



# **Regulating higher hazards: Exploring the issues**

Principles underlying the legal frameworks, as exemplified by the offshore, chemical, rail and nuclear regimes, with related discussion on the railway approvals system.

Any responses to this document should be sent to :

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to reach her no later than 28 January 2001  
Responses received by 1 December may be fed into the inquiry into  
the train collision at Ladbroke Grove.

The Commission tries to make its consultation procedure as thorough and open as possible. Responses to this discussion document will be lodged in the Health and Safety Executive's Information Centres after the close of the discussion period, where they can be inspected by members of the public or be copied to them on payment of the appropriate fee to cover costs.

Responses to this discussion document are invited on the basis that anyone submitting them agrees to their being dealt with in this way. Responses, or parts of them, will be withheld from the Information Centres only at the express request of the person making them. In such cases a note will be put in the index to the responses identifying those who have commented and have asked that their views, or part of them, be treated as confidential.

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DISCUSSION  
DOCUMENT

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# CONTENTS

	Paragraph number
<b>Summary</b>	1 - 6
<b>Chapter 1 - Introduction</b>	7 - 13
<b>PART I</b>	
<b>Chapter 2 - Principles of ‘permissioning’ regimes</b>	14
· Principle 1 - society’s views	15 - 19
· Principle 2 - the responsibilities of the risk creator	20 - 26
· Principle 3 - a goal-setting framework	27 - 33
· Principle 4 - the involvement of the safety regulator	34 - 44
<b>Chapter 3 - ‘Permissioning’ regimes: the legal frameworks</b>	45 - 48
· Nuclear	49 - 64
· Onshore major chemical hazards (COMAH)	65 - 78
· Offshore	79 - 96
· Railways	97 - 113
<b>PART II</b>	
<b>Chapter 4 - Initial integrity on railways</b>	
• Safety by design	114 - 115
• Railways approvals	
· <i>Current system</i>	116 - 118
· <i>Reasons for change</i>	119 - 125
• Issues for discussion	126 - 160
<b>PART III</b>	
<b>Chapter 5 - What happens next</b>	161 - 165
<b>Annexes</b>	
1 ‘Permissioning’ legal requirements: comparative summary table	
2 Legal requirements - some key points	
3 Risk related terms	
4 Abbreviations used in this publication	
5 References	
6 Invitation to comment and response form	

### **Principles of 'permissioning' regimes**

1. Through the political process, the regulator and the regulated are subject to society's views about the tolerability of risk:
  - *'permissioning' regimes are applied to high hazard industries, about which society has particular concerns.*
2. The legal duty to manage risks lies with the organisations that create the risks - 'permissioning' regimes require them to describe how, but a description is not sufficient without the active commitment of the duty holder in practice:
  - *duty holders must identify the hazards, assess the risks, develop effective control measures and keep a current documentary record of all this;*
  - *the control measures must cover design and hardware, systems and procedures and human factors in a coherent whole;*
  - *duty holders must implement control measures and keep them up to date;*
  - *duty holders must make and test arrangements for managing emergencies and mitigating their consequences.*
3. A goal-setting framework is preferable to a prescriptive one because it makes duty-holders think for themselves:
  - *the flexibility of goal-setting is more likely to lead to arrangements for controlling risk which are tailored to the particular circumstances, and which through safety case maintenance and re-submission will remain so;*
  - *within a goal-setting context, 'permissioning' regimes define elements of the management arrangements required.*
4. The involvement of the safety regulator through 'permissioning' should give society an added level of confidence that duty holders are capable of discharging their legal responsibilities to control the risks:
  - *'permissioning' regimes impose more rigid frameworks on the safety regulator and require more positive regulator engagement than other approaches to regulation;*
  - *'permissioning' regimes provide the safety regulator with additional levers, which can be developed in the light of the industry's performance;*
  - *the duty holders' documentation provides part of the basis for targeting safety regulator intervention;*
  - **but** *'permissioning' does not provide a guarantee of safety in the operation of the duty holders' arrangements.*

## SUMMARY

1. The need for public explanation of the basis for decisions arises in wide areas of public policy making. This document is one of a number recently published by the Health and Safety Executive (HSE) with the objective of increasing transparency, stimulating discussion and seeking views on its approach. Greater clarity should help all involved to understand each other's agenda and to work better together.

2. HSE regulates health and safety in a number of high hazard industries through what can loosely be termed 'permissioning' regimes. The term 'permissioning' is inexact, since only some of the regimes require explicit consent from the regulator to duty holder activity. However, the approach is characterized by requirements on the duty holder to document in advance the hazards, risks, and measures to eliminate or control them (often called a safety case); and on the safety regulator to examine the adequacy of these arrangements.

3. Part I of this Discussion Document sets out the fundamental principles that have underpinned HSE's 'permissioning' activity for some time, but have not previously been put forward for public discussion. Chapter 2 explains what they mean, and Chapter 3 illustrates their application through a description of the legal requirements for the railways, nuclear, offshore and onshore major hazards industries. It does not, however, evaluate the practical working of the regimes. A summary comparative table of the legal requirements is provided at Annex 1. HSE would like your views on the principles as set out. Once it has them, it will look again at the principles and use them to test its own approach, and to advise the Health and Safety Commission (HSC) on the legal requirements and policy issues. In line with its responsibilities for the adequacy of health and safety law and for advice to Ministers, any subsequent proposals for change would come from HSC, and be subject to the usual consultative process.

4. Consideration of safety at all stages, from concept selection and design is an important element in 'permissioning' regimes. Part II focuses in on the current system for HSE approval of railway works; describes issues which point towards change; and raises for discussion the possibility of modified arrangements. Features of such modified arrangements might include:

- increasing the non-regulator external assessment of proposals;
- broadening the scope of plans put forward for new or altered works;
- categorising schemes so as to improve the prioritisation of approvals;
- improving control over operation before final approval;
- increased powers for HSE, for example to enable it to impose conditions on the operation of partly completed schemes;
- clarifying the responsibilities of the duty holder.

5. This Discussion Document was prepared while the Inquiry into the train collision at Ladbroke Grove was taking place. Some parts of it cover topics on which the Inquiry might make recommendations. The document is not intended to second-guess or pre-empt such recommendations, but HSE will take account of the responses to the questions it asks when advising HSC on how to take forward the outcome of the Inquiry.

6. Comments are invited on the principles and on railway approvals. Views received by 1 December 2000 may also be fed into the Ladbroke Grove Inquiry. Annex 6 explains how you can make your comments.



## CHAPTER 1 - INTRODUCTION

7. The application of 'permissioning' with safety cases as a key element, has widened from the nuclear industry through major chemical hazard sites and other industries to the railways. The legal framework for each of the regimes differs, because each developed at a different time in response to different influences, including the 1957 Windscale fire; the Flixborough explosion; the Seveso Directive; Lord Cullen's report on the Piper Alpha disaster<sup>1</sup>; and issues related to privatisation identified in the HSC report *Ensuring Safety on Britain's Railways*<sup>2</sup>. Despite this, and differences in the nature of the risks, a number of common principles form the backbone of the approach. The joint Government / HSC strategy statement, *Revitalising Health and Safety*<sup>3</sup> endorsed the basic framework provided by the Health and Safety at Work Act. In this context, the objective of this publication is to increase transparency and to stimulate discussion.

8. Based on the arrangements for the railways, nuclear, offshore and onshore major hazard industries, Part I of this document discusses the principles behind 'permissioning', and the features which distinguish it from the generality of health and safety regulation. The discussion does not extend to HSE's statutory certification work, such as pesticides approvals, mining exemptions and asbestos licensing. Chapter 2 explains:

- why and where 'permissioning' is appropriate;
- the responsibilities of those with legal duties to manage the risks (duty holders);
- key elements of a 'permissioning' regime;
- the role of the safety regulator.

9. Chapter 3 goes on to describe the requirements of the four regimes, and how they line up in their different ways against the principles. The discussion throughout concerns only the legal framework, not the systems' effectiveness in controlling risks. Neither does the document's scope extend to matters relating to protection of the environment; this is an important limitation in relation to onshore major chemical hazards, where the relevant regulations cover both areas, and HSE regulates jointly with the environment agencies.

10. Early attention to hazards, risks and precautions, for example at design, construction and commissioning stages can eliminate some hazards, and is an important element of 'permissioning' regimes. Against the background of the Inquiry into the rail accident at Ladbroke Grove (LGRI) and in the context of the 'permissioning' principles, Part II focuses in on the current system for HSE approval of some railway works, plant and equipment. It discusses some reasons for change to the system, and raises for debate ideas about the form such change might take.

11. This document sets out the basis for a consistent approach to the development of policy and legislation, and for review of the current arrangements. More immediately, LGRI is likely to consider the operation of the safety case regime in relation to railways. HSC has already consulted on some proposed amendments to the Railway (Safety Case) Regulations<sup>4</sup>, and amended regulations are expected to be in force before the end of the year. LGRI may make further recommendations on this, as well as in relation to the railways approvals regime. HSE hopes that this document and the discussion which follows will provide a sound basis for advising HSC on the issues, and for responding to relevant recommendations.

12. All of the 'permissioning' regimes considered in this Discussion Document are subject to charging by HSE for the exercise of its regulatory functions. In the nuclear industry such charging has been in place since the Nuclear Installations Act 1965<sup>5</sup>; in the

other industries it was introduced in 1999. Charging in these areas will be subject to an evaluation after two years' operation, and the outcome reported to HSC. It is not considered here.

13. This publication is written primarily for an informed audience, for example health and safety professionals, safety regulators and the regulated from all high hazard industries, not just those described in Chapter 3. This version of the document will be of particular interest to those in the rail industry: a shorter version has been published for stakeholders in other major hazard industries, which omits the more specific chapter on railway approvals. The term 'safety regulator' is used throughout to distinguish HSE from other regulators, but encompasses its full remit, in relation to health as well as safety. The document asks a number of questions on which your views would be particularly helpful. The invitation to comment and a form summarising the questions are at Annex 6.

# PART I

## CHAPTER 2 - THE PRINCIPLES OF 'PERMISSIONING' REGIMES

14. This section explains the principles behind HSE's regulation of health and safety in the railways, nuclear, offshore and onshore major hazard industries, all of which are subject to 'permissioning' in some form. The first three principles also hold good for HSE's general approach to regulation: the subsidiary points draw out the specific application to 'permissioning' regimes, where the nature of the hazards is such that society seeks an additional level of control.

