Reference A&G/W&O/03 80398

Requirements Analysis: The Development of Regulatory Criteria and Assessment Tools for Safety Assurance Systems

Final Report

SUBMITTED TO

Eveline van der Stegen
Directie Arbeidsveiligheid en gezondheid
Ministerie van Sociale Zaken en Werkgelegenheid
Postbus 90801
2509 LV Den Haag
Wilhelmina van Pruisen 104

BY

The Noordwijk Risk Initiative Foundation
13 December 2004

CONTACT

Dr. J Kingston
Noordwijk Risk Initiative Foundation
P.O. Box 286,
2600 Delft,
The Netherlands

Tel: +44 (0) 1952 850 595
Fax: +44 (0) 1952 850 596
Mob: +44 (0) 7966 549 986
Email: j.kingston@nri.eu.com

EXECUTIVE SUMMARY

This report considers how SZW might approach the task of developing a tool to help inspectors assess the safety management arrangements of operators.

Assessment by SZW is not a neutral matter; the regulatory role governs the approach that needs to be taken. SZW needs data that are adequate for compliance and enforcement purposes. Such data need to reflect a standard of evidence suitable for use in legal contexts. There is also a need to gain information through the assessment process that enables SZW to ensure its competence as a regulator by acquiring accurate information about safety management and how to regulate it effectively.

The design of the assessment tool will be informed in a number of ways; two are noted here. The first is a description of how inspectors reach judgements about the adequacy of operators' safety management. The second is a model of safety management, developed to promote systematic assessment. Concerning the second of these, the scope of assessment is a challenging matter. Clearly assessment should be able to identify areas of weakness in the operator's safety management; but it is argued that this is not enough. Assessment also needs to gain insight into the circumstances of the operator that produce inadequacies in safety management. This is discussed in terms of self-regulatory capacity and SZW's role as a regulator of self-regulation.

The assessment tool is likely to have manual and software aspects. It is recommended that Decision Support System technologies are reviewed for use in the assessment process but that the case for adoption should be based on sound analysis of costs, benefits and risks.

It is likely that the range of tasks and contexts for assessments cannot be regarded as serviceable by one tool. It is helpful to think of an assessment 'toolkit' in which the tools are designed to be used together and to produce data in an inter-operable format. A toolkit also offers the flexibility to develop the constituent tools over time, which has practical advantages for project management and spreading costs.

The design philosophy advocated for the project is user-centred design; this is thought to best reflect the need to involve inspectors closely in the design process. Projects advertised as user-centred frequently do not involve users as closely as might be desired; this is often because of power imbalances amongst the various groups involved in the design. In view of this, a project steering board is advocated, constituted in a way that ensures the proper level of involvement not just for users, but all groups identified as having a stake in the assessment tool. If the toolkit is to be developed gradually, there may be a case for putting the project onto a long-term footing, in which case a partnership approach might be an appropriate option for steering the project.

CONTENTS

1 OVERVIEW

This study seeks to inform a project (hereafter called "Project-X") that could be undertaken to design a tool (hereafter called "Tool-X") for inspectors of sites within the scope of the Seveso II directive[1] and BRZO[2].

The accent in this paper is on a "systems approach" to the regulatory context of this work. Key concepts are identified and explained. On these foundations are established requirements that are specific to regulatory assessment of safety management systems in the major hazards setting. These requirements are also informed by an analysis of the Seveso II Directive and its implementation in Dutch law and through discussion with SZW staff.

The answer to the question "how to assess a safety management system?" depends on who is doing the assessment and why. Because of this, detailed consideration is given to the regulatory context in which assessments will take place. Also considered are the principles that apply to regulation of any kind (those of cybernetics) and the current social, political and legal principles of relevance to state regulation of business activities.

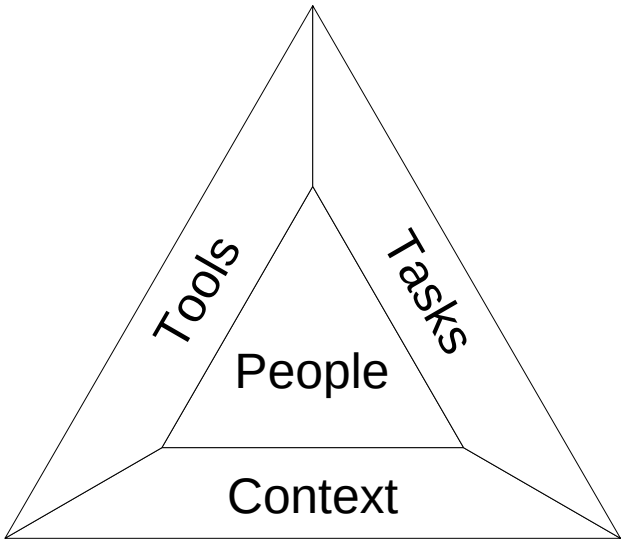
A central issue for Project-X is the development and application of a suitable model of safety management systems. As shall be argued, assessment is limited by the adequacy of the regulatory model used. There are many reasons why a single, normative model of a safety management system should be adopted, for example, for reasons of consistency and the potential for creating a verification system using outsourced (from SZW) human resources. However, a counter-case is presented that argues for a variable descriptive model that is operator-centred.

The requirements for Project-X are explored here using a framework that considers the regulatory context, the people involved, and the range of tasks and attributes of Tool-X. On these foundations, the attributes of a model for regulatory assessment of safety management system is presented. The final section collates the foregoing material into answers to the questions posed in the startnotie.

2 FRAMEWORK FOR THIS REPORT

The intention of this section is to identify relevant ideas that can be applied to SZW's task of assessing safety management of major hazard sites. Where ever possible, fundamental concepts are identified.

The design task for Project-X needs to be set in a suitable perspective. Four factors are considered, each in a sub-section:



- the **context** in which the tool is used, this section aims to identify concepts and requirements that frame the assessment task for SZW. In a way, this section explores different viewpoints on the purposes that will be integrated into Tool-X by Project-X;
- the **tasks** assisted by using the tool. This section considers how Project-X might develop adequate descriptions of the tasks to be supported in relation to assessment. This set includes both "sub-tasks" and associated tasks. Although Tool-X will be designed to assist inspectors to assess safety management systems, this is part of the regulatory function of SZW. Therefore the role of the tool in assisting the design of regulatory interventions is also to be considered;
- the **people** who will use the tool; this focuses mainly on inspectors, their needs and their goals. However, there are other stakeholders who need to be considered, both within and outside of SZW;
- The section on the properties of **tools** identifies the desirable properties and functions of Tool-X. Contrasting views of models and modelling are also presented.

Any issue identified in respect of one factor is likely to have an impact on the three others. The interrelations of these factors will need to be reconciled by Project-X; the implications for project governance and design philosophy are considered.

2.1 Context

The central theme of this study is the assessment of management arrangements at major hazard establishments. There are many ways this could be done; indeed there are many safety management assessment solutions available off-the-shelf. But whether these would be appropriate or not depends on whether the aims and needs of the safety regulator coincide with the requirements of safety management. To gain insight into this matter, this section considers regulation from various standpoints and seeks to identify generic aims and needs.

2.1.1 Regulatory principles

The literature survey reveals a growing discussion about the principles that should inform regulatory efforts in society. Much of this discussion arises from the *administrative simplification* debate which challenges the view of regulation as something done by Government to businesses and citizens. This paradigm of regulation is often referred to as *classic regulation* (e.g. BRTF 2003[3]) and sometimes *public regulation* (e.g. CEC 2002[4]). The question posed in the debate is whether the aims of government policy can be achieved by alternatives to centralised regulation.

Following the Dutch May 1998 elections, the coalition agreement described its approach to administrative simplification as seeking a *"new balance between protection and dynamism"* (OECD, 1999[5]). This is a familiar debate in the field of health and safety and is marked by milestones such as the Robens' Report (HMSO, 1972[6]). Robens made the point that a prescriptive approach cannot keep pace with technological change and the level of complexity encountered in the field of health and safety:

> *"There are severe practical limits on the extent to which progressively better standards of safety and health at work can he brought about through negative regulation by external agencies. We need a more effectively self-regulating system."… "The objectives of future policy must therefore include not only increasing the effectiveness of the state's contribution to safety and health at work but also, and more importantly, creating the conditions for more effective self regulation."*

Robens' conclusion has a number of implications for Project-X. Firstly, the *administrative simplification* debate often portrays public/classic regulation and self-regulation as dichotomous. The Robens' conclusion implies that the state can cultivate self-regulation; indeed, the present authors see these two forms of regulation as reciprocal and complementary.

Two questions for SZW are whether they agree with Robens' conclusion and whether they see a mission for themselves to develop self-regulatory capacity in the firms they regulate

and within the industry at large. The answer to this depends partly on interpretation of the Seveso II directive, and partly a judgement as to whether this is seen as a part of Dutch tradition of consensual approaches to regulatory matters, as evident in the use of covenants and permits.

SZW as a Regulator of self-regulation

Regulatory competence depends upon information, most of which is obtained from the operator[a]. In major hazards regulation, two channels stand out: safety report submission and the SZW/VROM inspection regime. However, it is not clear whether information gained via safety reports and inspections is appropriate to enable competent regulation of self-regulation; an uncertainty that forms a recurring theme. To put it another way: what is the relationship between management of major hazard safety and regulatory assessment; the two have much in common, but if there are differences, which of them have an impact on the regulatory process? To find an answer, a clear view is needed of safety management but also of regulation, which is discussed in the next section.

2.1.2 The cybernetic view of regulation

This section provides an overview of the cybernetic view of regulation. This makes a number of issues visible and introduces concepts and terminology that is used in the rest of the report. Much of the material in this section presents the view of regulation developed by Ashby and is advocated here as a simple, general scheme for framing problems of regulation.

The relationship between information, communication and regulation is well developed in cybernetics. Cybernetics has been defined as the science of control and communication (Weiner, 1948) and by Ashby (1956[7]) as the science of steersmanship (from which, via Greek, the word was derived). Cybernetics can be thought of as the study of steering of complex systems towards their goals in the face of difficulties. Heylighen and Joslyn (2001[8]) describe cybernetics as:

> *"… the science that studies the abstract principles of organization in complex systems. It is concerned not so much with what systems consist of, but how they function. Cybernetics focuses on how systems use information, models, and control actions to steer towards and maintain their goals, while counteracting various disturbances. Being inherently transdisciplinary, cybernetic reasoning can be*

[a] The Slechte Committee (Committee for Reduction of Administrative Burdens on Enterprises) in the Netherlands is noted for focusing its approach to reducing administrative burden on the costs imposed on enterprises. This singles out for reduction "the costs of the information enterprises have to supply to make law enforcement possible" (OECD, 2003[a])

applied to understand, model and design systems of any kind: physical, technological, biological, ecological, psychological, social, or any combination of those."

Ashby's formulations allow regulation to be seen as a process in which valuable assets are defended from unwanted change by selectively blocking disturbances. Perfect regulation is achieved when no information is transmitted from disturbances to these assets. In the present context, perfect regulation is achieved when, for the lifecycle of the plant, no harmful energies or substances (disturbances) escape containment to harm and pollute. In most systems, perfect regulation cannot be achieved; instead the aim is to prevent most but, reluctantly, to accept some disturbance of assets.

Ashby's Law of Requisite Variety

In the cybernetics tradition, a regulator is a function, not an identity. The function of the regulator is to offset the effect of disturbances. It achieves this by acting on the operational part of the system upon which the disturbance itself acts. Ideally, the regulator acts in time to limit unwanted outcomes. What this means is that the regulator has to respond to different disturbances with an appropriate action. Although some regulatory actions will apply to many different disturbances, the general argument is the same: the regulator must be able to respond to a variety of different disturbances with an appropriate variety of actions. If the regulator does not have enough variety it will not be able to offset the effect of the disturbance on the operational system; it will allow the disturbance to produce unwanted outcomes. When a regulator can offset all disturbances that could produce unacceptable outcomes, it is said to possess *requisite variety*. The notion that only variety in the regulator can force down variety in outcomes is called *Ashby's Law of Requisite Variety.*

A regulator acts as model of the system it regulates

This way of looking at regulation produces a number of far reaching conclusions; among them Ashby's law just mentioned. Another is that a regulator *acts as model of the system it regulates*[b] (Conant and Ashby, 1970[9]). Regulation is about the association of disturbances with unwanted outcomes and the reduction of these effects by altering the operational system. If the regulatory model is perfect, the action of the disturbance on the operational system has a one-to-one correspondence with the action of the disturbance on the regulator and the regulator's response. The better the approximation of the regulatory model to the system, the better the regulation that can be achieved.

