; Hutter, 1988; Niejmeijer, 1989.

¹⁴³ Bardach and Kagan, 1982; Hawkins, 1984; Mashaw and Harfst, 1991; see generally Kagan, 1994 for an excellent summary of the literature.

- 3.4.4.4 Explanations of compliance and non-compliance, therefore, involve a complex of factors.¹⁴⁵ Studies of compliance and non-compliance from the point of view of the regulated suggest that following factors affect the inclination to comply.
- 3.4.4.5 *Self-interest* may be both a positive and negative influence on compliance.
- 3.4.4.6 Self-interest is most widely interpreted as cost-related,¹⁴⁶ this very much reflects the focus of most studies of regulation upon the business sector. Profitability is regarded as a pressure militating against compliance. Some authors simply relate compliance and non-compliance to cost, but others regard financial resources alone as an insufficient explanation of compliance – and, one might add, non-compliance.¹⁴⁷
- 3.4.4.7 *Indirect costs* may be a pressure leading parties to comply.¹⁴⁸ These costs include the threat of private lawsuits, increased insurance premiums, the prospect of compensation payments and claims, and avoiding the indirect costs of accidents, including 'downtime' and labour dissatisfaction cost.¹⁴⁹
- 3.4.4.8 Self-interest may contribute a pressure to comply for more fundamental reasons. The most striking example of this involves sites where strict compliance is necessary to the viability of the works.¹⁵⁰ In such cases there is much more than profitability at stake for the whole site of production could be in danger. The most obvious example is a chemical works where, for example, safety considerations may be paramount as non-compliance may produce catastrophic results. In these cases, corporate and regulatory concerns coincide.
- 3.4.4.9 Self-interest arguments emerge as explanations of individual non-compliance.¹⁵¹ It is argued that there is a variety of pressures upon employees and that non-

¹⁴⁴ This is documented in Hutter, 1997.

¹⁴⁵ Di Mento, 1989; Massey 1979; Sigler and Murphy, 1988.

¹⁴⁶ Chelius and Smith, 1987.

¹⁴⁷ Di Mento, 1986; Wilson, 1980.

¹⁴⁸ Sigler and Murphy, 1988: 69.

¹⁴⁹ Bardach and Kagan, 1982.

¹⁵⁰ Genn, 1993.

¹⁵¹ Becker, 1968.

compliance may be caused where it appears more 'rational' to fulfil other more highly prized objectives such as finishing the job as quickly as possible.¹⁵² The decision to comply may thus be the result of a trade-off between risk taking and other objectives, some of which will incline towards compliance and others of which will lead to non-compliance.¹⁵³

- 3.4.4.10 *Corporate responsibility* may provide a motivation to comply. There are, of course, a variety of interpretations of corporate social responsibility¹⁵⁴ and these are reflected in compliance theory. The most clear-cut explanation of this type is that companies comply because of adherence to moral principles, for example a genuine concern for the environment or the health and safety of the workforce.¹⁵⁵ This suggests a commitment both to the spirit and the letter of the law.
- 3.4.4.11 Other companies may comply, not because they believe in the law, but because they feel that they have an obligation to comply out of 'good citizenship'. In this type of firm decisions are principled but this does not mean that compliance is inevitable, there is the possibility of principled non-compliance.¹⁵⁶
- 3.4.4.12 Individuals may also comply for moral reasons or because someone feels that they should be a 'good citizen'.¹⁵⁷ There is contradictory evidence about whether or not legal obligation plays a role in individual compliance.¹⁵⁸
- 3.4.4.13 *Protection of reputation* is regarded as a central influence leading towards compliance.¹⁵⁹ Large companies are seen as particularly concerned to protect their image and so are those whose relationships with the public are already or potentially strained. Business is clearly perceived to be susceptible to external

¹⁵² Dawson *et al*, 1988; Hutter, forthcoming.

¹⁵³ Hutter, 1997.

¹⁵⁴ Stone, 1975; Hutter, forthcoming.

¹⁵⁵ Sigler and Murphy, 1988; Hutter, 1997.

¹⁵⁶ Kagan and Scholz, 1984.

¹⁵⁷ Brittan's (1983) study of the impact of water pollution control on industry found that a 'moral obligation' to compliance was the major explanation of compliance.

¹⁵⁸ Brittan, 1983 cf Makkai and Braithwaite, 1994.