### *Principles of 'permissioning' regimes*

1. Through the political process, the regulator and the regulated are subject to society's views about the tolerability of risk:
  - *'permissioning' regimes are applied to high hazard industries, about which society has particular concerns.*
2. The legal duty to manage risks lies with the organisations that create the risks - 'permissioning' regimes require them to describe how, but a description is not sufficient without the active commitment of the duty holder in practice:
  - *duty holders must identify the hazards, assess the risks, develop effective control measures and keep a current documentary record of all this;*
  - *the control measures must cover design and hardware, systems and procedures and human factors in a coherent whole;*
  - *duty holders must implement control measures and keep them up to date;*
  - *duty holders must make and test arrangements for managing emergencies and mitigating their consequences.*
3. A goal-setting framework is preferable to a prescriptive one because it makes duty-holders think for themselves:
  - *the flexibility of goal-setting is more likely to lead to arrangements for controlling risk which are tailored to the particular circumstances, and which through safety case maintenance and re-submission will remain so;*
  - *within a goal-setting context, 'permissioning' regimes define elements of the management arrangements required.*
4. The involvement of the safety regulator through 'permissioning' should give society an added level of confidence that duty holders are capable of discharging their legal responsibilities to control the risks:
  - *'permissioning' regimes impose more rigid frameworks on the safety regulator and require more positive regulator engagement than other approaches to regulation;*
  - *'permissioning' regimes provide the safety regulator with additional levers, which can be developed in the light of the industry's performance;*
  - *the duty holders' documentation provides part of the basis for targeting safety regulator intervention;*
  - **but** *'permissioning' does not provide a guarantee of safety in the operation of the duty holders' arrangements.*

Q1 - HSE would welcome your views on the extent to which the four principles capture the key features of 'permissioning' regimes.

## Principle 1 - society's views about the tolerability of risk

Through the political process, the regulator and the regulated are subject to society's views about the tolerability of risk:

- *'permissioning' regimes are applied to high hazard industries, about which society has particular concerns.*

15. Safety regulators form part of the institutional structures established by Parliament, and are accountable to Parliament through Ministers. Through the political process they are subject to society's views about the tolerability of risk, which have a direct influence on their strategy, policy development, and resourcing.

16. Individual members of society have their own views about relative risks, and their concerns are not always directly related to actual risk levels. Their views may be shaped by perceived risk, by the nature of the consequences, by their confidence in the institutional controls, and by the degree to which a risk is taken voluntarily. The possibility of multiple fatalities from a single event with involuntary exposure to the hazard causes particular concern, regardless of how low the risk is. And while many people understand in abstract terms that absolute safety is impossible, this may become irrelevant to them when faced with an actual incident. All of these issues affect tolerability.

17. Within society judgements on any particular issue tend to vary across a spectrum. The views of pressure groups, local residents, and populations dependent on a workplace for employment may all vary. More broadly, such judgements are in part shaped by the media, and in part expressed through the media. They vary over time and between cultures. In Great Britain, society is more aware of hazards and risks, and more demanding in relation to their control than it was a few decades ago. It is also less trusting of 'experts', regulators, government and big business.

18. The safety regulator has a role in communicating, informing and stimulating debate. Effective communication, openness of information and transparency in the workings of the regulator are all essential to maintaining society's confidence. Formal representation of public interests on advisory committees and contact with interest groups increase transparency, providing fresh perspectives and valuable external challenge. The rights of stakeholders for access to safety cases and information from safety regulators are likely to increase under freedom of information legislation; this could play an important part in improving confidence, providing that it does not lead to the production of idealised safety cases for public consumption, rather than living documents which identify areas for improvement.

19. The very existence of 'permissioning' in high hazard industries reflects society's concerns, and its need for an added level of confidence. This is secured through requirements for a structured and documented approach by duty holders, which go beyond duties in more general legal provisions; and by a high level of safety regulator involvement. However, such regimes are resource intensive for both the regulator and the regulated, and can be perceived as diluting duty holder responsibility. For this reason 'permissioning' is used sparingly, where such regulator involvement is proportionate to the hazard and possible consequences.

Q2 - HSE would welcome your views on whether this basis for the application of 'permissioning' regimes is appropriate.

## Principle 2 - the responsibilities of the risk creator

The legal duty to manage risks lies with the organisations that create the risks - 'permissioning' regimes require them to describe how, but a description is not sufficient without the active commitment of the duty holder in practice:

- *duty holders must identify the hazards, assess the risks, develop effective control measures and keep a current documentary record of all this;*
- *the control measures must cover design and hardware, systems and procedures and human factors in a coherent whole;*
- *duty holders must implement control measures and keep them up to date;*
- *duty holders must make and test arrangements for managing emergencies and mitigating their consequences.*

20. The keystone of health and safety law is clear responsibility placed on the organisations which create risks. The involvement of the safety regulator through 'permissioning' must not detract from this. 'Permissioning' regimes also put over-arching duties on the body in overall control of a site, installation or activity, for example the railway infrastructure controller, the operator of a fixed offshore installation, the nuclear site licensee and the operator of an onshore major chemical hazard site. These duty holders have to take full account of the activities of contractors as well as their own employees, and must make arrangements to manage the associated risks, in the context of the operation as a whole.

21. 'Permissioning' regimes demand a structured approach, in particular through planning before operations start and through mechanisms for continued assurance. The overall objective is to secure an integrated and coherent approach to eliminating hazards and managing risks, which would work without the intervention of the safety regulator, but which is transparent and can be tested. Duty holders must:

- document in detail the hazards, their assessment of the risks and their control measures, in a form usually known as a safety case;
- implement them;
- keep the documentary record up to date.

They must have the necessary managerial and technical competence to ensure that they comply with their legal duties.

22. There is a range of approaches to risk assessment. Quantified Risk Assessment (QRA) is used widely in many of the industries subject to 'permissioning'. It can be an important part of the assessment of some risks, and help prioritise and target control measures, but it is subject to uncertainties and can not be used alone to decide the measures needed to control risk. The unacceptability of large scale loss of life and public mistrust of experts mean that more is needed than a mechanistic demonstration that the risk has been reduced through a QRA calculation. Any reduced risk values shown by QRA must be supported by a clear and satisfactory description of the practical measures which deliver them. And a quantified approach can not justify situations which run contrary to accepted good practice. Duty holders must show in their safety case that appropriate principles and standards of engineering and operation are applied.

23. 'Permissioning' regimes demand a coherent and broadly-based consideration of inter-related factors. The health and safety controls identified in the safety case need to achieve hazard elimination and risk reduction through:

- good design;

- hardware controls which reflect current good practice;
- systems of work and procedures which are effective in reducing risks, for example in relation to maintenance work and modifications;
- management and resourcing arrangements which ensure that the system works as intended;
- proper consideration of human factors, such as the way people behave in real life and the factors which affect their performance;
- emergency arrangements which would mitigate the effect of an incident, if all else failed.

24. For 'permissioning' to operate effectively, duty holders need to:

- be actively committed to making their arrangements work;
- have a robust health and safety culture, with work force involvement and ownership at every level;
- provide the safety regulator with good quality and accurate information.

Those with a robust safety culture are more likely be open in sharing information with the safety regulator, their own employees and other stakeholders, improving confidence through such transparency.

25. Where these elements are lacking there is an ever-present risk of standards deteriorating, even where there was an initially sound system. The safety regulator may devote significant resources to enforcement activity, but be unlikely to achieve more than the basic legal minimum. Recalcitrant duty holders determined to do no more than the minimum they can get away with, themselves face potentially high costs in terms of poor health and safety performance, criminal and civil legal expenses and their public reputation.

26. Many duty holders acknowledge the benefits of the structured approach to risk assessment that drawing up a safety case requires. However, **maintaining** that level of usefulness and relevance is more challenging. To play an effective part in managing hazards and risks, safety cases should be living documents - produced and used in a way which meets the duty holders' needs; not merely to satisfy the safety regulator. The effectiveness of the risk control measures depends on their day to day implementation. The duty holder must carry through the assertions and assumptions in the safety case to practices on the ground, and monitor and evaluate their implementation. The most powerful safety cases have relevance to managers and the work force through clear hierarchical links to procedures, operating limits and training.

HSE would welcome your views on:

- Q3 - whether principle 2 properly reflects the responsibilities and demands which should be placed on duty holders;
- Q4 - what more could be done to help safety cases to become living documents of practical relevance to the daily operation of sites.

### Principle 3 - a goal-setting framework

A goal-setting framework is preferable to a prescriptive one because it makes duty holders think for themselves:

- *the flexibility of goal-setting is more likely to lead to arrangements for controlling risk which are tailored to the particular circumstances, and which through safety case maintenance and re-submission will remain so;*
- *within a goal-setting context, 'permissioning' regimes define elements of the management arrangements required.*

27. Most of the health and safety law currently applying in 'permissioning' regimes and elsewhere is goal-setting in terms of controlling specific risks; it sets out what duty holders must achieve, but not how they must do it. Much of this law replaced earlier prescriptive requirements, which instead spelt out exactly what physical controls duty holders had to put in place. Prescriptive law such as this limits the ability of duty holders to develop their own solutions, and the discretion of the safety regulator. It can lead to blind compliance, narrowly based, rather than active and continuing consideration of the risks and the best means of controlling them. Irrespective of suitability to a particular plant, it provides ready-made solutions, which are likely before long to lag behind developing technology and good practice.

28. Goal-setting regulations do not, in themselves, provide the duty holders with the same degree of certainty as prescriptive law, and work best within a framework of codes, guidance and standards of good practice. Such supporting material helps spread good practice, promotes consistency of approach, and provides transparency to duty holders in terms of the yardsticks against which the safety regulator measures their approach and performance. Such material can also be updated more easily than statute law.

29. Much in the way of useful standards and guidance material is produced by duty holders themselves, often working through trade organisations, and facilitated by the safety regulator. National and international standards-making bodies have a significant role to play, as do regulators themselves - HSE produces a considerable amount of material in the form of Approved Codes of Practice and other guidance. Much of this is developed in consultation with industry and work force representatives.

30. Standards should aim to capture accepted good practice. It is important that the standards-making process is transparent. Those who apply standards must understand the context for which they were intended, and the assumptions behind them, rather than applying them blindly. Moreover, they must be able to develop solutions for situations in which the standards are not relevant, or do not reflect the full scope for improvement. Improved standards and modern good practice should not be automatically retrospective: updating older plant may not be reasonably practicable, and can introduce new risks. But there may come a time when the risks from continued operation are no longer tolerable, and such plant has to be taken out of use.