[b] The exact wording is "Every good regulator of a system must be a model of that system".

Two basic forms of regulation

There are two forms of regulatory action: (i) to act in anticipation of an unwanted outcome and (ii) to react to an unwanted outcome. In the first option, *feedforward or cause-controlled* regulation requires a regulatory model that has already been "programmed" with a response to the disturbance. In the second option, *feedback* or *error-controlled* regulation, the regulator has to generate the variety missing from its model.

Ashby (ibid.) provides a simple scheme for illustrating the various aspects of regulation. It has four terms: *essential variables (E), disturbances (D), transformation (T), and the regulator (R).*

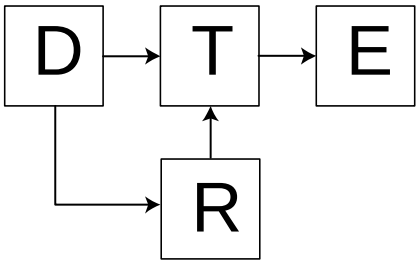


Figure 1. Feedforward or cause-controlled regulation

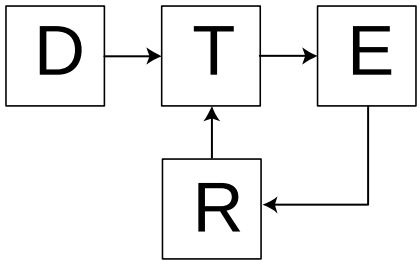


Figure 2. Feedback or error-controlled regulation

The feedforward form depends on pre-programmed response; how is the programming to be achieved? There are two ways of creating the necessary information: (i) by constructing and running simulation of D-T-E and (ii) in real-life by associating unwanted changes in E with changes in D (in this system or in similar systems). In other words, the feedforward form is supported by the feedback form.

In the major hazards setting, feedforward is clearly the preferable form of regulation for losses of containment. However, as Heylighen (ibid[8].) notes*: "No sensor or anticipation can ever provide complete information about the future effects of an infinite variety of possible perturbations [disturbances], and therefore feedforward control is bound to make mistakes. With a good control system, the resulting errors may be few, but the problem is that they will accumulate in the long run, eventually destroying the system".* Therefore, feedback regulation is essential rather than secondary in maintaining regulatory models.

Another point to be made here is that achieving regulation through feedforward is very complex whereas the feedback form can be very simple. But although simple, regulation through feedback may be too slow, allowing a catastrophic change in the state of essential variables before the regulator can adapt to the new disturbance.

There is, however, a third way which can be exploited to speed-up feedback response to

new disturbances. This is best introduced using examples from biology; cybernetics often uses knowledge of biological systems to inspire and test its insights. The feedforward mode can regulate animal behaviour in two ways: through the genes and by social transmission (other animals). If neither the genes nor other animals prepare the individual with an exact answer to a hazardous situation, it has to develop its own response. However, if random experimentation will take too long, is there a quicker way for the individual to gain the information missing from its genes and experience? The answer is that the information comes from the environment. Ashby (1962[10]) provides a memorable illustration:

> *"…there is advantage in the development of an adapting mechanism that is (1) controlled in its outlines by the gene pattern (for the same outlines are wanted over many generations), and (2) controlled in details by the details applicable to that particular generation.*
>
> *This is the learning mechanism. Its peculiarity is that the gene pattern delegates part of its control over the organism to the environment. Thus, it does not specify in detail how a kitten shall catch a mouse, but provides a learning mechanism and a tendency to play, so that it is the mouse which teaches the kitten the finer points of how to catch mice.*
>
> *This is regulation, or adaptation, by the indirect method. The gene pattern does not, as it were, dictate, but puts the kitten into the way of being able to form its own adaptation, guided in detail by the environment".*

It terms of the programming of the regulatory model, this insight points to the idea of *regulatory amplification*. If a complex regulatory model is to be built (and maintained), it may need to be done in two or more stages. Each stage informs the next and, at each stage, the regulator uses the sources of information available to develop its model. This regulation of regulation (or meta-regulation) allows requisite variety to be achieved in complex systems.

Ashby's observation, that the gene pattern does not dictate to the individual, is picked-up by Beer (1976[11] and 1989[12]) and applied to control in society and industry. Beer notes that the logic of staged amplification is sometimes ignored; higher regulatory levels try to dictate in too much detail. This has two potentially serious effects. The first is to use-up bandwidth in the communication channels between the higher and lower level regulators and the processing capacity of the two regulators. This means that there is less capacity overall for the feedback that maintains adaptation between regulators and changes in the system. The second problem is that the higher level regulator may insist on actions that may not be appropriate to the local situation but has no way of recognising this (other than in a very general way when unwanted outcomes begin to occur). To avoid these pitfalls, Project-X must explicitly consider how to apply the notion of regulatory amplification to the requirements of the Seveso II Directive[13] which states that:

"…the operator is required to prove to the competent authority…that he has taken all the measures necessary as specified in this Directive".

Other Options to balance requisite variety

Amplification of regulatory variety by stages is a very significant option; it allows systemic control to be achieved by having one regulator design another. When the system to be regulated is complex, the task of constructing a regulator is too complex to achieve in one stage and must use the method of successive supplementation so as to meet the requirements of the law of requisite variety at each stage and overall.

Although amplification is important, there are other ways of achieving requisite variety in regulation. From the Ashby scheme, the following points can be derived.

Allow a wider variety of outcomes in E

The less variety that is possessed by a regulator, the greater the variety of outcomes created by disturbances. In terms of losses of containment, this could equate to allowing a lower standard of protection (e.g. a steeper or higher F/N curve). This points to a desirable function for Tool-X: the ability to display changes in the variety of outcomes exhibited at a major hazard establishment. The nuclear industry and reinsurance businesses use a family of statistical methods called extreme value projection (EVP). EVP allows incident experience to be extrapolated into the future. This allows changes in the statistics of a system to be recognised for their major accident potential and provides a quantitative predictive method for detecting changes of the type characterised by Rasmussen (1996[14]) as the migration of behaviour "towards the boundary of acceptable performance" in the presence of strong gradients (i.e. disturbances).

Reduce the variety of the disturbance (D)

Disturbance may arise from the system itself (e.g. random fluctuations or performance or errors) or from external sources. In the major hazards context, the variety of internally generated disturbance can be reduced through plant design in a number of ways such as using standardised components (Frei et al, 2002[15]), simpler designs and less energy (e.g. Kletz, 1993[16], OECD, 2003[17]). Options for reducing the variety of disturbances from external sources of variety include choosing less volatile environments (in physical, social and economic dimensions, e.g. currency exchange rate, climate, security, stability of workforce, availability and consistency of materials etc).

Exploit constraints in the variety of Disturbances

In most cases, not all types of disturbance have equally probability of occurrence; some disturbances will be repetitive while others are rare, or are only theoretically possible but never encountered in practice. This constraint can be used to advantage if the variety of the regulator cannot be increased or disturbances artificially decreased. In risk terms, this is analogous to accepting the tolerable risks that remain after all reasonable modifications and precautions have been implemented.

Increase the variety of the regulator

The variety of a regulator is equal to the number of distinct states it can occupy. If the disturbance has a variety of 20 distinct ways it can act on the operational system to cause unwanted outcomes, but the regulator has only 10 distinct actions it can perform, some unwanted outcomes will not be prevented by R. Even if reconfigured to exhibit different actions, and so oppose different states of the disturbance, some unwanted outcomes will still result from those states of D that are not catered for. A minimum requirement in such circumstances is to increase the variety available to R to twenty-or-more states. This does not achieve adaptation (i.e. requisite variety) in the regulator, but it does satisfy the requirement for a sufficient number of states, which is a necessary condition.

Fundamental questions for designers of regulation: *what is important and what is wanted*?

Ashby formulates the regulatory situation in the following way:

> *"In practice the question of regulation usually arises in this way: The essential variables E are given, and also given is the set of states η in which they must be maintained if the organism is to survive (or the industrial plant to run satisfactorily) These two must be given before all else. Before any regulation can be undertaken or even discussed, we must know what is important and what is wanted."*

An outcome of this is that the more the range of acceptable values is restricted, the smaller (and harder to hit) becomes the target for regulating the effects of disturbances; in general terms, the variety of regulation is inversely related to the variety of acceptable states.

The tightness of the acceptable range of outcomes is compounded in complex systems, which often have many distinct essential variables within the η set (eta set). Attempts to maximise one essential variable may well have an impact on others because all the variables are products of the one system. Although some essential variables may seem very different, they are related – albeit indirectly – through the complex network of relationships that comprise the system to be regulated and its environment. In these circumstances, actions to maximise one essential variable will add variety to the disturbances acting on other essential variables. (EVP, discussed on page 11, is relevant here. There may be strong or weak relations between different control subsystems. The weakly related subsystems need to be

identified and plotted separately.

Managers face the self-regulatory challenge of optimising across a set of essential variables, ensuring that the implementation of their decisions do not produce outcomes outside the η set. This places large demands on modelling of the effects of decisions before implementing and, afterwards, on monitoring to be vigilant to unwanted effects. However, because of the complexity of the system, the connections between effects and causes are not always straightforward (either in the model or in the monitoring).

2.1.3 Major hazard safety: two classes of essential variable

The ideas discussed so far will be used in various ways in the ensuing discussion. For the moment, it seems opportune to note that there are two classes of essential variables of particular importance to the assessment context: prevention of losses of containment is one and the other is the reliability of barriers and controls:

(i) ***regulation*** (R) of the operating system (T, e.g. a chemical process) to avoid losses of containment (E). This will involve the development of regulatory actions (i.e. barriers and controls) using a model of the operating system and the impact of possible disturbances (D) of it. This development will occur at various times: before the plant is commissioned and afterwards. The result of this development is an evolving configuration of barriers and controls – a term for referring to the application of people, plant/hardware and procedures (PPP) to prevent unwanted events;

(ii) ***reliability*** of barriers and controls can itself be considered as an *essential variable* (E). In this case, T is the system of people, plant/hardware and procedures (PPP) that is vulnerable to disturbances. R's job here is act on PPP so as to stop disturbances from reducing the reliability of barriers and controls.

It is important to recognise that *barriers* and *controls* are used throughout this report in the way described in Frei, 2002[15]. *Barriers* are designed to protect against unwanted flows of energy (e.g. kinetic, chemical, electrical etc.); *controls* are designed to deliver operational goals, which offer protection as a by-product. Barriers and controls operate at the same level of system as the energy flows they are designed to affect. Barriers and controls are functions rather than identities. To illustrate this point, control of the traffic flow around the scene of a car accident can be achieved by a police officer directing traffic; the police officer is not 'the control' but the combination of the officer's presence, equipment and actions functions as a control. The distance between a residential area and a hazardous establishment functions as a barrier but is an area of land, trees etc. without dwellings and a volume of airspace. By this definition, such things as procedures, training courses and risk assessments are not barriers or controls (although these things may be instrumental in imple-

menting barriers or controls).

2.1.4 Regulatory principles from "administrative simplification"

As mentioned, the regulatory simplification debate which started in the mid-1990s has resulted in considerable activity in each of the OECD countries. Although the concerns of the Seveso II directive are so serious that they justify a high degree of "regulatory weight", compliance and enforcement activities still need be considered in the context of this influential development in thinking on public policy.
The OECD (2003[18]) identifies five international trends in the attempts to improve efficiency of regulation:

(i) pressure on regulators/legislators to ensure that unnecessary or unreasonable burdens are avoided;
(ii) increasingly integrated, top-down, government programmes of administrative simplification;
(iii) growing acceptance in public policy, that economic agents "should be free to conduct their business unless compelling arguments can be made for the need to protect sections of the public";
(iv) exploitation of internet visibility of bureaucracy by agencies pushing the administrative simplification agenda
(v) Such pressures often go beyond aspirations for further simplification of regulations. They also lead toward substantial changes in the applied regulatory means and measures.

Table 1: International Trends in Administrative Simplification (OECD, 2003[18])

The implications for Project-X fall into two types: justifying the costs (burdens) and benefits (to Seveso II aims) of applying Tool-X on businesses, and; ensuring that Tool-X is flexible with respect to the assistance it gives in informing regulatory actions.

Another set of criteria, which have been widely integrated into governmental departments and agencies in the UK, is that produced by the "Better Regulation Task Force". The BRTF is a standing committee established by the British Government in 1997. The criteria, which the BRTF calls the *five principles of regulation* (BRTF, 2003[19]) are summarised in Table 2.

Principle	Brief Description
Proportionality	Regulators should only intervene when necessary. Remedies should be appropriate to the risk posed and costs identified and minimised.
Accountability	Regulators must be able to justify decisions, and be subject to public scrutiny.
Consistency	Government rules and standards must be joined up and implemented fairly.
Transparency	Regulators should be open, and keep regulations simple and user-friendly.
Targeting	Regulation should be focused on the problem, and minimise side effects.