¹⁵⁹ Braithwaite, 1989; Clinard and Yeager, 1980; Miller and Sturdivant, 1977; Olsen, 1992.

pressures from a variety of sources, ranging from consumers to peer groups.¹⁶⁰ Indeed, it is precisely such pressures that identify publicity as an important form of social control for corporations.¹⁶¹ Individuals may also comply out of a desire to protect their professional reputations.

- 3.4.4.14 *Enforcement* of the regulations may be a significant motivation to comply but the evidence is contradictory. Some authors adopt a classical deterrence approach to the importance of enforcement and argue that penalties will only deter if sufficiently high to have an impact on profitability.¹⁶² Others can find no evidence that higher penalties provide more deterrence than lower penalties and emphasize instead the damaging symbolic effects of being punished at all.¹⁶³
- 3.4.4.15 The *likelihood of detection* may also be significant in explaining compliance,¹⁶⁴ but again the evidence is contradictory.¹⁶⁵
- 3.4.4.16 The most common explanation of workplace deviance is *ignorance* or a lack of awareness of the *law*¹⁶⁶ and some claim that ignorance is widespread.
- 3.4.4.17 A related explanation of non-compliance suggests that a *lack of awareness of the risks* is associated with non-compliance but the evidence is not conclusive since non-compliance may occur where the risks are well understood and even where they are known to be serious.¹⁶⁷
- 3.4.4.18 *Intra-organizational pressures* are significant factors in motivations to comply or not comply. Non-compliance may be associated with a negative corporate culture where compliance is not encouraged and where there may be peer pressure not to

¹⁶⁰ Di Mento, 1986.

¹⁶¹ Fisse and Braithwaite, 1983.

¹⁶² Carson, 1982; Clinard and Yeager, 1980; Gunningham, 1984; Pearce, 1976.

¹⁶³ Gray and Scholz, 1991.

¹⁶⁴ Witte and Woodbury, 1985.

¹⁶⁵ Brooks and Doob, 1984.

¹⁶⁶ Brittan, 1983; Dawson *et al.*, 1988; Genn, 1993; Sigler and Murphy, 1988.

¹⁶⁷ Hutter, forthcoming.

comply.¹⁶⁸ A positive corporate culture, may, could encourage compliance and lead to intra-organizational pressures to comply.¹⁶⁹

- 3.4.4.19 Associated factors include *low worker morale*, which may be a consequence of low pay or industrial action. Occupational health and safety inspectors in Britain have identified this was a major reason for non-compliance.¹⁷⁰
- 3.4.4.20 There may be *competing organizational objectives*, notably production pressures, which may conflict with regulatory objectives. This is a dominant theme in the literature on risk taking and is reflected in the trade-offs individuals make between risk-taking and compliance.¹⁷¹
- 3.4.4.21 *Assessing compliance levels may be difficult* - This is especially so where the risks are less than catastrophic and there is greater scope for negotiation and flexibility. Much regulatory non-compliance may also be hidden. There may be no third party aware of the non-compliance, indeed in the absence of a complaint or inspectors chancing upon non-compliance there may be no awareness of the offending. This is partly because no harm may have been caused, the nature of much regulation being to manage risks so as to prevent harm rather than just react once harm has been caused. This may place the regulated in a strong position both with respect to non-compliance remaining unknown and challenging regulatory decisions about what are acceptable levels of risk-taking.
- 3.4.22 Compliance is sought at a number of levels, notably the organizational and individual. Compliance theory offers limited guidance on what motivates people to comply. What is known is that it is complicated and changing. The evidence about the importance of differing factors is contradictory, it seems to depend in

¹⁶⁸ Massey, 1979; Sigler and Murphy, 1988; Whitehurst, 1977.

¹⁶⁹ Bardach and Kagan, 1982.

¹⁷⁰ Hutter, 1997.

¹⁷¹ Carson, 1982; Heimer, 1988; Hutter, forthcoming; Nelkin & Brown, 1984.

part on circumstances. The clearest policy message, therefore, seems to be to design a system which takes into account the variety of factors identified as being important and which can be responsive to the range of circumstances likely to be encountered.

3.4.5 *The Limitations of Compliance*

3.4.5.1 Complete compliance with the relevant rules may not reduce risks in the ways that policy-makers intend or desire. The 'right results' may not be achieved, even where there is compliance, for two main reasons. The first of these is that parties may indulge in 'creative compliance' and side-step the rules (as where an athlete avoids using a banned drug but takes a substance with the same effect as the banned drug).¹⁷² The rule is not broken but the rules' intention is flouted. The propensity creatively to comply around the rules will depend on the balance of costs and rewards involved, which, in turn, will vary according to such factors as the regulator's ability to clamp down on creative compliance with new rules, on the relevance of general rules (which may curtail creative compliance with particular rules); the period during which the benefits of non-compliance will be enjoyed; and the legal uncertainties involved.