31. HSE believes that goal-setting requirements are more likely than a prescriptive approach to lead to proportionate action, tailored to the specific circumstances, and reflecting current technology and emerging best practice. Goal-setting should also foster a sense of ownership by duty holders of systems they develop themselves. Under such law, the responsibility for developing solutions lies clearly with duty holders - it is not for the safety regulator to shoulder this by instructing them exactly what to do.

32. The contrast between goal-setting and prescription is not completely clear-cut: it is shaded along a spectrum. In relation to management systems the legal frameworks for 'permissioning' regimes move away from pure goal-setting; they introduce a number of explicit requirements, over and above important general provisions such as the Health and Safety at Work etc Act<sup>6</sup>, the Management of Health and Safety at Work Regulations 1999<sup>7</sup> and the Construction (Design and Management) Regulations 1994<sup>8</sup> (Annex 2). To varying extents, the 'permissioning' approach requires duty holders to:

- systematically assess in advance lifecycle hazards and risks, from design to decommissioning;
- eliminate hazards wherever possible;
- identify risk control and mitigation measures;
- implement, monitor and review the measures to ensure continued relevance and effectiveness;
- audit the whole process.

33. Many of the regimes have requirements for review, updating and re-submission of safety cases to the safety regulator. These help ensure the continued relevance of the controls which the duty holder puts in place.

Q 5 - In relation to all or any of the regimes, HSE would welcome your views on whether the current balance between goal-setting and prescription is appropriate.

#### **Principle 4 - the involvement of the safety regulator**

The involvement of the safety regulator through 'permissioning' should give society an added level of confidence that duty holders are capable of discharging their legal responsibilities to control the risks:

- *'permissioning' regimes impose more rigid frameworks on the safety regulator and require more positive regulator engagement than other approaches to regulation;*
- *'permissioning' regimes provide the safety regulator with additional levers, which can be developed in the light of the industry's performance;*
- *the duty holders' documentation provides part of the basis for targeting safety regulator intervention;*
- **but** *'permissioning' does not provide a guarantee of safety in the operation of the duty holders' arrangements.*

34. 'Permissioning' regimes impose more rigid frameworks on the safety regulator than other approaches to regulation. For example, the onshore major chemical hazards regime places legal duties on regulators if there are serious deficiencies in the duty holder's arrangements; and the offshore oil and gas provisions require regulator acceptance of safety cases. The effect of this intrusive safety regulator involvement is to provide an extra level of safety assurance, which should give stakeholders greater confidence that duty holders are capable of discharging their legal responsibilities to control the risks.

35. The duty holder's responsibility is fundamental to health and safety law, and to achieving better health and safety at work in practice. Nothing the safety regulator does should diminish this. In particular, the regulator's involvement must not be so detailed as to effectively take on responsibility that rightly lies with the duty holder. The safety regulator's

task is to evaluate whether the evidence from the safety case and inspection activities indicates that the duty holder has effective arrangements to manage health and safety; to test these arrangements; to seek further evidence in cases of doubt; and to take action to secure compliance with the law where necessary.

36. HSE's approach is based on targeted consideration of key areas of the duty holder's documentation, with a less detailed approach to other aspects. The same is true of inspection activity, which can be targeted on the basis of information available through the safety case, amongst other things. Assessment principles are available to duty holders and other stakeholders, to help ensure transparency of HSE judgements and to enable HSE to demonstrate consistency in the assessment process within regimes.

37. In maintaining clarity of responsibilities, its own credibility and its effectiveness in 'permissioning' regimes as elsewhere, HSE needs to be:

- targeted and proportionate in its inspection activities and examination of safety cases;
- consistent in taking a similar approach in similar circumstances to achieve similar ends;
- transparent about the basis of its assessment of the duty holders' arrangements;
- authoritative and sufficiently expert to be able to assure itself that duty holders are capable of discharging their responsibilities;
- independent and challenging, yet willing to co-operate with, and offer help and guidance to, those it regulates and others in the pursuit of its goals;
- adequately resourced and able to tailor its approach to the resources provided;
- accountable to Parliament through Ministers.

38. Absolute safety can not be guaranteed by any form of regulation. The terms *so far as is reasonably practicable* (SFAIRP) and *as low as is reasonably practicable* (ALARP) are often used in health and safety law in defining the goals to be achieved by duty holders in controlling risks. Annex 3 discusses the meaning of the terms, and summarises HSE's philosophy of risk control.

39. Neither legally nor in any other way does safety regulator acceptance of a safety case amount to a guarantee that all risk has been removed or reduced ALARP - this is not the role of the regulator, as the responsibility for managing the risk lies with the duty holder. The safety regulator provides an extra and independent layer of assurance to society that the duty holder has recognised the risk, and set measures in place to control it.

40. As elsewhere, HSE aims to secure compliance through advice, inspection and formal enforcement where necessary, as well as through considering safety cases. The standard levers of prosecution, Improvement and Prohibition Notices all remain available. Overuse of such legal powers can result in adversarial relationships, to the detriment of health and safety. However, they are powerful levers for improvement and their use provides reassurance that enforcement action can be taken to limit or control the activities, if the duty holder's approach falls short of what is required.

41. 'Permissioning' regimes offer safety regulators formal and informal levers over and above those available in general health and safety law. These include the dialogue which precedes acceptance of safety cases for offshore oil and gas installations; the availability of an additional form of enforcement notice under the Control of Major Accident Hazard Regulations<sup>9</sup> (COMAH); and the ability to require hold points through nuclear licences. Such

levers may be adapted to reflect the performance of the industry; thus the additional power to require amendment of the safety case being proposed for the railways regime, and HSE's ability to introduce new nuclear licence conditions. However, particular care is needed in defining for any regime the degree to which the safety regulator is involved in decisions to approve plant or authorise specific activities. While this gives the safety regulator a powerful influence, it may dilute understanding of the duty holder's responsibility. Aspects of this in relation to the railway industry are discussed in Part II of this document.

42. By their nature 'permissioning' regimes result in continuing relationships between the safety regulator and individual duty holders. This increases the possibility that inspectors might begin to consider issues through the eyes of duty holders, compromising their independence. This has become known as 'regulator capture'. Even unfounded perception of capture can be damaging, reducing confidence in the regulatory body as a whole. Defences are provided by transparency of the regulator's approach; internal peer review of key decisions; regular movement of staff; and effective management systems, for example in relation to enforcement decisions.

43. Extensive safety regulator involvement with the work force, its representatives, representatives of the interested public and pressure groups is also essential in counteracting any risk or perception of capture. Involvement with the work force and its representatives is central to an effective regime, while contact with the interested public and pressure groups exposes the safety regulator to external challenge. Developments in relation to the freedom of information are likely to lead to increased access to both safety cases and regulator reports. Such transparency is an important part of providing confidence in both duty holder and safety regulator.

44. Regulation in 'permissioning' regimes is characterised by the potentially very substantial consequences of enforcement decisions on society and the national economy. In many other contexts where equivalent impact could be made, the measures involved would be subject to secondary legislation and regulatory impact assessment. This places a considerable responsibility on the shoulders of safety regulators, who need to be able to balance the safety, social, economic and political implications of their decisions; it also establishes a need for a clear enforcement framework.

For any or all of the regimes, HSE would welcome your views on:

- Q 6 - the extent to which principle 3 adequately describes the place of the safety regulator in 'permissioning';
- Q 7 - whether safety regulator intervention is currently pitched correctly, bearing in mind that more activity requires more resource;
- Q 8 - the likely consequences of greater disclosure of safety cases and the safety regulator's reports.

## CHAPTER 3 - 'PERMISSIONING' REGIMES: THE LEGAL FRAMEWORKS

45. The principles described in Chapter 2 cover the basis on which 'permissioning' regimes are applied (principle 1); the requirements they place on duty holders (principle 2); the approach used to address the hazards (principle 3); and the safety regulator's role (principle 4). This chapter considers the origins and features of 'permissioning' legislation for the nuclear, onshore major chemical hazard, offshore and railways industries. It examines only requirements **over and above** the provisions of the Health and Safety at Work etc. Act 1974 (HSWA) and the cross-industry regulations made under it. Annex 2 summarises key provisions of HSWA, of the Management of Health and Safety at Work Regulations 1999 (the Management Regulations), and of the Construction (Design and Management) Regulations 1994 (CDM).

46. In line with principle 2, the relevant 'permissioning' regulations generally require a demonstration before an activity starts that associated hazards will be managed effectively. Consistent with principle 3, they are goal-setting, but tend to be more explicit than the general provisions about requirements for safety management systems. Consistent with principle 4, the regimes provide the safety regulator with additional leverage to ensure that the duty holder takes appropriate measures to deal with the hazards. Together these aspects improve the reliability and effectiveness of the measures in place and, so long as the process is sufficiently transparent, should provide stakeholders with added confidence that the risks are being properly controlled.

47. This chapter considers each of these aspects in relation to the industries in question. Annex 1 compares the key features of the regimes in tabular form and relates them back to the principles. Neither it, nor the description in this chapter relate to the performance of the industries in practice. They focus on the legal requirements, rather than what is actually done, which may go beyond the minimum required by law.

48. The legal requirements for the regimes differ because they developed in relation to different risks, and in response to different influences, at different times, against a changing background of general health and safety law.

### **Nuclear**

#### ***Background***

49. The origins of the current nuclear regime go back to the Nuclear Installations Act 1959, which defined the licensee's obligations and established the Nuclear Inspectorate (NII). This Act was influenced by the Fleck Committee report into the fire at the United Kingdom Atomic Energy Authority establishment at Windscale in October 1957<sup>10</sup>. NII was set up to regulate the nuclear reactors which were then being built for power generation. It now regulates a much wider range of organisations and facilities, including the nuclear fuel cycle activities of British Nuclear Fuels Ltd, the United Kingdom Atomic Energy Authority, the Atomic Weapons Establishment and nuclear activities at dockyards.