Table 2: The BRTF's Five Principles of Regulation (Source: BRTF, 2003[19])

If these criteria are agreed as binding on Project-X, it becomes clear that any regulatory decision informed by using Tool-X needs to be justifiable; Tool-X cannot be a wholly black-box.

2.1.5 OECD principles for public authorities

The OECD (2003[17]) have stated a list of roles (which they call "Golden Rules") for those they identify as stakeholders "who are involved or interested in, or potentially affected by, chemical accident prevention, preparedness or response". Although the "Golden Rules" are not binding on stakeholders, they do provide another source of requirements to be integrated in Tool-X. Eight roles are stated for public authorities:[c]

1. Seek to develop, enforce and continuously improve policies, regulations, and practices;
2. Provide leadership to motivate all stakeholders to fulfil their roles and responsibilities;
3. Monitor the industry to help ensure that risks are properly addressed;
4. Help ensure that there is effective communication and co-operation among stakeholders;
5. Promote inter-agency co-ordination;
6. Know the risks within your sphere of responsibility, and plan appropriately;
7. Mitigate the effects of accidents through appropriate response measures;
8. Establish appropriate and coherent land-use planning policies and arrangements.

[c] Which the OECD (ibid.) defines as including *"national, regional and local authorities responsible for any aspect of chemical accident prevention, preparedness and response. This would include, inter alia, agencies involved in environmental protection, public health, occupational safety, industry and emergency response/civil protection."*

2.1.6 Stakeholder relationships and negotiated regulation

Some of OECD's "Golden Rules" (especially item 2, above) point to the issue of relationships and regulation. Within the administrative simplification debate, most of the discussion about relationships is confined to consultation over new legislation or regulations. However, because safety management systems are not easily defined in detail, there is considerable scope for dialogue between the regulator and the regulated to determine what is appropriate given the operational context. This is an example of what Ashby refers to as "regulation by the indirect method" as discussed earlier on page 10: the information missing from the regulatory model (e.g. BRZO or Annex III of Seveso II) is provided by the environment of regulation; in this case, it is generated by the interplay between SZW and the operator.

However, this approach is not without political tensions; the "*Final Considerations*" report of the committee for investigation of the Enschede disaster (Ministry BZK, 2001[20]) puts the issue of relationships between regulators and other stakeholders into sharp relief.

> *"… for the themes of supervision and enforcement a certain tension also exists among the opinions of the government as it does in society. In this case it also involves, on the one hand, the desire that the government recognise the responsibilities that citizens and companies have themselves, and correspondingly maintain a certain distance and offer opportunity.*
>
> *This is reinforced by notions such as those of negotiating administration, and of horizontalisation between government and private entities. A voluminous file of supervisors and enforcers is not appropriate for this, nor a public administration which imposes sanctions from a vertical position.*
>
> *On the other hand, there is a strong tendency in society to hold the government immediately responsible for lack of supervision and lack of courage and willingness to enforce as soon as a calamity takes place. At that time the government is apparently expected to act – and to have already acted – from its vertical position, as the government, and that it has and maintains sufficient personnel in readiness. The ongoing debate on the fireworks disaster in Enschede and the café disaster in Volendam will, in the opinion of the Committee, not be able to get away from the tension between these two types of opinions and expectations."*

Although this tension exists, within the domains of environmental protection (e.g. Elcock, 2000[21]) and occupational health and safety there are a growing number of examples of *negotiated regulation* (Ashford and Caldart, 2001[22]). Negotiated regulation can be seen as a means by which a general set of regulations are tailored to a particular context. Ashford and Caldart identify three main areas of negotiation:

(1) *negotiated rulemaking*, for setting regulatory standards;

(2) *negotiated implementation*, to determine how an agreed regulatory standard is to be applied to a particular firm, and;

(3) *negotiated compliance,* used to determine "the terms by which regulatory standards will be enforced against a particular firm"…"that is out of compliance with a particular regulatory standard".

In Ashby's terms, negotiation helps to communicate what is good (i.e. the aim of the law, such as Article 1 of Seveso II[d]) and what is wanted in terms of specific criteria for compliance. Negotiation is needed when laws do not specify requirements at a low enough level of detail to be used as criteria for assessing compliance. Negotiation is a means of generating the variety missing from laws, such as goal-setting laws, that describe what is to be achieved rather than prescribe the actions of operators.

In terms of the three areas noted by Ashford and Caldart, the safety report regime set-out in Seveso II and BRZO is an example of negotiated implementation. However, it is possible to see many of the compliance activities undertaken by SZW inspectors as operating in this paradigm. Where there is a deviation between the safety report and actual arrangements on the floor, there are a number of strategies open to the inspector, some of which fall within the category of negotiated compliance.

The principle of generating missing variety seems particularly appropriate in respect of management systems (i.e. within the meaning of Article 7 of Seveso II). This is because so much depends upon the technological context of the installation and the idiosyncrasies of the organisation that operates it. Although imposing a given management system prescription on all operators has certain attractions, not least consistency, there is a danger that it will not have requisite variety. Even if one opts for a very detailed prescription, some degree of tailoring will be needed to make the general prescription fit the specific context. In this respect, the question seems to be not <u>if</u> missing variety should be generated by dialogue between the competent authority and the operator but <u>how</u>. What is important is that the <u>admixture</u> of competent authority and operator achieves regulation of losses of containment.

Outside of the major hazards context, the Australian legal system has a method called "enforceable undertakings"; these are examples of Ashford and Caldart's category called *nego-*

[d] Article 1 of 96/82/EC states: "…the prevention of major accidents which involve dangerous substances, and the limitation of their consequences for man and the environment, with a view to ensuring high levels of protection throughout the Community in a consistent and effective manner."

tiated compliance. Enforceable undertakings are formally developed agreements that set-out changes to be made by a business in order to comply with a law from which its practices are assessed to be non-compliant. The purpose of mentioning these here is not to advocate them as a desirable option for SZW but to illustrate many of the principles, advantages and disadvantages of a negotiated approach to regulation.

Authorities such as the Australian Competition & Consumer Commission and Civil Aviation Authority are reported to (Parker, 2004[23]) approve of enforceable undertakings because they can deliver such advantages as:

(a) superior identification and accountability of businesses and their managers;
(b) top management attention and commitment to solve problems and prevent recurrence;
(c) effective remedies for alleged breaches;
(d) quicker, cheaper and more predictable than court actions.

However, enforceable undertakings have been criticised because they can be seen as a soft option, in which business crime is treated as less serious than street crime and as an abrogation of responsibility on the part of a regulator (i.e. weak vertical regulation in terms of the quotation from the Enschede report given earlier).

Enforceable undertakings have also been criticised in the "horizontal dimension" as allowing a regulator to dictate to businesses and as legal sanction for arm-twisting by regulators. Although there is little evidence that these concerns have been manifested in reality (Parker, 2004[23]), the point remains that criteria to be applied to enforceable undertakings to ensure their probity and effectiveness. In this connection, Yeung (2004[24]) argues that five criteria should apply to all regulatory decisions: (i) authorised by law; (ii) certain and stable; (iii) accountable and transparent; (iv) procedurally fair, and; (v) proportional, consistent and rational.

Insofar as these criteria apply in Dutch law (which Project-X would need to verify), these criteria also apply to Tool-X. Project-X will need to analyse these issues with due rigour. For the purposes of illustration, set out in Table 3 are some of the implications of Yeung's criteria for Tool-X.

Yeung's criteria	*Illustrative implications for Tool-X*
(i) authorised by law;	Tool-X can be applied within the powers of SZW and, SZW can use the results of applying Tool-X without exceeding their powers.
(ii) certain and stable;	Tool-X should promote reliable interpretation of legal requirements by SZW
(iii) accountable and transparent;	Inspectors conclusions should be traceable to the data used in Tool-X for a given operator
(iv) procedurally fair, and;	Tool-X should be integrated into SZW procedures and its compatibility should be demonstrable.
(v) proportional, consistent and rational.	There should be a demonstrable relationship between conclusions reached using Tool-X and any breach identified in the operator's arrangements (validity). Different inspectors should reach similar conclusions using Tool-X to assess the operator's safety management arrangements (reliability). The inputs to and outputs from Tool-X should be correlated.

Table 3. Yeung's criteria for regulatory decision making

Another aspect of enforceable undertakings is the style of interaction between regulators and regulated. Parker (2004[23]) makes the point that face-to-face dialogue between officers of the regulatory agency and managers employed by the operator (and sometimes representatives of other stakeholders) promotes effective remedial change because it encourages managers to take personal responsibility. The question of interaction between inspectors and operator's representatives is certainly an aspect of regulation generally and Tool-X may have a role to play in promoting effective communication here.

2.2 Tasks

To design Tool-X, Project-X needs to be well-informed about the tasks to be supported.

2.2.1 Initial breadth of scope for identifying tasks

Project-X will need a broad scope for identifying the relevant tasks. At the early stages of the project, this scope could include ancillary (meaning secondary or peripheral) tasks that may be affected by how the assessment is done, rather than just those tasks that are central to assessment. This is because ancillary tasks may influence the functioning of Tool-X or be affected by it, even if they do not require direct support within Tool-X. Later on in the project, when the design for tool-x has reached a suitable stage of maturity (e.g. just before prototyping), change analysis could be used to assess the impact that Tool-X will have on these ancillary tasks.

2.2.2 Development of functional criteria for Tool-X through task analysis

Project-X needs to identify the relevant activities of SZW. These include annual preferred area inspections; inspections dictated by the inspection plan; follow-ups from previous improvement notices; accident/incident investigations; complaint investigations and thematic visits. A map of the relevant activities will provide a coarse-grained picture to be refined through task analysis.

Within and around these activities, there will be a number of high-level tasks that require further description via task analysis. By way of illustration, the following examples of high-level tasks emerged from discussion:

(i) tasks related to assessing safety management
- e.g. bottom-up assessments such as Investigation of accidents and incidents or Scenario testing (sometimes called "pre-investigation"[25])
- e.g. top-down "audits" of safety-relevant functions (e.g. maintenance, control of change, competence assurance) or whole safety management systems.

(ii) tasks that inform the assessment process
- e.g. inspection planning, safety report assessment, research.

(iii) tasks that are informed by assessment
- e.g. developing improvement notices, bringing prosecutions, advising operators, informing the inspection plan (for a given operator and more widely), informing the public.

For each of the tasks identified as central to the assessment of safety management at sites, a more detailed task analysis will be needed to identify:

(a) Goals (for each task, as seen by the key stakeholders);
(b) Task intrinsics (which Schneiderman[26] refers to as task semantics and syntax);
(c) Task dependency;
(d) Task structure;
(e) Performance criteria (this should include careful consideration of the standard of evidence needed by the task[e])
(f) User discretion;
(g) Task demands (including the effects of working environment on inspection);
(h) Likely problems.

With regard to this list, the discussion in section 2.1 identifies relevant considerations that will inform the analysis of tasks, particularly so in respect of items (a) goals, and (e) performance criteria. For example, criteria such as consistency, transparency, accountability,

[e] For example, the standard of evidence for advice to an operator is not likely to be the same as would be needed for the purposes of prosecuting an operator who is in breach.

targeting and proportionality (presented in Table 2, on page 15) are likely to be relevant to many tasks.

As part of the data for this analysis it is suggested that Project-X should collect existing descriptions/norms for relevant inspector's tasks. These should be contrasted with inspector's perceptions of their tasks to identify gaps.

2.2.3 Project-X analysis of decision requirements of tasks

Task analysis will provide Project-X with a descriptive model of what inspectors and others do at present. Developing descriptive models of this kind is a longer and more complicated undertaking than developing a normative model, or indeed a prescriptive model to decide how inspectors should approach assessment. The apparent efficiency of normative/prescriptive modelling makes it a tempting route to Tool-X, but it is not equivalent to descriptive modelling: they have different uses. In the present context a descriptive model would represent observed choices made by inspectors, a normative model would represent a theoretical basis for inspectors' decisions and a prescriptive model would represent a protocol designed to constrain inspectors' decision-making.

Project-X needs to exploit each of these in the design of Tool-X, but in the early stages (and later by feedback from field use of Tool-X) a descriptive model will be needed to inform the idealised models that follow. A purely normative/prescriptive route may unwittingly worsen overall performance by limiting the inspectors' scope to apply their own skills and reasoning processes and how they interact with others. Tools always make poor masters.