3.4.5.2 A second reason why compliance may not reduce risks efficiently is that the rules involved may be under-or over-inclusive. Under-inclusive rules fail to cover all of the creators of the relevant risks, over-inclusive rules may reduce the relevant risks but may discourage or prevent desirable behaviour and this may prove socially costly.

4. **Conclusions**

4.1 Good risk regulation and management regimes must satisfy a number of desiderata.¹⁷³ They must be effective in reducing risks to appropriate levels and must achieve the right balance of reductions across different risks – an objective

¹⁷² See McBarnet and Whelan, 1991; Baldwin and Cave, 1999, pp.102-3.

¹⁷³ For a discussion of benchmarks see Baldwin and Cave 1999, chapter 6 and for governmental yardsticks see DTI, 1998, and Better Regulation Task Force, 1998.

that itself raises issues on the appropriateness of (or mandate for) any given set of trade-offs between different risk reductions. Effectiveness also demands that regimes are flexible and responsive to new information and varying circumstances. They must be efficient in so far as the above objectives are achieved at reasonable (or even least practicable) cost. They should, in addition be accountable, open and fair. They must, accordingly, be subject to proper democratic controls, disclose information reasonably, adopt processes that give access to interested or affected parties and produce results that are not biased or disproportionate.

- 4.2 As has been seen, risks can be controlled in a variety of ways: within organisations and externally; by compulsion or voluntarily; and by an array of devices. Tactically and philosophically a number of approaches can be contrasted: anticipatory versus resilience; blamist versus non-blamist, quantitative versus qualitative; rational versus social; result-based versus process-oriented¹⁷⁴.
- 4.3 Within government and industry there is a rapidly growing appreciation, first, that risk assessments have a role to play in decision and policy-making processes and, second, that approaches to risk have to take on board the qualitative and perceptual dimensions as well as the quantitative. Within such strategies as the HSE's ToR and Total Quality Management, efforts have been made to integrate risk assessments into the broader standard-setting and managerial approaches but counter tendencies have been encountered in the Cabinet Offices' espousal of CBA-driven regulation.
- 4.4 The optimal stage at which to intervene in a risk creation process is an important issue. In different circumstances it may be best to exert control at the preventive, the act or the harm stage of an activity. A pitfall to be avoided is an approach that seeks always to intervene at a particular stage. Preventive and precautionary approaches may be called for in certain circumstances (where harms are extreme and/or irreversible) but, under different conditions such strategies as screening

¹⁷⁴ See Royal Society, 1992, p. 159.

and the regulation of potential risk creators may involve very high costs and restrictions for no material gain. An astute approach to the point of intervention will direct actions towards the stage that gives the best combination of cost and risk-reducing benefit while taking account of relevant policy or distributional concerns.

4.5 In relation to institutions, particular attention was paid to professional, self-regulatory bodies and note taken of claims and criticisms. A review of self regulation, however, reveals that it can be operated in conjunction with a variety of forms of governmental oversight, with degrees of lay input, openness, and accountability. As a result, it is difficult to conclude that self-regulation is intrinsically more or less suspect in its operations than fully independent regulation. Both have strengths and weaknesses as risk control devices. In relation to both types of institutional framework the way forward lies in devising combinations of controls that offer satisfactory performance on the various fronts discussed in section 4.1. above. Self-regulation can work badly and is prone to a number of weaknesses but it is a mode of control that can be harnessed to good effect.

4.6 Looking to enforcement, we found that a number of factors have been found to conduce to the effective exertion of control and to the tendency of parties and firms voluntarily to comply with the relevant rules. It was noted, however, that securing compliance with formal rules may not always suffice to achieve desired ends. The rules may be under or over-inclusive, parties may 'creatively comply' around the rules, and formal rules may not be the best tools for influencing certain forms of behaviour – attention, in many sets of conditions, might more profitably be devoted to such matters as staff selection, education and training methods, peer group pressures, incentives in employment, public promotional work, review processes and procedures.

4.7 Areas of professional judgement, it was noted, present special problems of risk control particularly through the application of formal rules. The decisions involved are often of high importance, low visibility and high discretion. Professionals tend to cherish such domains of judgement and to be resistant to control devices.

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