50. The requirement in the Nuclear Installation Act 1965<sup>5</sup> (the Act) for licensing of installations is the basis of the current regime. Under the Act, HSE has wide ranging powers to impose licence conditions in the interests of safety. The details of the 'permissioning' requirements are in the conditions<sup>11</sup> and in formally approved arrangements made under them. These dictate aspects of the safety management system; require safety cases; and require independent non-regulator scrutiny of aspects of the safety arrangements. This approach is fundamentally different from that adopted for the other industries considered in this document, where the framework is set out in regulations. Under the Licence Conditions HSE can require licensees to:

- seek its approval before changing aspects of their arrangements;
- secure consent before proceeding with an activity past a specified hold point.

51. The Act translates to British law international requirements for nuclear regulation. Its application has been debated, shaped and endorsed by various public inquiries.

### **Key features**

#### Documented case for safety

52. Licence Condition (LC) 14 sets out the primary requirement for licensees to make and implement adequate arrangements for the production and assessment of safety cases, consisting of documentation to justify safety during the installation's lifecycle. LC 23 requires an adequate safety case which identifies limits and conditions (operating rules), and which demonstrates that all operations which may affect safety are safe.

53. A safety case for a nuclear plant is not a single document or suite of documents which is produced at any one time: it is the whole body of information and argument which justifies the activity or operation. It takes the form of a set of documents which grows and changes with time, as the operations and activities change. Unlike an offshore oil or gas installation, a licensed nuclear site may not have a single safety case, but a number of safety cases to reflect the different activities which take place.

54. As the plant goes through the stages in its lifecycle, various LCs require arrangements to justify the safety of the proposed activity, be it construction or installation (LC19), modification (LC 20 and 22), commissioning (LC 21) or decommissioning (LC 35). At all stages of a plant's life cycle, the safety of the activity must be justified and documented as safe. In practice this justification must include a demonstration that risks are ALARP.

55. HSE does not normally accept, approve or agree to a nuclear safety case as such: the licensing powers are used to agree or consent to an activity or to approve a procedure, which needs to be justified by safety documentation. The safety case must be produced for the licensee's own safety management purposes, and is then used to support a request for the relevant permission from the Inspectorate.

56. HSE has published the Safety Assessment Principles for Nuclear Plants<sup>12</sup>(SAPs) which it uses in assessing nuclear safety cases. The present SAPs have gone through a series of developments since the first version appeared in 1979.

57. Licensees must periodically review their nuclear safety cases (LC15). Fundamental reviews normally take place every 10 years, but other reviews may be more frequent, for example in relation to Magnox reactor pressure vessels. Lower level review takes place after each shut down for periodic inspection and maintenance.

#### Safety management systems

58. Taken as a whole, the LCs cover the main elements of a nuclear health and safety management system.

59. The recently introduced LC 36<sup>13</sup> requires licensees to make and implement adequate arrangements to control any change to their organisational structure or resources which may affect safety. While the other regimes considered here require resubmission of safety cases as a result of significant organisational change, only the nuclear regime requires a documented submission of **how** organisational changes will be routinely managed. The

requirement was introduced following concerns about possible safety implications of staff reductions, contractorisation, and experiences in other countries.

60. The nuclear regulatory regime puts a strong emphasis on getting things right at the design stage. LCs 19 and 20 require adequate arrangements for the management of construction, installation and modifications. A justification of the proposed design is required at various stages of its development (LC 14). Duty holders are required to set out the management arrangements for subsequent stages of the design process as part of these submissions. In assessing the design, HSE looks at the design philosophy, the principles used, the engineering practices followed and the safety analyses used to develop the design, including QRA.

61. All the other regimes considered in this document require auditing of the duty holder's arrangements. The nuclear regime goes further by requiring the licensee to make and implement adequate quality assurance arrangements (LC 17). These encompass auditing, but also include such things as independent peer review, traceability of critical decisions and the provision of Nuclear Safety Committees. LC 7 requires the investigation of nuclear related incidents.

62. LC 11 places a duty on the licensee to put in place and test arrangements for dealing with on-site emergencies and their effects. This includes identifying and instructing those with duties under the arrangements, and consulting those whose assistance is required, including the work force by implication. No duty for work force consultation appears elsewhere in the Conditions, although general provisions apply which require consultation of representatives appointed by trade unions, and of employees not in groups covered by such representatives.

63. LC 13 requires duty holders to set up a Nuclear Safety Committee, one or more of whose members must be independent of the licensee's operations. The Nuclear Safety Committees must scrutinise the safety cases which support proposed changes to key hardware and procedures. This scrutiny follows peer review by a group independent of the licensee's operational arm. The licensee is responsible for ensuring adequate scrutiny by the Committee, although through the Licence Conditions HSE can influence the composition of the Committee and the issues brought before it. HSE monitors the operation of the arrangements.

#### Safety regulator involvement

64. Levers available to HSE in assuring itself that licensees are discharging their legal duties include:

- the imposition of Licence Conditions;
- the requirement for safety cases to be submitted in advance of an activity taking place;
- the issuing of directions requiring the licensee to take a particular course of action;
- the power to approve aspects of a licensee's arrangements, and require subsequent re-approval before any change;
- the setting of hold points beyond which licensees require consent to proceed, for example at various stages of design, construction, installation, and commissioning;
- the approval of arrangements for installation outages, with consent for subsequent restart.

Licensees prepare an index of information to demonstrate how they meet each Licence Condition. This and the associated safety cases provide a basis for subsequent regulatory inspection and audit.

## **Onshore major chemical hazards (COMAH sites)**

### ***Background***

65. A number of major chemical accidents occurred in Europe during the 1970s. These included the Flixborough explosion and the accidental production and release of dioxin by a runaway chemical reaction in Seveso, Italy in 1976. Such incidents, and the recognition of the differing standards of controls over industrial activities within the European Community, led the European Commission to propose a directive on the control of major industrial accident hazards (Seveso I).

66. The recent Seveso II Directive<sup>14</sup> retains the basic principles of major accident hazard controls set out in the original Seveso Directive, but addresses some weaknesses and omissions identified from experience of its application. It is implemented in Great Britain through the Control of Major Accident Hazards Regulations 1999<sup>9</sup> (COMAH). COMAH is enforced by a Competent Authority made up of HSE with the Environment Agency in England and Wales, and with the Scottish Environment Protection Agency in Scotland. In the other regimes considered in this study HSE is the sole enforcing authority. Only health and safety aspects of COMAH are considered here.

67. It is the quantities of named or generically classified hazardous materials on site (not the risks they actually pose) that determine firstly whether the regulations apply, and then the extent to which they apply. The quantities themselves are set through international negotiations. Those sites with the largest quantities of specified materials are known as top tier sites: their operators have more extensive duties than those of lower tier sites. Like any threshold system, this offers the potential for operators to reduce inventories in order to avoid additional regulatory burden.

68. The regulations require operators of all onshore major hazard sites to prepare a Major Accident Prevention Policy (MAPP). Operators of top tier sites must prepare a more detailed document called a Safety Report, and submit it to the regulator. In the case of new top tier establishments, they must submit a report before construction takes place and before any dangerous substances are added at the operational stage.

### ***Key features***

#### Documented case for safety

69. Safety Reports must demonstrate that all necessary measures have been taken to prevent or mitigate the major accident hazards. The link between the hazards and the measures to achieve control must be clearly made. The reports must provide evidence that adequate safety and reliability has been incorporated in the design. The need for diversity of protection measures explicitly required under the nuclear regime to achieve adequate reliability of safety critical systems is implicit here. The reports must include a MAPP describing how the duty holder will deal with the major hazards. The regulations set out a clear structure against which operators must describe their safety management systems.

70. Operators of top tier sites must submit their Safety Reports to the regulator for consideration (but not approval or acceptance). If deficiencies in the measures are serious, the regulator must prohibit the operation, or the part of the operation related to the serious deficiencies. Assessment Principles are available to help ensure transparency of the process<sup>15</sup>. The Competent Authority developed these in consultation with duty holders.

71. Operators must revise the Safety Report in the light of new information, review it every 5 years and keep the MAPP up to date. Unlike the other regimes, there is no explicit duty to adhere to the Safety Reports, although the duty holder is required to ensure it reflects reality, and to notify the regulator of any revisions which have significant implications for major accidents. This means that material changes can be made before safety regulator scrutiny of the proposals. In practice, a site operator would be unwise to make such changes without involving the regulator at the planning stage.

72. Operators of lower tier sites must keep the MAPP up to date and notify the regulator in advance that they intend to start construction and operations. They are not required to submit the MAPP. Once operational, the duty holder must notify the regulator of any significant increase in the quantities of dangerous substances, and of significant changes to their physical form or the processes employing them.

### Safety management systems

73. The COMAH Regulations explicitly require duty holders to outline:

- their safety aims and principles;
- their arrangements for hazard identification and risk assessment;
- their operational control arrangements;
- how they investigate incidents;
- their arrangements for managing change;
- how they audit their safety management systems.

In addition, duty holders must indicate how the MAPP is to be developed and implemented within their general management system.

74. The arrangements for managing major hazards set out in the MAPP must cover the activities of both employees and sub-contractors. Specific reference is also made to operational control (including maintenance and temporary stoppages). Unlike other regimes considered in this study, COMAH does not specifically require external non-regulator scrutiny of any aspects of the arrangements for health and safety. However, duty holders are required to make their safety report publicly available.

75. Duties are placed on the site operator to manage on-site emergencies, and on local authorities to manage off-site emergencies. Site operators must consult those whose assistance is required, specifically people employed in the establishment. Operators must also inform the public within a zone set by the regulator about the arrangements in the event of a major accident. They must plan for site emergencies, and put in place measures to limit the consequences of an accident. Their emergency arrangements must cover the roles, responsibilities and training requirements of those involved. Duty holders are not required to provide information to local authorities for emergency planning purposes before starting up.

### Safety regulator involvement

76. COMAH is unique amongst regimes covered in this study, in that it places specific duties on the regulator in relation to major hazards. The regulator must:

- prohibit operations if there are serious deficiencies in the measures taken to prevent and limit major accident consequences. This test is different from the risk of serious personal injury required in the case of a Prohibition Notice under HSWA, and the power is unique to COMAH. The Notices are subject to the

same appeal mechanism as HSWA Notices, and remain in force until the outcome of the appeal.

- organise an adequate system of inspections to ensure, in particular, that operators can demonstrate that they have taken appropriate measures to prevent and limit the consequences of any major accidents on and off the site;
- report major accidents to the European Commission.