A solely normative approach will tend to underestimate the subtlety of the task in context. SZW's assessment of safety management can be seen as a subtle interplay of its regulatory aims, the decision-making informed by the assessment and the subject itself. As Klein et al. (1997)[27] note:

> *"When designers are not given a good sense of the decision requirements of the task , they may fall back on a technology-driven strategy of adding in the newest and fanciest technology that is available , or a data-driven strategy of packing the most data elements into the display, to make sure that nothing essential is left out . The technology-driven approach results in initial enthusiasm, often followed by disillusionment as the operators find they still must wrestle the interface. The data-driven approach is safe, but creates frustration when operators cannot find important data items or detect trends and thereby are unable to make key judgments under time pressure."*

Section 2.2.2 lists the ergonomics headings for the various technical data that a task analy-

sis would need to obtain, especially if Tool-X is manifested wholly as software or has a large software component. It is always a matter of judgement how far to go in decomposing tasks to lower levels of detail and not all tasks will require detailed analysis. A desirable outcome of the task analysis, one of general usefulness to Project-X and possibly elsewhere (such as training and development of inspectors and others fulfilling an assessment role) would be to answer the sort of questions posed by Bell et al[28], paraphrased as follows:

> *How do inspectors (and other would-be users of Tool-X) think and behave? How do they perceive uncertainties, accumulate evidence, learn and update perceptions? How do they learn and adapt their behaviour? What are their hang-ups, biases, internal conflicts? How do they talk about their perceptions and choices? Do they really do as they say they do? Can they articulate the reasons for their actions? How do they resolve their internal conflicts or avoid such resolutions? Do they decompose complex problems, think separately about component parts of problems, and then recompose or integrate the separate analyses? Or do they think more holistically and intuitively? What are the differences in types of thought patterns for inspectors of different backgrounds, of different experience levels? What is the role of tradition, imitation, superstition and decision-making (or non-making)? How can "approximate" real behaviour be described?*

2.2.4 Software Mediation of Tasks

Although still on the subject of tasks, the probable software manifestation of Tool-X (in part or in full) allows the possibility of doing things within the assessment process that could not be done before. Another way of looking at this is that adopting new technology often creates new tasks and new goals that will need to be integrated with those existing.

Prudence dictates a circumspect approach to adopting new technology and the extra functionality it offers. The question to be asked in each instance is whether there is sufficient gain in functionality, quality or productivity to outweigh the costs that software development may bring to Project-X and the lifecycle of Tool-X. Similarly, the decision to choose a particular technological option is best informed by analysis of the risks it poses to task performance (both central and ancillary tasks) and to Project-X (e.g. by adding complexity to project management).

Having sounded a particularly Luddite[f] note, there are of course considerable advantages that software could bring to Tool-X; these are discussed in section 2.4.2, on page 25.

2.3 People

Project-X will need to consider who will be affected by Tool-X and how; adopting a user

[f] After Mr Ned Ludd: a celebrated English technophobe and destroyer of machine looms in the industrial revolution.

centred design (UCD) philosophy is one way of ensuring that this is done to best advantage. UCD could provide an approach that balances the requirements for Tool-X as seen by SZW management, expert Project-X advisors and the task requirements as experienced by front-line personnel, such as inspectors. Although these views are not expected to be in opposition, a design solution that maximises functioning to one set of requirements cannot be assumed to optimise to a wider range. What will be needed is to find the right degree of involvement of SZW inspectors in the design process for Tool-X as illustrated in Figure 3.

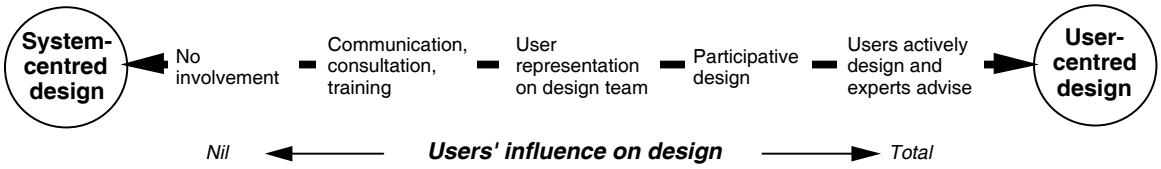


Figure 3. The spectrum of user involvement in design (After Damodaran, 1986)[29]

With regard to the idea of "the user", within the ICT (information and communication technology) development community, there is a movement away from seeing users as individuals working in relative isolation, towards a view of people as *social actors* (Lamb and Kling, 2003[30]). This view emphasises the social context of work in which ICT plays a part but not a dominating role, and also stresses that one social actor will play several roles, each with a different set of requirements for the ICT available to them. Seen this way, the user is clearly the master, and tools are the servant; a point that seems obvious at the outset of ICT design projects but seems to get a little lost by the end of some of them. In the following quotation, Lamb and Kling (2004)[30] are discussing the design of CSCW (Computer Supported Collaborative Work) systems, but what they say in this respect is of application to design generally:

> *"Scholars who recognize the end-user's capacity for innovative uses of ICTs have suggested that one way to tap that wellspring is to provide them with highly configurable systems" … "However, this approach has been criticized for adhering to the "ICT as a tool" perspective, which also supports the user concept." … "Most CSCW researchers, therefore, have cast their lot with some kind of participatory design solution. When taken into organizations, however, the systems that these approaches produce have met with mixed reviews." … "As developers and users work together on system design, power imbalances frequently prevent users from making a real contribution".*

The social-actor viewpoint also highlights the importance of human and corporate relationships to the regulatory task. Tool-X will become a factor in these relationships, by mediating aspects of communication between SZW and operators and by influencing how SZW interpret information from assessments and acts on them.

2.3.1 User characterisation

One of the challenges for Tool-X will be to decide who needs to be accommodated in the design; who is Tool-X for? The obvious group is the inspectors who currently assess operators' safety management. But Tool-X will have interfaces (both computer-based and in other ways) with a wider range of people than this. Stakeholders seems to be a reasonable term for the whole population of people who need to be considered.

The initial identification of stakeholders for Tool-X will need to include external groups as well as those internal to SZW. Given that joint inspections (e.g. involving SZW, VROM and local authorities) are a feature of the domain in which Tool-X will be applied, these partners need to be involved. A wider population than this is indicated by OECD "Guiding principles" document[17], which mentions communities/public, first responders, industry, international organisations, labour, non-governmental organisations, other public authorities, research/academic institutes). Even if not involved in applying Tool-X, some of these groups will nonetheless have some connection with its functioning and some contribution to make to its design. In section 4.2, this point is discussed further in relation to the governance of Project-X.

The topic of joint assessment and other forms of cooperation raises the issue of data sharing. Project-X will need to consider(a) what the scope is for this, (b) who might share which data, (c) the legal and security implications of this and (d) the impact on the quality of data collected.

One of the issues that is visible from this viewpoint is the need to satisfy Schneiderman's[26] golden rule of design "to recognise diversity" and to accommodate it in design. The variety of people who will use Tool-X, or who will have a stake in its functioning, may well have different expectations and goals. If Tool-X is to succeed, Project-X will need to identify this diversity and overcome any significant incompatibilities.

Most aspects of user characterisation would be accounted for in the task analysis steps described in section 2.2.2. It is possible that this might focus more on the users as means-to-an-end rather than as an end in themselves. It is recommended that Project-X explicitly considers the needs of users in their work role, and as employees and citizens more generally. For example, Tool-X will have some impact on the transparency and accountability of SZW and others. Although, transparency and accountability are seen as welcome, they do need to be balanced against such matters as inspectors' employment rights and confidentiality of 3rd party information. The scope of this characterisation (e.g. who is considered and in what dimensions) will need to be considered in Project-X.

2.4 Tools

A tool can be defined as "an instrument which conveys some advantage to its user in the execution of a task" (Frei et al., 2003[31]). The first point here is that the Project-X task analysis is likely to reveal several tasks. This means that there may be more than one tool under the heading Tool-X (or to keep to the one metaphor; more than one tool in "Toolbox-X"). It also means that for each task, there will be a set of functions each of which could be supported by a tool. Not all of these will need to be computerised to achieve good results.

2.4.1 Usability Criteria

Usability is a key criterion for Tool-X. A rough, usable tool can be refined through use, whereas an excellent but unwieldy tool will be left in the "far too difficult" drawer.

The general criteria for usability are long-established in ergonomics/human factors. Gould and Lewis (1985)[32] provide the criteria: *"should be easy to learn (and remember), useful, that it contains what people really need in their work, and be easy and pleasant to use).* Shackel (in Johnson, 1992)[33] suggests four general criteria, proposed on the basis of measurability:

(i) *learnability*, the ease and speed of learning;
(ii) *effectiveness*[g], the extent to which users can and do utilise the functions built into the system;
(iii) *flexibility,* the degree to which the system can accept changes to tasks and components from those originally specified;
(iv) *attitude*, the extent to which users feel positive about the system.

Project-X will need to develop usability criteria for use in formative and summative evaluation of Tool-X and its components. Formative evaluations are carried out during the early stages of the design process and produce data that guides the design through feedback. Typically, this type of evaluation yields qualitative information, that is, information about what aspects of the design require attention and why. Summative evaluations would aim to measure the performance of Tool-X, or a component of it, against a set of acceptance criteria. In summative evaluations, the primary information sought is quantitative and the criteria developed by Project-X will need to reflect this.

2.4.2 Decision Support System (DSS) Options

As stated in section 2.2, the scope for computer based support in Tool-X needs to be carefully evaluated. Project-X should consider the set of technologies grouped using phrase

[g] Sometimes referred to as throughput.

"Decision Support Systems" (DSS) for exploitation in the assessment of safety management and the tasks associated with it.

There is no universally accepted definition of DSS. However, the definition proposed by Keen and Scott Morton (cited in Turban and Aronson, 2001[34]) captures the partnership between human and machine absent from more computer-oriented descriptions.

> *"Decision support systems couple the intellectual resources of individuals with the capabilities of the computer to improve the quality of decisions. It is a computer-based support system for management decision makers who deal with semi-structured problems"*

Decision Support Systems is a phrase used to delineate an area of software development by what the software does (e.g. support of human decision-makers) rather than what it is (e.g. a set of technologies and methods). It should be noted in some texts the phrase Management Support System (MSS) as an equivalent term to DSS.

The significant characteristics of DSS include:

- useful for assisting initial analysis;
- facilitate scrutiny of models using users' experience, judgment, and intuition;
- allow application of approximate models (e.g. model mathematically correct, but incomplete);
- permit rapid analysis;
- permit flexible analysis.

Project-X should explicitly evaluate the DSS options listed below for their potential benefits and detriments to the tasks and goals identified in relation to safety management assessment.

(i) Group Support Systems (GSS)
(ii) CSCW (Computer Supported Collaborative Work)
(iii) Enterprise (Executive) Information Systems (EIS)
(iv) Enterprise Resource Planning (ERP) and Supply- Chain Management (SCM)
(v) Knowledge Management (KM) Systems
(vi) Expert Systems (ES)
(vii) Artificial Neural Networks (ANN)
(viii) Hybrid Support Systems
(ix) Intelligent Agents (and intelligent decision support)

This evaluation should be sensitive to the varying requirements of different groups in SZW and to different decision-making phases, discussed below.

2.4.3 Decision phases and scope for DSS support

The three phase decision-making framework proposed by Simon in the 1960s still has currency in the DSS literature (e.g. Turban and Aronson, 2001[34]). In this framework, decision-making is subject to the following phases:

(i) Intelligence: searching for conditions that call for decisions;
(ii) Design: inventing, developing, and analyzing possible courses of action;
(iii) Choice: selecting a course of action from those available.

Project-X, should consider the range of potential users of Tool-X in terms of the type of support that could be offered through Tool-X to each phase of decision-making. The aim here is to populate the cells of table for use as a wish-list (e.g. functions and DSS options for integration into Tool-X over time) and as an accompaniment to the task analyses within Project-X.

	Frontline Inspectors	Inspectorate managers	SZW policy makers
Intelligence			
Design			
Choice			

Table 4. Table for displaying the different functions and DSS technologies that could be exploited by different users of Tool-X .

Lastly, with regard to the three phases, Project-X should explicitly consider the linkage between Tool-X and inspection plan, and the scope for Tool-X support of, and use of data from, safety report assessment.

3 REGULATORY MODELS AND ASSESSMENT OF SAFETY MANAGEMENT

The assessment of safety management systems, is a deceptively simple proposition; there seem to be two main areas of difficulty. The first difficulty is one of definition – what is a safety management system? It is not overly difficult to say what a safety management system does; and there are many authoritative functional descriptions such as those given in Annex III of the Seveso II directive and the further detail supplied in the guidance[35] provided by the Major Hazards Bureau [h]. However, what a safety management system does is not the same as what the system is; and here no definitive or wholly unambiguous description exists.

In Annex III of Seveso II (summarised in Table 5) this difficulty is acknowledged implicitly. The annex includes consideration of far-reaching aspects of management, as well as the list of safety management system elements mentioned. These far-reaching aspects are connected to the "major accident prevention policy" (MAPP) and the relevant parts of the operator's general management system (as defined in paragraph (b) of Annex III).

The second difficulty is how operators translate the law into their organisations. In this respect, Annex III can be seen as an attempt to include into the law, the transfer function that translates (or maps) the systematic requirements of major hazard management into the unique organisational context of the operator.

(a)	The MAPP should describe in writing the "operator's overall aims and principles of action"
(b)	A safety management system "should include the part of the general management system which includes the organizational structure, responsibilities, practices, procedures, processes and resources for determining and implementing the major-accident prevention policy"
(c)	The following issues shall be addressed by the safety management system:
	(i) organization and personnel;
	(ii) identification and evaluation of major hazards;
	(iii) operational control;
	(iv) management of change;
	(v) planning for emergencies;
	(vi) monitoring performance;
	(vii) audit and review.

Table 5. Summary of Annex III, Seveso II Directive

[h] Also worthy of note here is the "Metatechnical Evaluation System" manual (2002) produced by the Chemical Risks Directorate of the Belgian Federal Ministry of Employment and Labour. http://www.meta.fgov.be

3.1 Defining boundaries for the assessment

The transfer function issue, how an operator translates legal requirements into appropriate organisational arrangements and systems, can be seen as one aspect of *self-regulatory capacity*. As discussed on page 6, assessment of safety management can be as needing to include addressing this issue. For example, although an operator may have a patent deficiency with, say, its risk assessment processes, this finding may shed little diagnostic light on the underlying problem which may not be even expressible in safety management terms.

Although Project-X needs to ensure that Tool-X is properly grounded in law, this should not be permitted to deliver a conservative reading of SZW powers and remit. If limited in this way, Tool-X would be of limited use as an instrument of inquiry, meaning a tool developing insight into and understanding of operators' difficulties. Restricting Tool-X to use as a means of advocacy seems to be wasteful of limited inspection resources. As discussed on page 10, maintaining competence as a regulator requires a learning mechanism which facilitates SZW developing variety by interacting with operators. A tool of advocacy does not serve this function; it is an attenuator of variety, useful in its place but with a tendency to dominate. If "regulating self-regulation" is seen as a legitimate part of SZW's mission, Tool-X could be one means for gaining insight into how to approach this.

3.2 Safety management or safety management system?

In the foregoing paragraphs, the term safety management system has been used because that is the phrase mentioned in Seveso II and in the questions posed by SZW in this study. As stated above, there are problems arriving at a satisfactory definition of what constitutes a safety management system (SMS). Furthermore, it could be argued that this underlies some of the problems with compliance observed when Seveso II was implemented into the laws of member states.

As contended in the following discussion, SMS may be too-limited as construct on which to base Tool-X and it might be more productive to frame Project-X in the context of safety management. Implicit here is that *safety management* and *safety management system* (SMS) do not mean the same. Safety management is a *theme*, a shorthand way of referring to all of the activity that determines safe operation. SMS allows the definite article ("an SMS", "the SMS") demonstrating that the term SMS implies a separable entity.

An analogy might serve to illustrate this point. The human nervous system is a construct, an abstraction. A textbook of neural science will contain a list of physiological structures and

organs, but not even the most meticulous anatomist could dissect it out and put it in a bottle marked "*THE HUMAN NERVOUS SYSTEM*". Trying to understand why someone's fine motor control is poor (e.g. their hands are not steady) could be approached by study of the nervous system but this would not often not reveal much of diagnostic usefulness. More promising would be to look at the wider pattern of interaction between the individual and his or her environment (coffee drinking, missing meals, consumption of alcohol etc.). In other "nervous system" is a useful construct for categorising data and knowledge but is a limited guide to understanding behaviour.

As a phrase, *safety management system* encourages users to think in terms of system and environment, forcing them to locate a boundary between these two. In general, a system boundary can be located as follows: the environment contains everything that is relevant to the performance of the system but which is not controlled by the (regulatory part) of the system. The SMS is of central relevance to achieving safe operation, but like the nervous system, it is a construct that is artificially delineated from the wholeness of the business and industry in which it coheres. Beyond that delineation are all the "non-SMS" issues that are relevant to safety performance. For SZW to understand (i.e. to achieve requisite variety in their model) what is going on, what is producing the observed physical and administrative conditions on the site, requires a perspective that sees both the safety management system and the wider picture of control. Otherwise there will be any number of phenomena that are not understandable to or expressible by SZW if their thinking confined in an SMS model. In terms of legitimacy, the scope of "major accident prevention policy" as described in Seveso II, provides competent authorities with plenty of licence to seek information beyond an SMS boundary. What is needed is to make the wider picture of control more tractable to inspection and regulatory decision-making.

3.3 Assurance and the "self-regulatory focus"

In the control of major hazard sites, society looks for a steady corporate hand of self-regulation. Here, a steady hand is one that supports the complex of barriers to and controls of losses of containment. A steady hand also absorbs the twists and turns of the business environment. These echo the dual focus for regulation (discussed on page 13) which is re-stated below in Table 6.

Ashby term	*Safety focus*	*Self-regulatory focus*
Essential variable	Safety, health, freedom from pollution	Availability of barriers and controls
What is important	That process disturbances are not transmitted to the detriment of people and the environment	That business disturbances are not transmitted to the detriment of barriers and controls
What is wanted	The establishment and "here-and-now" readiness of barrier and control arrangements. These to achieve explicit probability x consequence curves	The establishment and "here-and-now" readiness of self-regulatory arrangements. These to achieve explicit performance (e.g. availability) geared to loss of containment *pc* curves

Table 6. The "steady hand" in Ashby's terms of regulation

But how is the 'steady hand' of self-regulation to grasp these arrangements? A key attribute is assurance.

Assurance is the corporate function that determines the extent to which the objectives of policy (e.g. MAPP) are *actually achieved* at the site. Many major accident inquiries are accompanied by reports that the senior managers of the organisations concerned were fundamentally surprised when confronted with the actual state of safety management and control as determined by the investigators. This could be looked at cynically (individuals seeking to deny guilty knowledge) but could equally support the view that these individuals genuinely did not know the true state of their businesses with respect to safety.

If corporate belief and actuality are different, there is clearly a problem in the assurance function in the organisation; one that can be explored as an issue of validity and reliability of measurement, issues which will be developed later in this report. For the moment it is noted that reliable measurement of the wrong things can create a false belief as surely as would poor measurement (i.e. unreliable) of the right things.

In the authors' discussions, these issues of assurance and measurement have surfaced as crucial areas for Project-X. As part of this, a number of diagrams (Figure 4, Figure 5 and Figure 6) were developed to explore the topics of assurance, control and operation and to help identify a principled basis for safety management, one that would reveal the essential functions.

In Figure 4. “Operate” means operate the process (e.g. a storage vessel) with the necessary barriers and controls in place. The control loop which governs the configuration of plant, people and procedures (i.e. the components of the process), it has three functions:

(i) keep the barriers and controls the same;
(ii) change the barriers and controls;
(iii) maintain criteria to decide whether (i) or (ii) applies.

The assurance loop governs the control loop. It mirrors the structure of the control loop but measures how well the functions are performed. SZW clearly have a role in monitoring the adequacy of the assurance loop, using data gained from inspection of the control-loop and of the operation itself.

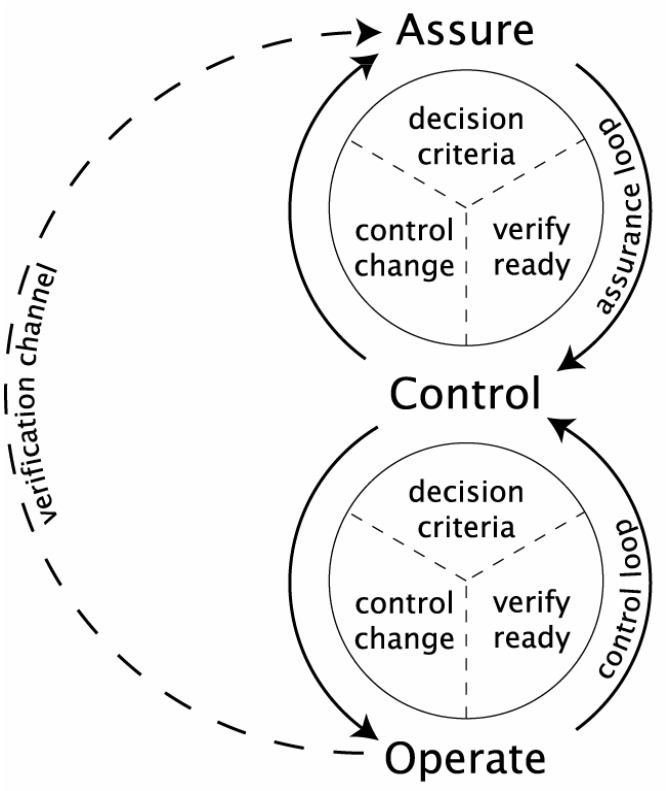


Figure 4. Assure, Control and Operate

Reading Figure 4 in its **proactive** direction: an operation (e.g. a chemical manufacturing process) needs a set of protective systems (barriers) and work/process controls to ensure safety. These barriers and controls are designed as configurations of people, plant and procedures (PPP). The design and implementation of these barriers and controls is achieved as a controlled change subject to appropriate decision criteria. Thereafter, their “here and now” readiness (also expressed in PPP terms) is subject to continual verification. All of this falls within the control loop. The assurance loop measures the performance of the control loop from data gained by direct measurements of the control loop and indirectly from the availability of operational barriers and controls (via the verification channel).

> Note that barriers and controls are defined as stated on page 13: *Barriers* are designed to protect against unwanted flows of energy (e.g. kinetic chemical electrical etc.); *controls* are designed to deliver operational goals which offer protection as a by-product. Barriers and controls operate at the same level of system as the energy flows they are designed to affect. Barriers and controls are functions rather than identities.

Reading Figure 4 in its **reactive** direction: Unplanned change in the availability of barriers and controls (i.e. the operation) is looked for and responded to by the control loop. These changes will be manifest as changes in the behaviour of people and performance of plant and procedures. Unplanned change in the control loop functions are looked for by the assurance loop (manifest as changes in the availability of barriers, or changes in the performance of the control functions). The assurance loop can respond in two ways: first, requiring fine-tuning of the control loop and second, by inquiry into the reasons for the change in control performance if the change is not predictable (in terms of the model of the control loop maintained in the assurance loop, which is why Figure 4 has the same "segments" in both loops).

Another way of showing the same ideas but emphasising the inter-dependencies between the parts, is shown below in Figure 5.

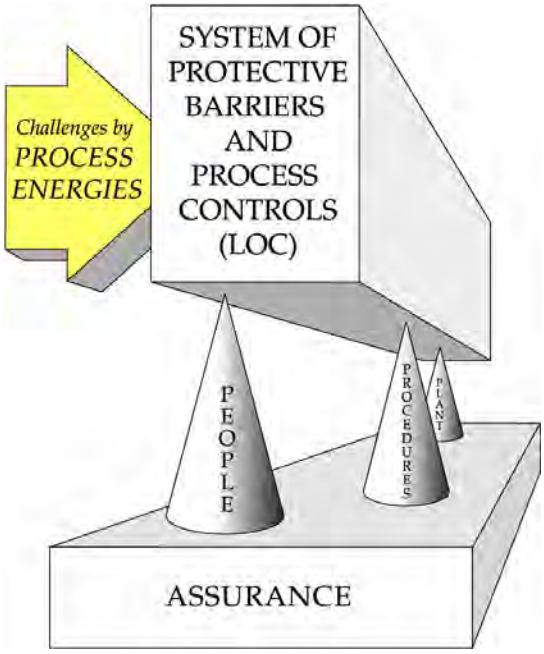


Figure 5. The interdependencies of (ACO): Assurance, Control (PPP) and Operational barriers and controls

In Figure 5, the full system of barriers and controls are shown supported on three cones. Each cone represents the control loop governing the configuration of plant, people and procedures. The inter-dependence of plant, people and procedures is conveyed by the idea that the barriers and controls are supported on three points, if one point changes, there must be compensation before the barriers and controls lose stability (that is, become unavailable or unreliable). The correct functioning of the control loop, its dynamic balance as it were, is subject to monitoring by the assurance block.