77. The regulations also provide levers over and above those in general provisions:

- prohibition powers, in addition to those outlined above, to deal with a failure to submit a Safety Report or to provide the required information;
- an operator of a new top tier site cannot start construction or operation before receiving the conclusions of the regulator's assessment. This requirement does not apply to new installations on existing sites where the Control of Industrial Major Accident Hazard Regulations 1984<sup>16</sup> (CIMAH) applied, and there are in practice few completely new establishments. Existing plants can continue to operate, but the regulator's conclusions are influential, because of the power to prohibit operations.

78. As elsewhere, the regulator makes use of information from Safety Reports and notifications associated with lower tier sites to help target inspection activity.

## **Offshore**

### ***Background***

79. This regime aims to reduce the risks from all major accident hazards to people involved in activities on offshore installations, or in any activity connected with such installations. Along with requirements for pipelines safety outlined in the Pipeline Safety Regulations 1996<sup>17</sup>, the regime implements the central recommendations of Lord Cullen's inquiry into the Piper Alpha disaster<sup>1</sup>, in which 167 people died. These recommendations were themselves influenced by the CIMAH regulations<sup>16</sup>, which were then in force in relation to onshore major chemical hazard sites.

80. The Offshore Installations (Safety Case) Regulations 1992<sup>18</sup> are the corner stone of the regime. They are supported by:

- the Offshore Installations and Pipeline Works (Management and Administration) Regulations 1995 (MAR)<sup>19</sup>;
- the Offshore Installations (Prevention of Fire and Explosion, and Emergency Response) Regulations 1995 (PFEER)<sup>20</sup>;
- the Offshore Installations and Wells (Design and Construction etc.) Regulations 1996 (DCR)<sup>21</sup>.

81. These three sets of regulations underpin the safety case requirements. DCR and PFEER set out objectives relating to the integrity of offshore installations; prevention of loss of life from fire and explosion; and evacuation, escape, recovery and rescue if the need arises. MAR replaces earlier prescriptive legislation on the management of offshore installations, with more broadly based requirements setting out the objectives to be achieved.

82. The regime requires the owners and operators of installations to submit a case for safety to HSE. It is an offence to operate an installation without an accepted safety case. The safety case must demonstrate that:

- risks to people from all hazards with the potential to cause a major accident have been, or will be reduced ALARP;
- there is a safety management system in place that will, if implemented, ensure compliance with **all** relevant statutory provisions under HSWA.

### **Key features**

#### Documented case for safety

83. The safety case must address all hazards with the potential to cause a major accident. These are defined within the regulations as:

- fire, explosion, or the release of a dangerous substance involving death or serious personal injury;
- an event involving major damage to the structure of the installation or plant, including loss of stability;
- collision of a helicopter with the installation;
- life threatening diving incidents;
- any other event arising from a work activity involving death or serious personal injury to five or more people.

84. Within the regulations, a distinction is made between fixed installations and mobile installations. Requirements for fixed installations include:

- a design safety case submitted to HSE in sufficient time before completion of the design to ensure the duty holder is able to take account of HSE's comments (HSE acceptance is not required);
- an operational safety case to be accepted by HSE before specified operations start;
- an abandonment safety case to be accepted before abandonment (removal) of the installation.

Mobile installations must have an operational safety case accepted by HSE before moving into UK waters with the intention of operating there.

85. Where two or more installations are temporarily carrying out a combined operation, a combined operations safety case is required covering the risks from the joint activity. The operators of the installations have to agree a safety case, submit it to HSE and secure acceptance before the combined operations start.

86. Safety cases must demonstrate that measures have been, or will be taken, to reduce major accident risks ALARP, in respect of both design and operations. The duty holder must set out the assumptions underlying the ALARP demonstration, and provide a statement of performance standards against which the continuing effectiveness of the measures can be judged. There is no explicit requirement for diversity of protection measures.

87. The ALARP demonstration must use suitable and sufficient QRA in relation to the protection of people following an incident from the hazards of explosion, fire, heat, smoke, toxic gas or fumes, before and during their evacuation from the installation. This is the only regime where such a requirement is written into the legislation. In the nuclear regime the need for QRA is set out in the underpinning Safety Assessment Principles.

88. Schedules to the regulations define the information required in the various types of safety case. A similar approach is used onshore and for the railways. Published assessment principles<sup>22</sup> increase the transparency of the assessment process.

89. Once a safety case is accepted, duty holders must comply with it, and keep it up to date. They must revise operational safety cases every three years, and submit that revision to HSE for acceptance, irrespective of whether there have been any changes. If changes are needed in the meantime that will materially affect the case for safety, the duty holder has to resubmit the case and secure HSE acceptance in advance.

90. In developing and revising the safety cases, duty holders are required to consult elected work force safety representatives. The need for co-operation and communication between all those involved is enshrined in both the safety case regulations and in MAR.

#### Safety management systems

91. The regulations require a demonstration that duty holders' management systems ensure compliance with all relevant statutory provisions. Thus the management system must address all hazards (unlike the nuclear regime which is limited to nuclear-related hazards, and the onshore regime which is limited to major accident hazards).

92. When addressing major hazards, the duty holder must comply with the framework in DCR and PFEER relating to the integrity of the installation, prevention of loss of life from fire and explosion, and the provision of rescue and recovery arrangements. The requirements cover, amongst other things, roles and responsibilities and the associated training needs. Like the safety case requirements, DCR, PFEER and MAR place the management duties on the operator or owner of the installation, irrespective of who actually does the work that creates the risk. MAR requires the duty holder to provide operational instructions, procedures and permits to work.

93. The regulations explicitly require arrangements for audit. Unlike the other regimes, the duty to investigate incidents remains implicit. However, regulation 9 of DCR requires duty holders to report to HSE any significant threat to the integrity of an installation, and any action taken or planned to avert it.

94. The offshore regime is unique among the 'permissioning' regimes considered in explicitly requiring a written scheme for the independent verification of all safety critical elements. Safety critical elements are those parts of the installation whose failure could cause or contribute substantially to a major accident, or which are intended to prevent or limit the effect of a major accident. The identification of an item as safety critical should follow from work to identify major accident hazards. The verification requirement and its focus on hardware has its origins in earlier certification requirements, which, in the wake of Piper Alpha, were felt to blur responsibilities and fail properly to involve the duty holder. The current arrangements place responsibility for the effective running of the regime fairly and squarely on the duty holder, and are designed to ensure that the integrity of safety critical elements is maintained, following their identification.

#### Safety regulator involvement

95. The offshore regime is the only 'permissioning' regime within the scope of this study where there is a legal requirement for HSE acceptance of the documented case for safety and the associated demonstration of ALARP, before operations can start (though nuclear installations may not operate without a licence). Acceptance means that HSE is satisfied with the case made for health and safety within the document. HSE accepts operational safety cases, abandonment safety cases, and combined operations safety cases. HSE notifies the duty holder about matters which have arisen during its assessment of a design safety case and in turn is notified by the duty holder before certain activities take place.

These formal interactions enhance confidence in the robustness of the duty holder's risk control measures.

96. Under the regulations, as well as securing acceptance of the safety case, duty holders must notify HSE before starting specified well operations and construction activities, and when entering or leaving UK waters.

## **Railways**

### ***Background***

97. The origins of the current system stem from the privatisation of British Rail. The subsequent entry of new operators into the railway industry, and the division of control between different companies, created the potential for introducing new and inadequately controlled risks onto the system. HSC was asked to examine the health and safety implications. In January 1993 it published, jointly with the Department of Transport, its report *Ensuring Safety on Britain's Railways*<sup>2</sup>. This concluded that new regulations would be necessary to safeguard existing standards of safety. The report's recommendations were accepted in full by Government, and implemented by three new sets of regulations:

- Railways (Safety Case) Regulations 1994<sup>23</sup>;
- Railways (Safety Critical Work) Regulations 1994 (SI 1994/299) (RSCW);
- Carriage of Dangerous Goods by Rail Regulations 1994 (now superseded by the Carriage of Dangerous Goods by Rail Regulations 1996 (SI1996/89)).

98. At the same time, the system for approving railway schemes was revised, resulting in the Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994<sup>25</sup> (ROTS). This chapter concentrates on the safety case requirements. Chapter 4 discusses ROTs in more detail.

99. The three sets of regulations were put in place to maintain the safety 'status quo' following privatisation, not as a direct result of a public inquiry or a high consequence incident, as was the case for the other regimes considered in this study. More recently however, as a direct result of the Southall and Ladbrooke Grove accidents, HSC has proposed changes to the Railway (Safety Case) Regulations 1994. Following wide public consultation<sup>4</sup>, HSC has now submitted proposals to Ministers in the form of draft Railways (Safety Case) Regulations 2000 (the proposed Regulations), which should be in force by the end of the year, and will replace the 1994 Regulations. As drafted, the proposed Regulations will introduce a number of significant changes to the regime, which are covered in the following paragraphs.

### ***Key features***

#### Documented case for safety

100. The Railway Safety Case Regulations (1994) (the 1994 Regulations), require duty holders (infrastructure controllers, train operators and station operators) to:

- address all significant hazards;
- demonstrate how their safety management systems ensure compliance with all relevant statutory provisions;
- address specific aspects of safety management within that demonstration;
- summarise the significant findings of risk assessments made under Regulation 3 of the Management Regulations;

- summarise the arrangements made to prevent and protect against risks under Regulation 4 of the Management Regulations (unlike other regimes, there is no specific requirement for a demonstration that the arrangements will secure adequate control of risks).

101. The proposed Regulations will enhance the risk assessment requirements, in particular by requiring the safety case to include a description of the risk assessment process followed, the method of calculation used, and the assumptions made. They will also strengthen the provisions by requiring the identification of further risk reduction measures and an associated safety case improvement plan.

102. Duty holders cannot operate without an accepted safety case; once accepted they must conform to it and keep it up to date. Before introducing a change which makes a material difference, duty holders must, in consultation with the safety representatives and safety committees, revise the safety case and submit it for re-acceptance. Every three years they must thoroughly review the safety case, and send a report to the accepting body.

103. The 1994 Regulations put in place a 'cascade' system of safety case acceptance. HSE accepts the railway infrastructure controllers' safety cases, and the railway infrastructure controllers accept the safety cases of the station and train operators in relation to risks imported to the network. The infrastructure controller has a responsibility to ensure that each operator's safety case can be implemented without creating risks to other operators. Duty holders (including the infrastructure controller) are required to work within the requirements of their safety case to ensure that these interfaces are managed.