Figure 6 illustrates that instabilities should be felt by the "hand" of management that supports the assurance block. The hand is connected to the corporate body, which is moving through a dynamic, sometimes turbulent business environment. As it negotiates through this, the corporation must keep the apparatus supported and balanced.

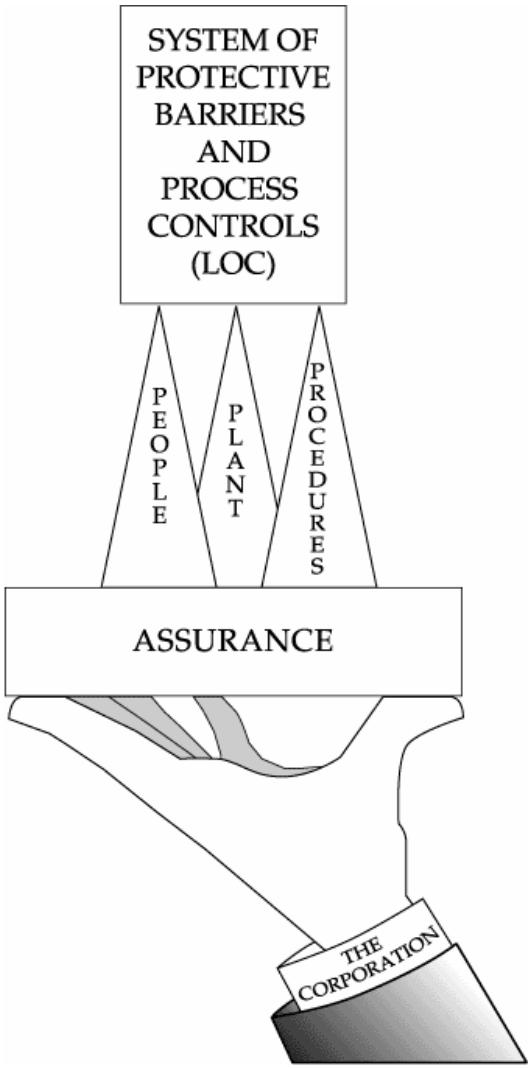


Figure 6. ACO Interdependencies and the corporate "steady hand"

Response to change in ACO and to change in the business environment are two classes of response that Project-X could develop criteria to allow these aspects to be assessed. This could be referred to as corporate governance.

Information about the corporate environment may have a role as intelligence for SZW (e.g. knowing about changes of ownership, share price, market changes, staff changes, competition for key personnel). This might influence the timing and focus of inspections, allowing inspectors to verify the capacity of the organisation to self-regulate its major hazard arrangements during difficult times.

As was said earlier, society looks for a steady corporate hand (page 30), but it also wants to see a firm government hand taking the pulse. The assurance function — with its pivotal role in self-regulation — has special importance for SZW. If an operator cannot assure SZW about the adequacy of its control loop for major hazard safety, it cannot assure itself. For this reason, identifying criteria for assurance needs to be part of Project-X. Some of these criteria for assessing assurance will be straightforward reflections of the control loop functions

("here and now readiness", "controlling change", and "decision criteria"). However, there will also be "meta-criteria" (meaning criteria for the "assurance of assurance") such as qualities of measurement and decision-making and action based on those measurements.

Figure 5 and Figure 6 also illustrate another concept for Project-X to explore. In these figures, gravity is assumed to be always acting on every part of the apparatus. The system of barriers and controls (the block) is shown balanced on the control loop functions (cones). If the barriers and controls change, the block shifts, changing the pressure on the cones. If the cones react (as in an "equal and opposite reaction"), they return the block into a balanced position. If the cones do not react, they stay deformed (i.e. a deformation visible to active assurance) and the changed centre-of-gravity of the whole assembly is perceptible (passive assurance) to the corporate hand. In cybernetics, particularly evident in the work of Ashby and Beer, this intimacy and constancy of communication is a basic principle. It provides an essential property for the dynamic interrelation of parts within systems and between systems. Whereas the analogy used in the figures relies on gravity, more formal models (which Project-X could develop) would need a more general concept such as that of homeostasis as used in cybernetics (the very act of change in one part causes a counter-change in another part to restore balance overall).

Lastly, all of these criteria will need to be reconciled with the categories described in Seveso II, Annex III; this is to ensure read across with BRZO, information systems containing data derived from applying Tool-X will need to be expressed in BRZO terms. In most instances, there should be obvious read-across between the two systems (Tool-X and BRZO) but there is also likely to be some asymmetry. The expectation is that Tool-X will contain criteria that cannot be reconciled with BRZO (as has AVRIM 2), this corresponds to the areas labelled 2 and 3 in

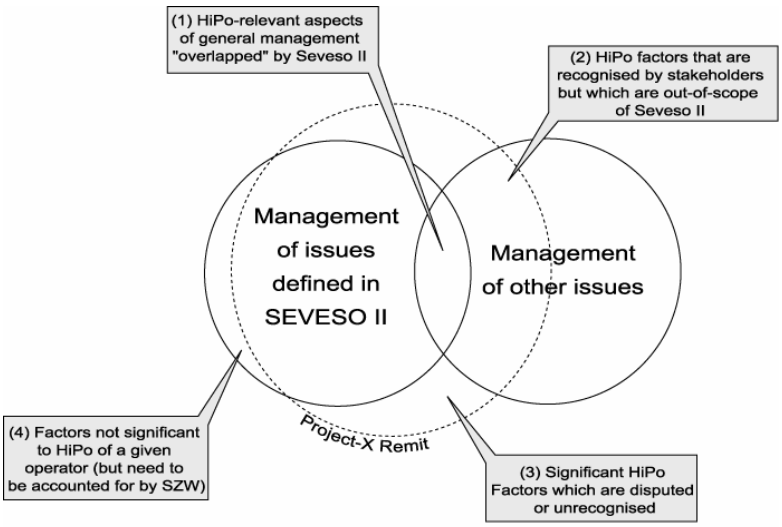


Table 7. Boundaries of legitimate assessment

3.4 Validity, Models and Modelling

Perhaps it is clear already, but it is worth acknowledging that the criteria to be developed by Project-X in respect of safety management assessment can support several types of model or modelling processes. This means that Tool-X can be versatile, allowing data arrived at from quite different approaches to assessment to be captured within a coherent regulatory view of safety management. The technological options mentioned in section 2.4.2 on page 25, are relevant here, particularly with respect to Knowledge Management (KM) Systems.

3.4.1 Accommodating different aims of modellers in SZW

Earlier discussion (page 21) touched on three different classes of model: *Descriptive, normative and prescriptive*. The three terms are often treated as delineating different classes of models but it is probably more truthful to say that they represent different aims on the part of model makers. In cybernetics the intentions of the modeller are of primary concern, and models seen as an essential currency in human interaction. Because of this, the emphasis is more often found on modelling than on the extent to which a model is a truthful representation of some external reality. Espejo (1988)[36] describes this view of models:

> *"A model is expected to provide a setting, a common frame—in other words, it is expected to make visible a set of constraints, within which certain problems can be enunciated in a particular way, and certain problems solved. Let us be clear about this. A model is a convention—a way of talking about something in a manner that is understandable and useful in a community of observers. It is not a description of reality, but a tool in terms of which a group of observers in a society handle the reality they find themselves interacting with. … But whatsoever, an individual may never communicate what is accessed to another individual except in terms of models. This is not a limitation, but is precisely the motor for the generation of a consensual domain. A consensual domain is none other than the play of a particular set of interacting models."*

In informal discussion with SZW inspectors (and extrapolating from discussions with inspectors of major hazard sites other member states) there is a certain distrust or scepticism about the value of models as manifest in safety management assessment tools. This looks like familiar territory; Beer (1981)[37] notes that organisations rely on individuals pumping-in the variety missing from managerial models and arrangements derived from those models. In terms of inspectors, looking at operators' organisations through any model (in-the-head or external), removes variety. But the anxiety for inspectors is that their internal model of the operator will not achieve requisite variety because of information filtered-out by the external model. In these circumstances one can expect assessors having to "peer round the back" of the model; making separate inquiries and inferences in respect to the model "in their heads". Although criteria such as consistency and transparency (page 15) urge management towards the "holy grail" of wholly externalised models, it is exceedingly difficult—

perhaps impossible— to invest a model of this type with requisite variety. "The map is not the territory" as Alfred Korzybski coined it; Tool-X can be a guide to the territory, but inspectors make the journey. To do this, they generate the variety missing from the map by interacting with the territory itself.

With this in mind, it is unlikely that Tool-x could be manifested as a single model, invariable in detail and structure. As mentioned in section 2.4.1, a usable tool should "*contain what people really need in their work"* and that is likely to vary with the context of the inspection and the inspector. In cybernetics, these sorts of problems are often treated as opportunities for "variety engineering". In other words, before opting for prescriptive approaches to the assessment task which attenuate variety, Project-X should evaluate the potential for exploiting sources of variety in the assessment context. For example, if Tool-X is to enable learning in SZW about the subject of safety management, self-regulatory capacity and how to regulate these, there need to be feedback loops from the field. If Tool-X is based on a fixed normative model, there is very little scope for adaptation except minor fine-tuning. Indeed a fixed normative model essentially blocks a major channel through which SZW maintains its competence to regulate these matters.

It is possible to imagine Tool-X as a two-way channel connecting the inspector to the central resources of SZW. Inspectors who want a defined structure within which to arrange the inspection will welcome a prescriptive model communicated from SZW HQ, as it were. Data gained during an inspection could be used to refine the models in use at HQ. Inspectors wanting HQ support to design an intervention with an operator (e.g. an improvement notice) might represent their data in a descriptive model to improve the communication with their HQ peers (and, conceivably with the operator also). This viewpoint emphasises the DSS definition of a coupling of the "intellectual resources of individuals with the capabilities of the computer"

In relation to the use of prescriptive models for decision-making, Bell et al[28] note:

> *"What should an individual do to make better choices? What modes of thought, decision aids, and conceptual schemes are useful, not to idealised, mythical, and de-psychologised automata, but for real people. And since real people are different, with differing psyches and emotions, capabilities and needs, good advice has to be tuned to the needs, capabilities, and emotional make-up of the individuals for whom the prescriptive advice is intended. It becomes even more complicated when individuals who think one way have to interact with experts who think along different paradigmatic lines, as for example, between a rational decomposer and an holistic 'intuiter'.*
>
> *For some individuals a wise prescription might be: 'behave as you normally do. You're doing well and any new mode of analysis might inhibit your creative*

thinking'. For others the advice might be: 'it is important that you decompose your problem and get external advice from experts on such and such a component part, because otherwise you will not be able to constructively integrate and synthesise what you know together with what others know'."

In addition to flexibility of structure, this quotation points to flexibility of prescribed detail. An experienced inspector may not need the same degree of steering as one more junior. Instead, they might want just the headings of a normative scheme which they will amplify with their own interpretations and through the assessment activity with the operator. The idea of flexibility of form and detail in the model underlying Tool-X would be interesting to explore in Project-X.

3.4.2 Descriptive modelling

For the hypothetical inspector just mentioned, a more pressing need than prescription is a means for facilitating description: recording what they find and the reasons behind judgements they reach. Apart from note-keeping functionality in Tool-X, the descriptive aspect also includes the facility to experiment with different ways of visualising the data for the inspectors own understanding as well as for communicating with others.

The quotation on page 36 contained the phrase "A model is expected to provide a setting, a common frame—in other words, it is expected to make visible a set of constraints, within which certain problems can be enunciated in a particular way, and certain problems solved". Whether as a way of supporting explanations between inspectors and operators, or assisting communication between inspectors, models of safety management Project-X used descriptively may be a helpful aspect of Tool-X.

Normative models could be used this way, to supplement descriptions by allowing inferences (AVRIM 2 is a useful resource here). Similarly, Tool-X might allow aspects of the descriptions noted by inspectors to be associated with historical data for this and other operators, allowing such to be available to the inspector for their own understanding and to communicate with others.

3.4.3 A normative model of safety management development

On page 28, it was noted that the law (i.e. BRZO) does not describe in detail how an operator may develop the prescribed arrangements and systems summarised earlier in Table 5. This was characterised as a "transfer function" problem. This problem can be seen as another example of Ashby's law of requisite variety (first discussed on page 8). Operators amplify written laws; in effect the law requires the operator to build a regulator to achieve control over its major hazards but the law does not describe how this can be done. All the law does say is that certain features (e.g. the items in paragraph (c) of Table 5) are required, but not what these mean in the context of the operator. This is not a criticism of the law; as explained on page9, there are serious limits on what can be achieved through feedforward

regulation.

In view of potential gap between the assumptions of the law and the capacities of the firm, the dialogue between SZW and the operator (through the safety report and inspection regime) can be seen as an iterative process by which SZW assists in regulatory design. In this way, the transfer function missing from the law is developed though the dialogue between SZW and the operator.

The utility of a developmental viewpoint is based on the idea that safety management arrangements will reveal a range of different self-regulatory abilities amongst operators. There may be developmental stages and these may be additive and co-dependent. Meaning if there are 4 stages (a, b, c and d), an operator at stage (b) cannot get to stage (d) without first developing the organisational competencies necessary at stage (c).

The developmental problem can be explained with an analogy. In the 1930s, a biologist called Spemann conducted a series of experiments mixing the embryonic cells amphibians. In one experiment, Spemann introduced embryonic salamander cells into a frog gastrula (both the salamander and frog gastrula were sufficiently developed to allow approximate identification of the host and donor regions). The result of this was a frog tadpole with a salamander mouth. In effect, the ectoderm (salamander) says to the inducer (frog) "you tell me to make a mouth; alright, I'll do so, but I can't make your kind of mouth; I can make my own and I'll do that" (Gilbert, 1994[38]). It is generally straightforward for an inspector to recognise a major omission in the safety management arrangements of an operator (e.g. an inadequate process for risk assessment). Nor should it be too difficult to convince the operator that they need to fill the gap. However, it is quite possible (and, anecdotally, not uncommon) for the operator to make good the omission with a poor solution or one that is not well fitted to their organisation— a Salamander mouth!

As much as certain solutions to problems in the operator's management arrangements may seem obvious to the inspector or the consultant, "grafting them in" runs into Ashby's law of requisite variety. The operator may give some appearances of compliance, but the new system may not have requisite variety vis-à-vis the unique variety of disturbances in the situation in question. From a developmental viewpoint, devising a suitable intervention with an operator needs to reflect the underlying competence of the operator to regulate its own safety management.

This viewpoint puts the Tool-X assessment process into a particular perspective. Amongst the various reasons for undertaking assessment, an important one is developmental (or "evaluative" if seen as part of a cyclic process of design). This is quite distinct from a certification role which is generally summative and in which the candidate safety management system is either adequate or not. Tool-X may need to cater for both, but Project-X is more likely to deliver an adequate summative assessment tool by developing a satisfactory evaluative assessment tool.

3.4.4 Validation criteria for Tool-X

Reliability and validity are two qualities often associated with matters of measurement. *Validity* is the extent to which the assessment measures what it purports to. *Reliability* is the extent to which an assessment tool gives consistent results and is uninfluenced by other factors. The two qualities are connected: an assessment tool cannot be valid without being reliable; but a reliable assessment tool can be invalid.

Validation is best seen as a continuous process through which evidence accumulates to support the interpretations arrived at through using Tool-X and the uses of these to design interventions. As data accumulates, it should be possible to analyse the data for patterns which can be used to refine and strengthen the tool.

For Tool-X, a simple way of stating this is that the results of assessing of an operator's safety management should be justified both in the general plan of what is assessed and in the specific judgements reached.

In the general plan, this means that there is evidence that the items being assessed are all relevant to safety management. This can be approached in a number of complementary ways. First, each item must have an explicit theoretical relationship to safety management. This can be obtained from the literature and by Delphi studies. Second, items should be empirically supported from case studies (e.g. accident and incidents).
It is suggested that Tool-X makes these sources of evidence visible to the users of the tool; this also provides support for the face validity of the item and the tool as a whole. A third approach is to test the degree of agreement between the assessment and other, independent, measures of the same attributes.

In the specific case (i.e. a for a given operator) the criteria used by the assessor to reach the judgement should be available either as written comments by the inspector making the assessment (if the tool is fairly low in prescriptiveness) or as range statements that demonstrate the meaning of scores. This will also promote reliability and consistency of application.

4 STRATEGIC GUIDANCE FOR STEERING "PROJECT X"

The first part of this report concluded that the assessment of safety management depends on its purposes – how to define the system to be assessed, how to weigh its different attributes, are two examples of issues that can only be decided by considering the aims of the assessing body; SZW is a part of the whole system, not outside of it nor independent[i] of it. The terms set out in BRZO provide some definition of the objects to be assessed in respect of operators' safety management but, as this report has argued from various standpoints, BRZO is just one notable artefact in a complex blend of social, political and industrial influences.

Project-X needs to embrace this richness of context in three complementary ways: (1) through the requirements specified in the contracts in Project-X (including the explicit criteria developed in this study); (2) by conducting Project-X in a way that allows it to be informed by relevant social, political and industrial influences; (3) through the implementation and management of an exit strategy that enshrines continual improvement in the products and conduct of Project-X.

As an example of the second way, Project-X will need to consider what purposes are served by assessment and provide a clear understanding of what assessment means in the BRZO context to stakeholders in the assessment process. If a user-centred approach is taken to the design (see section 2.3, page 22), this 'understanding' may need to be revisited throughout the lifecycle of Project-X. This is because this philosophy has been found to be far less linear than system-centred design, and can radically transform stakeholder views by discovering assumptions and new goals (Plaisant and Shneiderman, 2004[39]).

Continual improvement in Project-X could be treated as a part of the regulatory system. A useful aspect of Ashby's work in cybernetics is its recognition that design conforms to the same principles as regulation; one could say that design and regulation are two sides of the same coin. Whereas regulation is about the communication between regulator and regulated, design is the process of communication from designer to product. Just as the regulator selects for desirable states from a wider set of those possible, the designer selects one design outcome that satisfies all the criteria defining what was wanted in the product. This means that everything said earlier about the cybernetic view of regulation applies, with little or no modification, to design. It would be entirely consistent for Project-X to be an open-ended commitment in SZW.

[i] Which is not to say that regulatory capture by operators is inevitable; integrity (rather than independence) is the essential quality to be managed to avoid capture.

4.1 Involvement of stakeholders

Wilson and Charlton (1997)[40] make the point that *"Successful partnership management depends upon attaining the appropriate level of involvement for all its stakeholders".* In addition, the lessons learned from ADAPT (Ecotec, 2000[41] and 2001[42]) show that this level is likely to vary. The upshot is that the relationships manifested in project work, are dynamic and partners' expectations are likely to change with time. In view of this partners' expectations need to be periodically re-evaluated as part of managing the effects of change.

4.2 Stakeholder mapping

Project-X will have an impact on many different groups inside and outside SZW. These groups need to identified and included in Project-X appropriately. There are many reasons for this, three of the most important are (i) that the success of Project-X depends on gaining adequate information and this is held by the stakeholders, (ii) the successful implementation of Tool-X requires support by stakeholders and (iii) Project-X and the use of Tool-X will have an impact on the relationships between the stakeholders and this will need to be managed.

What constitutes appropriate inclusion in Project-X will require explicit consideration. One method that may help here is *stakeholder mapping*. There are a number of variations, all aim to assist gaining a clear focus on stakeholders and the context for the relationships between them. This is particularly important in the strategic management of the relationships between partners, helping priorities to be set and allowing the user to think about the different styles of communication that are likely to be required. Stakeholder-mapping acknowledges that project partnerships may need to be discriminating about how they invest limited resources for relationship building and communication. Illustrated in Figure 7 below is the Johnson & Scholes' approach (cited by Wilson and Charlton[40]) takes a list of stakeholders and partitions it according to the degree of power and the amount of interest in the project.

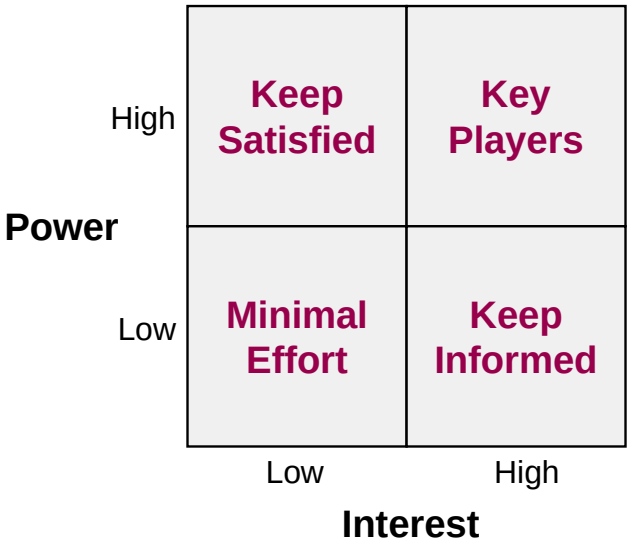


Figure 7. A power x interest stakeholder map

The result is a basis on which to consider the strategies for the relationships with stakeholders depending on where they fall on the map. For example, a prudent strategy with a powerful but uninterested stakeholder is to consult and keep them satisfied about the project. On the other hand, a stakeholder in the low power/high interest quarter might need to be empowered with regard to a project if they are identified as a being particularly affected by Tool-X. The most obvious outcome is to identify and build relationships with stakeholders in the high power/high interest quarter.

A particular issue for the mapping exercise(s) in Project-X will be to identify and balance the positions of the Project-X customer (i.e. the person who signs off on completion of Project-X) with that of Tool-X users (e.g. front-line inspectors). As noted earlier (page 23), because of power imbalances in design projects, even design processes that are ostensibly user-centred, frequently fail to ensure that users make a real contribution.

4.3 Project-X steering group

As noted earlier, a peculiarity of Tool-X is that its design could be seen to be a part of the regulatory process. Although the main group of users is thought to be inspectors (at the time of writing) there are many other stakeholders who can make valuable contribution to the validity of assessments and decision-making assisted by Tool-X. For this reason it seems clear that these stakeholders need to be involved in steering Project-X. In addition, the transformational nature of the design process may provide additional benefits to the stakeholders. If a long-term view is adopted for Project-X, it is recommended that SZW considers a partnership approach.

5 THE QUESTIONS POSED TO THE STUDY

This section collates the material presented in the foregoing sections and provides answers to the questions posed. Section 5.1 summarises the material to reflect the questions posed in the startnotie. In section 5.2, the material is reordered to answer questions derived from a suggested mission statement for Project-X.

5.1 The questions as posed in the start notice

The questions posed in the start notice are shown below in Table 8.

	Research questions as set by SZW	Research questions (NRI translation)
(1)	Beschrijf op heldere wijze de problematiek rondom de normering van het veiligheidsbeheerssysteem.	Identify and describe the issues associated with producing a set of criteria for the assessment of SMSs.
(2)	Beschrijf de randvoorwaarden voor een onderzoek dat zal leiden tot effectieve normering van het VBS.	Produce a set of requirements for a research project aimed at producing effective regulatory norms for SMSs.
(3)	Formuleer de onderzoeksvragen die aan een dergelijk onderzoek ten grondslag liggen.	Formulate the research questions to be answered by the research project.
(4)	Beschrijf de randvoorwaarden voor een inspectieinstrument waarmee de kwaliteit van een VBS beoordeeld kan worden.	Describe the properties of an inspection tool/method for assessing the quality of an operational SMS.

Table 8. Questions posed in the start notice (as given originally in Dutch and with translation into English)

5.2 Questions from a suggested mission statement for Project-X

One view of the aim of Project-X is to *design a tool to help inspectors to assess the "management system and the organization of such sites with a view to major accident prevention"* (to paraphrase the directive). The items below reflect this statement in terms of the material developed in this study.

(a) What does assessment mean in the context of SZW's remit?
Assessment of safety management by SZW, means measurement of an operator's success in translating the requirements of the law into its own arrangements and systems. In addition, assessment needs to be cognisant of the operator's self-regulatory capacity, particularly as manifest in their safety management assurance arrangements and corporate governance as it relates to safety.

(b) What criteria apply to measurement within assessment?
In general, the assessment tool needs to demonstrate reliability and validity: that it address

all the relevant issues and measures them consistently. For individual assessments, the standard of measure should allow traceability of results to the data that was collected. There should be a long-term programme to measure the validity of the tool.

(c) What is the scope of assessment for management systems and organisations?
The assessment tool could explore issues of corporate governance and self-regulatory capacity. A developmental view could be taken to ensure that the right problem is addressed even where this is not a safety management system issue (subject to demonstrating the relevance to SZW's remit).

(d) How are the set of variables (for assessment) to be identified?
Initially, this will be from an analysis of BRZO and MAHB guidance but then through descriptive models derived from analysis of how inspectors currently make decisions about safety management. This will be supplemented by developing normative models of safety management development and self-regulation.

(e) What process of design should be used?
It is suggested that Project-X adopts a user-centred design philosophy. Software should not be the default manifestation of Tool-X functions; software development should be justified against benefits of improved quality or productivity.

(f) Within what type of project?
The project may benefit from a wide variety of stakeholders. It will need to identify the most beneficial way of achieving this, for example, through establishing a steering group and or a partnership. It is conceivable that Project-X might become a long-term aspect of the system in Dutch major hazard regulation.