104. The proposed Regulations put forward a system of HSE acceptance of all safety cases, following independent scrutiny by an assessment body and, in the case of train and station operators, infrastructure controller scrutiny as well. The proposed Regulations introduce new duties on infrastructure controllers to report to HSE situations where operators are not complying with either their safety case, or with reasonable safety requests made by the infrastructure controller, if such non-compliance affects the network.

105. The proposed Regulations should improve transparency by:

- introducing an independent appeal mechanism following non-acceptance;
- requiring duty holders to make their accepted safety cases publicly available.

### Safety management systems

106. Under the 1994 Regulations the safety case must cover:

- the health and safety objectives;
- arrangements for communicating information;
- cooperation with other duty holders;
- consultation with employees;
- arrangements for ensuring the competence of staff;
- procedures or arrangements relating to operations or maintenance;
- investigating accidents and incidents;
- audit;

- the management of contractors;
- design and procurement;
- emergency response.

107. The requirement for an explicit description of the procedures for design and procurement of premises and plant is unique amongst the regimes examined. It complements the requirements for approval of schemes under ROTS, and enables HSE and the infrastructure controller to evaluate the design process, and to ensure that sufficient regard is given to health and safety.

108. The 1994 Regulations require duty holders to describe procedures for handling incidents and emergencies. The testing of those procedures is mentioned in the associated guidance, as is the need to define emergency roles and responsibilities and provide the necessary training. New requirements in the proposed Regulations relating to the provision of equipment and arrangements for the evacuation of trains reflect recommendations made by Professor Uff following the Southall train accident<sup>30</sup>, which were reinforced by the experience of the Ladbroke Grove accident.

109. External non-regulator involvement in aspects of health and safety management or hardware is not specifically required in the 1994 Regulations, except insofar as the infrastructure controller accepts safety cases. The proposed Regulations introduce such involvement by requiring independent non-regulator assessment of safety cases before submission to HSE, and annual independent non-regulator audit of operations. These are to be carried out by an assessment body (a term defined within the Regulations).

#### Safety regulator involvement

110. HSE's involvement under the 1994 Regulations is built on its acceptance of safety cases submitted by infrastructure controllers, including those that are also operators of trains and stations. Re-submission is not required, unless there is a material change, but HSE also receives information in the form of the reports on duty holders' periodic safety case reviews. Once it has accepted a safety case, HSE's leverage stems from the standard powers under the HSWA and through ROTS approvals (Chapter 4).

111. Under ROTS, works capable of materially affecting safe operation require HSE approval. Formal approval can only be given once the work is complete. HSE can grant exemptions and attach conditions to those exemptions. Under RSCW, HSE has the power to approve schemes for the assessment of staff in safety critical jobs.

112. The proposed Regulations will provide HSE with additional levers:

- HSE will accept all safety cases, and have the power to require changes to an accepted case;
- HSE will for the first time receive a copy of reports of audits; it will also receive from infrastructure controllers reports of situations where train and station operators have not complied with either their safety case, or with the controller's reasonable safety requests.

113. A number of the regimes examined, including railways, explicitly require a description of the arrangements for producing, implementing and reviewing safety management systems. The information, and the increased emphasis in the proposed Regulations on the requirements for arrangements as opposed to procedures, should assist HSE in determining whether or not the duty holders are and will remain capable of discharging their duties.

## Questions

In relation to the principles, and to any or all of the regimes covered in Chapter 3, HSE would welcome your views on:

- Q 9 - whether the description of the key features matches your understanding of them;
- Q 10 - the extent to which the differences between the 'permissioning' regimes are necessary and appropriate;
- Q 11 - the role and value of external non-regulator scrutiny in a 'permissioning' regime (for example, as set out in paragraph 94).

## PART II

### CHAPTER 4: INITIAL INTEGRITY ON RAILWAYS

#### Safety by design

114. The Health and Safety at Work etc Act 1974 (HSWA) requires the design of articles to eliminate or minimise risks to health or safety. Such an approach offers a powerful and cost effective means of improving safety. Problems identified at the drawing board can be swiftly remedied, but the further a design develops, the harder it becomes to make changes. Initial integrity goes further in looking also at proper construction, installation and commissioning. All the regimes considered in this document pay attention to initial integrity, as well as to operational safety. However, the degree of direct safety regulator involvement varies.

115. As discussed in relation to the fundamental principles of 'permissioning' regimes, society's views must be taken into account in judging the correct balance of safety regulator involvement, and the involvement of the safety regulator should give society an added level of confidence that duty holders are capable of discharging their legal responsibilities. Because of the implications for huge numbers of members of the public, society has required greater safety regulator involvement in the railway system than in some other high hazard industries. The points set out below suggest some approaches which might develop from existing safety regulator involvement, without diluting the duty holder's responsibility to ensure safety. Some suggestions for alternatives to the current regime follow, and HSE invites your views on approaches to modifying the railway approvals system.

#### Railway approvals

##### *Current system*

116. The original purpose of Her Majesty's Railway Inspectorate (HMRI) was to recommend to Government whether to approve the taking into use of new railways, '*To prevent wild and visionary schemes being tried out on the public at great risk to life and limb*'. (George Stevenson 1839). Since Victorian times, HMRI has issued written standards on most aspects of railway construction in 'the Requirements' (now *Railway Safety Principles and Guidance*<sup>24</sup>), and assessed stated compliance against them. The legislation has evolved over the decades. The Railways and Other Transport Systems (Approvals of Works, Plant and Equipment) Regulations 1994<sup>25</sup> (ROTS) consolidated the position and extended approval to rolling stock. Under ROTS, HSE approval is required before taking into use new or altered works which are capable of materially affecting the safe operation of a relevant transport system (subject to certain exemptions for minor works).

117. The Railway (Safety Case) Regulations 1994<sup>23</sup> require railway undertakings to produce a safety case covering all aspects of their operation. The safety case must state the procedures to be adopted to ensure that all works, plant and equipment are properly designed, constructed, installed and used safely. It must also describe the technical specifications, and procedures or arrangements relating to operations or maintenance. Although the safety case sets out essential underpinning systems, its acceptance does not remove the requirement to submit works for approval. While more is being done to integrate the two approaches better operationally, the current safety case legislation seems to offer adequate scope to do this and it would be possible to make better use of the existing link, rather than to rewrite it.

118. It might be argued that sufficient safety regulator involvement could be secured through the Safety Case Regulations, or by relying on duty holders to self-regulate their approach to new works on the basis of the arrangements set out in their safety case.

However, public reassurance is generally improved by the safety regulator acting as a counterbalance to commercial interests; more direct involvement, with the additional leverage it provides, may be appropriate at a time when many new firms have entered the railway industry, and a strong safety culture has yet to emerge.

### ***Reasons for change***

119. A number of factors currently point to a need to consider changes to the approvals system. In the broad European context, two Directives on High Speed Trains and Conventional Interoperability<sup>26,27</sup> have recently been agreed. They seek to establish common technical and operating standards throughout the European network to allow through running of trains. The Directives create eight categories of sub-systems, such as infrastructure, signalling and rolling stock, and set out a number of 'Essential Requirements' for each. They require a Notified Body to be involved at every stage of the development of a sub-system, including final certification that it meets the relevant specifications and standards. They also require Member States to authorise sub-systems to come into service on the basis of information from an approved Notified Body anywhere in the EU. Member States are to ensure that the Notified Bodies do their job properly through the use of conformity assessment, and can withdraw authorisation to act as a Notified Body.

120. Similar consequences arise from other European legislation. Implementation of the Cableways Directive will disapply the ROTS requirement to approve new funicular railways, and transfer the responsibility for ensuring that the new system is safe to operate to an appointed Notified Body. The implementing regulations will also be used to disapply the ROTS requirement for HSE approval of new lifts installed on railway premises, as under the Lifts Regulations 1997, similar Notified Body arrangements will apply.

121. These Directives will affect HSE's statutory role in the approvals regime, since HSE, as a government body, cannot become a Notified Body. The governments' part in the process is to authorise the placing in service of sub-systems in their territories, and to monitor the work of the Notified Bodies. They cannot play a dual role of authorisation and supervision. However, there remains a critical role for the safety regulator to oversee the way that duty holders manage the interfaces between sub-systems, and to ensure that they are capable of discharging their legal responsibilities in this and other respects. At the moment, the full practical effect of the Directives is difficult to predict.

122. Even without the changing international picture, an internal inquiry by HSE following the Ladbroke Grove accident in 1999<sup>28</sup> pointed to the increasing and unanticipated level of demand for approvals following privatisation, and to difficulties in dealing with these. There are a number of additional reasons for considering change, including:

- unease about the long timescales involved in major projects, during which the operator can continue to use the system, without notifying HSE and without approval;
- doubts about whether the regime is appropriate for an industry that is now heavily fragmented, and where confidence in the ability of industry to self-regulate is low;
- the need to examine the clarity, strength and fit of the links between the approvals system and the safety case;
- a need for more flexibility in prioritising HSE's work, so as to focus its technical expertise where it will add most value;

- possible misunderstanding by some stakeholders about HSE's role, and about the fact that approval by the safety regulator does not diminish the fundamental responsibility of the duty holder.

123. In her evidence to Part 1 of the Ladbroke Grove Inquiry, HSE's Director General explained that HSE was considering options for bringing the approvals regime more into line with other high hazard industries. Suggestions made at that time included:

- categorisation of works according to risk;
- removal of approval by the safety regulator in low risk areas; and
- third party verification against codified standards by accredited bodies.

124. There are constraints on change which need to be taken into account. Any suggestions need to fit with the regulatory structures imposed by privatisation, such as the respective roles of the Rail Regulator, the infrastructure controllers and the Train Operating Companies. Some of these structures are still developing. For example, the role of Railway Safety, as an independent body responsible for safety issues within the Railtrack Group, needs to be established in practice before HSE can give proper consideration to how any changes to the approvals mechanism might integrate with its work.

125. Much of the focus of the second part of Lord Cullen's Inquiry will also consider the appropriateness of the current regulatory structures, and HSE would not wish to pre-empt his recommendations. Some initial ideas are set out for discussion in this document but firm proposals, for example on amendments to regulations, will not be made until Lord Cullen has given his views and HSC has considered the way forward.

HSE would welcome your views on:

- Q12 - the extent to which a system of approvals is still relevant to the regulation of the railway industry, where safety cases are now an established procedure. If it is, how should it be delivered?
- Q 13 - how the development of Notified Bodies will affect the approvals regime, and what the role of the safety regulator should be.