(g) What are the basic functions of the tool?
Assessment of operators' safety management should be summative and formative. The tool should assess the capacity of the operator to make improvements in its safety management as well as identify the problem that needs to be addressed. The tool should facilitate SZW's organisational learning in the topic of safety management and its competence as a regulator of self-regulation amongst the operator population.

(h) What performance is required of a tool in this context?
The tool should perform well against usability criteria as well as against criteria such as transparency, accountability, proportionality, targeting and consistency.

(i) Who would be affected by the tool and how?
Tool-X has the potential for influence on users and other stakeholders. This includes inspectors, their managers, staff of other competent authorities in the Netherlands, operators and their contractors, training organisations and intermediary organisations. The impact of

the new assessment tool needs to be considered in the research project.

(j) How will the tool support inspectors to perform their tasks and attain their goals?
Task analysis and user characterisation are needed to identify the support required by inspectors. It is hoped that the tool will exploit technology to make centrally held data available to inspectors during assessments. The tool should allow as much flexibility to inspectors as can be achieved in balance with the need for consistent assessment.

The relationship between these questions and answers and those posed in Table 8 is shown below in Table 9:

Research questions for this study		
Startnotie questions		Subsidiary questions (summary answers above)
(1)	Identify and describe the issues associated with producing a set of criteria for the assessment of SMSs.	*(a) What does assessment mean in the context of SZW's remit?* *(b) What criteria apply to measurement within assessment?* *(c) What is the scope of assessment for management systems and organisations?* *(d) How are the set of variables (for assessment) to be identified?*
(2)	Produce a set of requirements for a research project aimed at producing effective regulatory norms for SMSs.	*(e) What process of design should be used, and* *(f) within what type of project?*
(3)	Formulate the research questions to be answered by the research project.	*See section 5.3*
(4)	Describe the properties of an inspection tool/method for assessing the quality of an operational SMS.	*(g) What are the basic functions, and* *(h) what performance required of a tool in this context?* *(i) Who would be affected by the tool and how?* *(k) How will the tool support inspectors to perform their tasks and attain their goals?*

Table 9. Relationship between derived research questions and those posed in the startnotie

5.3 Requirements and questions for the research project

This section lists research questions that have been derived from this report. The referring page numbers are shown in parentheses.

The research project should:

1. explore the scope for promoting self-regulation through the assessment process (7);
2. compare and contrast the assessment context of operators with the corresponding context of regulators such as SZW (7);
3. consider how to apply regulatory amplification principles to assessment and decision-making tasks (11);
4. evaluate the use of predictive and forecasting statistics, such as extreme value projection (EVP) (12);
5. conduct an impact assessment that demonstrates the costs of the assessment process to industry and the benefits to regulation (15);
6. develop a method to integrate into the assessment tool the five criteria for regulation advocated by the UK BRTF (16);
7. evaluate the relevance and impact of Yeung's criteria for regulatory decisions (19);
8. evaluate the relevance of the OECD golden rules to the assessment tool and the research project (16);
9. explore the implications of Yeung's criteria for regulatory decisions on the assessment tool (20);
10. explore the possible ramifications of a conservative reading of SZW's remit on its ability to develop competence as 'a regulator of self-regulation' in the context of major hazards; (29);
11. identify which tasks are to be supported by the assessment tool (20);
12. identify relevant ancillary tasks, that is, tasks which are not central to the assessment but which influence it or are influenced by it (20);
13. identify the impact of the assessment tool on ancillary tasks (e.g. by change analysis) (20);
14. identify norms and procedures for inspectors tasks related to assessment (21);
15. compare that the norms and procedures for inspector's tasks to inspectors' perceptions of the same tasks (21);
16. explore and data sharing aspects related to the assessment. What scope is there for datasharing, who and what data are involved, what are the legal and security implications, and what is the likely impact of these factors on data quality (24);
17. who are the stakeholders of the research project (24);
18. how should the stakeholders be involved in the project (this to include a stakeholder mapping study) (42);
19. what is the strategy for ensuring appropriate levels of involvement of stakeholders in

the research project (42);

20. identify the diversity of stakeholder (including users) needs (with respect to the assessment tool) and identify any significant incompatibilities between them (24);
21. establish usability criteria for the formative and summative evaluation of the assessment tool (24);
22. explore the scope for exploiting the set of technologies grouped within DSS. Give particular consideration to the needs and tasks of different groups in the different decision-making phases proposed by Simon (28);
23. explore the scope for using the fault trees derived for AVRIM-2, as an online resource for inspectors undertaking assessments (38);
24. explore the advantages and disadvantages of institutionalising the development of the assessment tool as a part of major hazard regulation in the Netherlands (45);
25. evaluate different models of project steering, including partnership models (45);
26. explore linkages between the assessment tool, inspection planning and safety report assessment. (27);
27. explore the possible role for the assessment tool as a means of developing SZW's competence as a regulator of safety management and operators' self-regulatory capacity (29);
28. compare and contrast safety management with safety management systems (30);
29. develop criteria for the assurance function in major hazard safety (35);
30. develop sampling strategies for assessing assurance, control and operational conditions of barriers and controls (20, 32);
31. develop criteria to assess how operators respond to problems of safety management assurance as corporate entities (35);
32. research the effects of business turbulence and difficulties on safety management (35);
33. evaluate the scope and validity of business intelligence as a factor for informing safety management assessments (34);
34. explore the cybernetics concept of homeostasis as a principle for building models of safety management (35);
35. develop matrices that allow read across between the contents of the assessment tool and components of the BRZO (35);
36. explore ways that feedback loops can be established for the assessment tool to ensure that it is improved and subject to challenge (37);
37. develop a short, intermediate and long-term validation program for the assessment tool (40);
38. evaluate the opportunities for improved communication that could be offered by the assessment tool (26);
39. explore the scope for flexibility of structure and detail in a normative model for safety management assessment (38).

6 REFERENCES

[1] Council Directive 96/82/EC, On the Control of Major-Accident Hazards Involving Dangerous Substances.

[2] BRZO '99 (Besluit Risico's Zware Ongevallen – 1999)

[3] Better Regulation Task Force, 2003. Imaginative Thinking for Better Regulation.

[4] CEC, COM (2002) 21 final. "Proposal for a Directive of the European Parliament and of The Council on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification, Brussels, 23.1.2002

[5] OECD, 1999. Regulatory Reform in the Netherlands: Government Capacity to Assure High Quality Regulation.

[6] HMSO (1972), Committee on Safety and Health at Work Safety and Health at Work: Report of the Committee (Robens Committee), London.

[7] Ashby, W.R. (1956). Introduction to Cybernetics. London, Chapman and Hall.

[8] Heylighen, F. and Joslyn, C. (2001) Cybernetics and Second-Order Cybernetics. In: R.A. Meyers (ed.), "Encyclopaedia of Physical Science & Technology" (3rd ed.), AP, NY.

[9] Conant, R. and Ashby, W.R. (1970). Every Good Regulator of a System Must be a Model of that System. International Journal of Systems Science, 1970, Vol. 1, No. 2, pp. 89-97.

[10] Ashby, W.R. (1960). Design for a Brain. 2nd edition, London, Chapman and Hall.

[11] Beer, S. (1979). The Heart of Enterprise: The Managerial Cybernetics of Organisation. John Wiley & Sons, Chichester.

[12] Beer, S. (1985). Diagnosing the System for Organisations. John Wiley & Sons, Chichester

[13] CEC (1996) Council Directive 96/82/EC of 9 December 1996, on the control of major-accident hazards involving dangerous substances. Article 5(2).

[14] Rasmussen, J. (1996). Risk Management in a Dynamic Society: A Modelling Problem. Key-note address: Conference on human interaction with complex systems. Dayton, Ohio, August 1996. *Later published under the same title in: Safety Science, Vol.27, No. 2/3, pp. 183-217, 1997.*

[15] Frei, R., Kingston, J., Koornneef, F., and Schallier, P. (2002), NRI MORT User's Manual. Ref. NRI-1 (2002), Pub. Noordwijk Risk Initiative Foundation, The Netherlands. www.nri.eu.com

[16] Kletz T. (1993). Lessons from Disaster. Gulf Publishing Company, Houston.

[17] OECD (2003). OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response. OECD Environment, Health and Safety Publications Series on Chemical Accidents, No. 10, 2nd Edition.

[18] OECD (2003) From Red Tape to Smart Tape: Administrative Simplification in OECD Countries.

[19] BRTF (2003) Principles of Good Regulation.
http://www.brtf.gov.uk/taskforce/reports/PrinciplesLeaflet.pdf

[20] Ministrie van Binnenlandse Zaken en Koninkrijksrelaties (MinBZK) 2001. Final considerations on the firework disaster in Enschede.
www.minbzk.nl/contents/pages/00001947/eindrapport_final_oosting_2-01.pdf

[21] Elcock, D., Gasper, J., Moses, D.O., Emerson, D., and Arguero, R. Alternative Future Environmental Regulatory Approaches for Petroleum Refineries. Environmental Science & Policy 3 (2000) 219–229

[22] Ashford, N.A., and Caldart, C.C. (2001). Negotiated Environmental and Occupational Health and Safety Agreements in the United States: Lessons For Policy. Journal of Cleaner Production 9 (2001) 99–120.

[23] Parker, C. (2004). Restorative Justice in Business Regulation? The Australian Competition and Consumer Commission's Use of Enforceable Undertakings. Modern Law Review (2004) 67(2) 209–246.

[24] Yeung, K (2004). Securing Compliance: A Principled Approach. Hart Publishing, Oxford, UK.

[25] Hendrick, K. and Benner, L. (1987), "Investigating accidents with STEP". Marcel Dekker.

[26] Shneiderman, B. (1998) Designing the User Interface: Strategies for Effective Human-Computer Interaction. 3rd Edition. Addison Wesley.

[27] Klein, G., Kaempf. G.L, Wolf, S., Thorsden, M and Miller, T (1997). Applying Decision Requirements to User-Centered Design. *Int. J. Human – Computer Studies* (1997) **46,** 1–15.

[28] Bell, D.E., Raiffa, H., and Tversky, A. (1988) "Descriptive, Normative, and Prescriptive Interactions in Decision Making". Cambridge, Cambridge University Press.

[29] Damodaran, L. (1986). User Involvement in System Design. Data processing, 25 (6), pp. 6–13

[30] Lamb, R. and Kling, R. (2003). Reconceptualizing Users as Social Actors in Information Systems Research. MIS Quarterly Vol. 27. No. 2, June 2003

[31] Frei, R., Kingston, J., Koornneef, F., and Schallier, P. (2003), "Investigation Tools in Context". JRC/ESReDA Seminar on "Safety Investigation of Accidents" in Petten, The Netherlands, 12–13 May 2003. http://www.nri.eu.com/Tools~final.pdf

[32] Gould, JD., and Lewis, C (1985) Designing for Usability: Key Principles and What Designers Think. Communications of the ACM, 28, pp. 300–311.

[33] Johnson (1992). Human Computer Interaction: Psychology, Task Analysis and Software Engineering. McGraw-Hill.

[34] Turban, E., and Aronson, J.E. (2001). Decision Support Systems and Intelligent Systems. 6th Edition. Prentice Hall, NJ.

[35] Mitchison, N. and Porter, S. (1998). Guidelines on a Major Accident Prevention Policy and Safety Management System, as Required by Council Directive 96/82/EC (Seveso II). Luxembourg: Office for Official Publications of the European Communities, 1998.

[36] Espejo, R. (1989). A Cybernetic Method to Study Organisations. In: The viable system model: interpretations and applications of Stafford-Beer's VSM. Edited by Espejo. R., and Harnden. R. John Wiley & Sons, Chichester. pp. 361-382.

[37] Beer, S. (1981). Brain of the Firm: The Managerial Cybernetics of Organisation. John Wiley & Sons, Chichester.

[38] Gilbert, S.F. (1994). Developmental Biology. 4th Edition. Sinauer Associates, Sunderland

[39] Plaisant, C., and Shneiderman, B. (2004). Designing the User Interface: Strategies for Effective Human-Computer Interaction, Addison Wesley.

[40] Wilson, A. & Charlton, K. 1997. Making Partnerships Work. Joseph Rowntree Foundation.

[41] Ecotec, Ltd, 2000. A Project Manager's Guide to Inter-Agency Working. Employment Support Unit. www.employment.ecotec.co.uk

[42] Ecotec, Ltd, 2001. Partnership Working: Good Practice and Lessons from ADAPT. ADAPT Support Unit. www.adapt.ecotec.co.uk/publications/thematic.htm