### **Issues for discussion**

126. Many elements discussed below reflect current best practice, but it is arguable that formalising them by changes to the legislative framework, supported by a mixture of Approved Code of Practice and guidance would clarify responsibilities, aid transparency, streamline the system and strengthen HSE's powers and focus.

127. Rather than offering any firm view, the rest of this Chapter addresses how things might develop, if an approvals regime were to continue. Particular points on which HSE would like your views relate to:

- non-regulator external assessment of proposals;
- the scope of plans for new or altered works;
- improving the prioritisation of approvals;
- operation before final approval;
- achieving improvements after approval;
- safety regulator powers;

- clarifying responsibilities.

Each of these areas is considered in more detail below.

### ***Non-regulator external assessment of proposals***

128. Principle 2 makes clear that systems set up under 'permissioning' regimes should be sufficiently robust to operate effectively without the safety regulator's involvement. There is a danger that current arrangements for the railways could lead duty holders to rely on HSE to spot flaws in their proposals. To address this, some of the other 'permissioning' regimes require external non-regulator scrutiny of safety critical activities, processes or hardware.

129. Each railway undertaking is already required to set out as part of its safety case the standards it will apply. Applications for approvals state which standards are to be met, with any proposed deviations notified and explained. The proposer's own procedures for checking the initial integrity of the proposed works against these standards should also be spelt out in the safety case and, in future, might usefully place a greater emphasis on external assessment. Proposed revisions to the 1994 Safety Case Regulations already include an increased use of external scrutiny in relation to safety cases and the audit of operations. It is worth considering whether Railway Safety, an independent body responsible for safety issues within the Railtrack Group, might, in future, perform this type of verification role for railway works and equipment as well.

130. HSC's general policy statement on conformity assessment states that HSE should place increasing reliance on conformity assessment schemes, referring back to standards, and overseen by an external body. This is entirely in line with developments coming from Europe. Making greater use of external assessment in the railway approvals context would help to emphasise that HSE approves systems, not the detail of all individual applications. It would provide an added layer of safety assurance, although the true effectiveness of risk control measures depends on their day to day implementation.

131. The question of standards raises a more general issue about who should be responsible for drafting and promoting them. HSE's role has been to facilitate this, and to comment on any new standards put forward. However, the major impetus lies with the industry, which has proved slow to come to common agreement about standards, or indeed about a proper forum for discussing them. As mentioned in the HSE Director General's evidence to Part 1 of Lord Cullen's Inquiry, this lack of progress on agreeing standards has significantly increased HSE's burden and skewed resourcing, which was based on an assumption of greater progress.

132. Professor Uff<sup>30</sup> has recommended the creation of cross-industry Systems Authorities to oversee the development and implementation of new technologies. The Strategic Rail Authority will take this forward. Notwithstanding, there may be merit in requiring the Plans for complex and multi-faceted schemes to include the use of System Authorities as part of the process of overseeing the safety aspects.

Q 14 - HSE would welcome your views on the role of external non-regulatory scrutiny in all proposals for works on the railway, and on the place for conformity assessment schemes.

### ***The scope of plans for new or altered works***

133. As discussed under principle 2 in the first part of this document, duty holders in 'permissioning' regimes need to identify hazards and develop control measures that cover design, hardware, systems, procedures and human factors as a coherent whole. This includes modification controls for minor changes as well as for major ones, since even an apparently trivial change can have significant effects. Operators acknowledge and generally

take account of this, but some serious accidents have occurred because a procedural point has been overlooked.

134. In the light of this, requirements for an application for approval might be extended to provide a better documented demonstration that all aspects of the proposed change which might affect the safety case had been considered, including any effects on equipment already in place. As a working title, to distinguish it from the existing system, the following paragraphs refer to such an application as a works safety plan (Plan). The choice of term is to emphasise that it is the overall plan that would be scrutinised, rather than just the equipment it covered.

135. Schedule 2 of ROTS sets out the documentation currently submitted to HSE, which includes a certificate of compliance signed by the applicant. The certificate must list details of the relevant 'Requirements' and standards to be met, and explain all proposed deviations. There seems no particular need to alter this aspect of the existing approach. However, the Plan might usefully be extended to provide a coherent overview of the implementation of all health and safety aspects of the project, giving particular attention to:

- identifying the new hazards introduced by the change, and the process of change, assessing the risks and proposing control measures to satisfy all relevant statutory provisions under HSWA;
- how the duty holder proposes to operate safely during and after completion of works in respect of risks to both the public and the workers, including those carrying out the works;
- standards relating to human factors (including competencies needed), management systems, testing and commissioning, as well as hardware;
- demonstrating that equipment, particularly novel equipment, is safe, suitable for the proposed application and compatible with existing layout/equipment;
- future maintenance and inspection procedures, with the initial design explicitly considering arrangements for maintenance, for example, safe access;
- procedures to check the standard of the work being carried out;
- procedures to commission and test the safety and viability of the new works once installed.

136. Much of this would merely require the documentation of present good practice, but there would arguably be benefits in such a plan, with milestones setting out what was to be achieved at each stage, and the sequence in which the work was to be carried out. From the duty-holder's perspective, consideration of all the relevant factors together might provide a better management tool. And while it might not be possible to think through all aspects at the outset, such an approach would enable both duty holder and safety regulator to spot gaps and influence change before details were fixed.

Q 15 - HSE would welcome your views on:

- extending the contents of the application;
- requiring it in the form of a written plan;
- the elements that should be included in such a plan.

### ***Improving the prioritisation of approvals***

137. The level of investment in the railway industry post-privatisation has exceeded expectations. HSE's specialist railway resources are insufficient to assess all submissions to the same level of detail, nor is this necessary to achieve safety objectives. There is an

opportunity cost if too many specialist staff are involved with the approvals system, rather than other important work, such as investigation and inspection.

138. One possible way of improving the position would be to formalise and increase the transparency of the approach to prioritisation which HSE currently uses to manage the approvals system, so as to better focus expertise where it is most required. This might be achieved by introducing a requirement to classify schemes into two or three risk categories, perhaps along the lines of:

- Category 1: major or novel works, with a high consequence potential, where Plans might be submitted in advance and subject to HSE consent before work could start;
- Category 2: lesser, non routine works notified to HSE before commencement and subject to selective scrutiny;
- Category 3: routine works where the risks and control measures are well known, and the Plans might be logged by the company so that HSE could inspect them selectively after completion.

139. The key to the effectiveness of such an approach in helping target resources on areas of most significant risk would lie in the definition of the categories. Descriptions of the types of works to be included in each of the categories would probably best be given in guidance. To an extent a categorisation system already exists, in the distinction made between major and minor works set out in the *Guide to the approval of railway works, plant and equipment*<sup>29</sup>, and this could be considered as a starting point. One option might be to equate Category 3 with minor works as defined in current guidance and then to subdivide the current definition of major works between Categories 1 and 2. However, it might be arguable whether the differences in handling a second and third category justified making the distinction between them at all.

140. It might also be possible to define categories by using totally new 'goal-setting' definitions. For example, Category 1 might cover major or novel works:

- with the potential to cause derailment;
- with the potential to bring two trains into conflict;
- involving any use of technology for which adequate standards were not available against which to demonstrate compliance.

141. Unlike the railways, some non-railway transport systems, such as trams, may be self-contained and run by just one operator. One option might be that in such circumstances some applications could be put into Category 2 or 3, on the grounds that they would be intrinsically less risky, because they involved fewer organisational interfaces. In such cases greater reliance might be placed on the appropriate use of external non-regulator assessment specified as part of the Plan.

142. Operators would be required to complete a full plan for all categories, but to routinely submit to HSE only those for Category 1. The complexity of the plans would be related to the nature of the work. HSE would have the right to examine any proposal in Category 2 or 3 and to use powers under HSWA if the examination showed deficiencies in the works, the Plan, or in application of the categorisation procedures set out in the safety case.

143. Safety cases would need to include arrangements to ensure that schemes were allocated to the proper category. Part of HMRI's auditing function in relation to the lower categories would be to check that allocation procedures had been appropriately followed.

This aspect could also be explored as part of a routine inspection to examine the operation of the safety case.

144. ROTS currently allows individual and general exemptions to be issued, and such flexibility would probably still be needed. As at present, like for like replacements and emergency works (for example points failures or broken rails on a heavily used commuter line) would fall outside the categorisation scheme, and be covered under the normal safety case procedures.

Q 16 - HSE would welcome your views on a prioritisation approach using 2 or 3 categories and what it might be appropriate to include in the definition of each.

### ***Operation before final approval***

145. Currently works may legally continue in operation for years under ROTS 4(4)(a), without 'approval', often because quite insignificant items remain outstanding. This is largely because approval cannot be given until the works are complete, and conditional approval is not allowed. The original purpose of this provision (Annex 2) was to prevent unnecessary disruption to services during staged works. Duty holders still need to comply with the general duties of the HSWA to ensure safety of these unapproved workings. However, there is some unease over the current extensive use of ROTS 4 (4) (a) by the industry. Questions have been asked about whether members of the public should be conveyed on new or altered works before approval. This section considers ways of tackling the issue.

146. Many large schemes are carried out in stages over a long period of time. The current guidance suggests that where this is over 18 months, some milestones should be agreed with HSE. There might be advantages to formalising this process for any major works which are complex or where staging is required, regardless of duration. In their Plans duty holders could propose to HSE suitable stages that might be given individual sign off, in advance of completion of whole scheme. Such stages could be defined geographically, or by a particular aspect e.g. completion of all electrical wiring, or issue of all operational manuals. Depending on the nature of the project, the signing off of a particular stage might be required before the next was started. Such sequencing would need to form part of the Plan, and be subject to mutual agreement between the proposer and the safety regulator. However, in all of this HSE would not wish to cause unnecessary inconvenience to the public and some sort of more restricted exemption provision, or conditional consent might be required to keep the railways working.

147. As a variation to this approach, which is essentially based around the idea of hold points, a consent system might be developed with 3 main stages:

- design consent - ie agreement that the new works proposed meet all relevant safety standards;
- consent to continue operating during the works, given on receipt of a satisfactory Plan - ie agreement that the proposer's implementation plan was acceptable;
- final consent - at the end of the project the proposer would inform HSE that the project had been completed according to plan (or, as now, explaining any deviations from the original plan) and seek removal of any special conditions that had applied during the works.

Q 17 - HSE would welcome your views on the need to introduce additional controls on operators before final approval, and how this might best be achieved.

### ***Achieving improvements after approval***

148. In the report on the Southall Inquiry<sup>30</sup>, Professor Uff expressed concern about how to secure improvements in existing rolling stock. Although other health and safety powers could be exercised, under the current approvals legislation HSE has no power to require upgrading of any schemes already approved. However, as described in Chapter 3, the proposed Railways (Safety Case) Regulations 2000 will require the identification of measures to improve safety, and where those measures are reasonably practicable, a plan to ensure their timely implementation. This development in the safety case framework should address the issue.

### ***Safety regulator powers***

149. The approach to the approval system as an on-going process of negotiation, with the sole power being denial of final approval might have been sufficient when the relationship was largely confined to one 'customer': with the diversity of players post-privatisation, this no longer holds good. The interfaces are more complex and there is a greater need for the commitments given to be recorded, so that they can be tracked and pursued.

150. The licence conditions imposed by the Rail Regulator require the operator to have an accepted safety case and to meet its terms. The Rail Regulator has the power to revoke the licence for serious breaches of the Safety Case Regulations, or to take enforcement action for non-compliance. HSE and the Rail Regulator exchange information on breaches of safety cases. However, there is scope to strengthen the link between safety and permission to operate. For example, HSE's 'approval' could be expressed as a consent for the relevant works to continue in operation during a period of change, or consent for new works to be brought into use. This might logically also involve a power for HSE to withdraw such consent. Of course any such power would have to be subject an appeal mechanism in the usual way.

151. Many operators already recognise the benefit of involving the safety regulator at the drawing board stage. However, for major and novel works with high consequence potential (ie those in Category 1 as defined), there might be benefits in a legal requirement to enable HSE to examine the design before the operator made any irrevocable decisions, for example signing a construction contract, or booking a tunnel boring machine. The purpose of such an examination would be for HSE to look at design feasibility and to point out where initial proposals would not be adequate to meet the relevant standards; the full details of the implementation plan would not be needed. The responsibility to develop the design would need to remain squarely with the duty holder. To add value, such early safety regulator involvement would take place before aspects of the design had been fixed by Notified Body certification. The next natural point for requiring HSE involvement would normally be when the Plan was put forward. At this stage subsequent referral to HSE could be discussed, for example in the context of any arrangements for staged approval or consent.

152. Under the current regulations, operators may suggest operational limitations in their applications for approval. However, there is arguably no statutory mechanism for HSE to apply such conditions. Although HSE does not give approval until any limitations offered are satisfactory, this approval comes right at the end of the process. It would be more straightforward if HSE were given the power to apply conditions for the duration of works, and to impose operational limitations on the eventual running of the works, where necessary to ensure the safety of either the public or workers. This might be used, for example, if schemes had not been completed to the criteria set out in the Plan. To emphasise the responsibility of duty holders for safety, the onus could remain with them to propose limitations to the safety regulator in the first instance. Such powers might encourage operators to plan works more realistically, reduce delays and to complete them expeditiously, so that the additional dangers introduced by the process of change itself could be minimised.

153. A new duty on the operator to notify HSE if proposed works were to be subject to significant delay or cancellation after a submission had been given initial consent, would also help avoid taking up scarce HSE specialist resource with unnecessary work.

HSE would welcome your views on:

- Q 18 - turning approvals into a consent regime as outlined;
- Q 19 - introducing a safety regulator scrutiny point at the design stage for major works, before the detailed development of the Plan, and whether this should be statutory or voluntary;
- Q 20 - enabling HSE to impose conditions on the operator either during or following the completion of the works;
- Q 21 - placing a duty on operators to notify the safety regulator if works were significantly delayed or cancelled.

### **Clarifying responsibilities**

154. As set out in Part I of this document, the keystone of health and safety law is clear responsibility placed on the organisation which creates the risks (principle 2). Some of the secondary legislation may have clouded understanding of this fundamental principle in the railway industry.

155. There has been some uncertainty over who was responsible for what under the 'cascade' model for safety cases. Proposals to address this are to be taken forward in revised regulations through changes to the cascade arrangements, and through the requirements for monitoring and independent audit. In respect of railway approvals there has also been some misunderstanding about HSE's role in the system. This is not helped by the terminology itself: some might understand the term *approval* to mean that HSE has conducted a thorough and detailed assessment of each and every design, and given a favourable opinion that it represents a good standard of health and safety.

156. In fact under the current approvals legislation, HSE is not responsible for approving the equipment but rather **its first bringing into use**. HSE's consideration is limited to *works, plant or equipment which are capable of materially affecting the safe operation of a relevant transport system*. HSE's approval currently means that, insofar as it has examined the application (and this scrutiny may be selective), it sees nothing to object to in the proposal. However, in line with principle 2, the overriding legal duty to ensure that the undertaking is safe lies squarely with the operator, whose own scrutiny system should be sufficiently robust to operate safely without the HSE's involvement. The approvals system might benefit from increased clarity about who has the primary responsibility. Given the increasing trend for putting together partnerships to develop schemes, this could be developed to require clear allocation of responsibilities in the case of such arrangements.

157. The perception of HMRI's approval function as covering every nut and bolt is misinformed but hard to correct. The possible changes to the system explored in this Chapter might make the term *consent to operate* more appropriate. Other suitable terms might be *scrutiny* or *audit*, to reflect that consideration of the proposal by the safety regulator does not diminish the fundamental responsibility of the duty holder.

Q 22 - HSE would welcome your views on whether there is a need for a more explicit statement of where the primary duty lies.

### **Level crossings**

158. Level crossings are subject to approval, but the underpinning legislation is complex, as each crossing is generally the subject of an individual variation to an Act of Parliament. While final approval of works on crossings should remain subject to whatever regime emerges as suitable for other parts of the network, it is suggested that more detailed consideration of this area be deferred, as its complex legislative basis would significantly complicate and delay progress on the whole issue. At a later stage HSE might explore whether all the various legislative elements relating to level crossings could be consolidated into one set of regulations, and whether this could be more visibly aligned with the generally applicable processes.

## **Costs**

159. The public interest in railways is unique, since as well as a desire for a safe system there is also a requirement for it to be efficient, economic and effective. While HSE's primary concern is with the integrity and safety of the system, it does not wish to inhibit investment which could in itself bring safety benefits through modernisation of equipment or procedures.

160. Government bodies are required to prepare a regulatory impact assessment as part of any proposal to make or amend regulations. This must consider the balance of benefits and costs, other possible impacts and the appropriateness of the measures proposed. It is recognised that some of the developments outlined in this Chapter, such as seeking external non-regulator scrutiny would have costs, but some of these might be offset by reduced chargeable time being taken by HSE to assess the proposal. The selection of what types of works are to be included in Category 1 might similarly have a significant effect on costs.

Q 23 - HSE would be grateful for any information you wish to provide on the economic impact of the various discussion points set out in Chapter 4.

## PART III

### CHAPTER 5 - WHAT HAPPENS NEXT

#### 'Permissioning' regimes

161. This document has set out what HSE believes to be:

- the principles which underlie current 'permissioning' regimes; and
- the features which distinguish them from the generality of health and safety regulation.

The document distils thinking from within HSE to explain the current position and raise some regulatory issues in an area where policy has developed over time. The aim is to increase transparency and stimulate discussion.

162. It is intended that this publication and the subsequent discussion will provide a firm basis for HSC to consider future policy in relation to 'permissioning' and to review and develop existing provisions as necessary. Your comments on any aspect of the issues would be welcome.

#### Railway approvals

163. It is possible that the Joint Inquiry under Professor Uff and Lord Cullen, and the second part of the Ladbroke Grove Inquiry will make recommendations relating to the railways approvals system. It would be inappropriate to pre-empt those recommendations. For this reason HSE is seeking views through this document, rather than proceeding with the development of firm proposals. The response to this publication will provide HSE with current and broad-based information on the views of stakeholders when advising HSC how to take forward whatever suggestions the Ladbroke Grove Inquiry makes. Any subsequent proposals for legislative change would be subject to full consultation and regulatory impact assessment.

164. While HSE welcomes general comments on the structure and operation of the railways approvals system, and on the suggestions made in Chapter 4, **it cannot accept any specific observations in relation to the Ladbroke Grove accident**, since that is strictly the province of the Inquiry.

165. Comments are invited on the principles and on railway approvals. Views received by 1 December 2000 may be fed into the Ladbroke Grove Inquiry. Annex 6 explains how you can make your comments.



## List of Annexes

- 1 'Permissioning' legal requirements: comparative summary table
- 2 Legal requirements - some key points
- 3 Risk related terms
- 4 Abbreviations used in this publication
- 5 References
- 6 Invitation to comment and response form

**‘Permissioning’ legal requirements: a comparative summary**

**Legal requirements over and above the general provisions for the nuclear, onshore major chemical hazard, offshore oil and gas and railway industries: a summary of how they relate to the principles of ‘permissioning’ regimes.**

**Principle 1:** ....‘permissioning’ regimes are applied to high hazard industries, about which society has particular concerns.....

Key feature	Nuclear	Onshore	Offshore	Railways
- Applies to	All nuclear related hazards on licensed sites.	Major accident hazards from sites holding quantities of specified substances. Duties depend on whether quantities cross initial or higher threshold.	All hazards with the potential to cause a major accident. (as defined in regulations). Management arrangements relate to all relevant statutory provisions.	All significant hazards.
- Duty holder	Licensee.	Site operator.	Operator or owner.	Infrastructure controller, train operator and or station operator.

40

**Principle 2:** The legal duty to manage risks lies with the organisations that create the risks - ‘permissioning’ regimes require them to describe how....

Key feature	Nuclear	Onshore	Offshore	Railways
- Documented case for safety	Operations must be justified by an adequate & current safety case, which is extensive in scope and depth. ALARP demonstration part of adequacy judgement. Aspects of management arrangements approved by safety regulator. Requirements for periodic review of safety case. Review of arrangements for compliance as part of adequate Quality Assurance arrangements. Documentation showing how licensee complies with licence conditions provides overview.	Top tier sites require Safety Report demonstrating all necessary measures have been taken, including MAPP, describing how duty holder will deal with major hazards. Reports submitted for conclusions to be drawn. Prohibition if serious deficiencies in measures. Must revise Reports in light of new information & review 5 yearly. Must ensure reflect current conditions & inform HSE of revision. Must keep MAPP up to date. Lower tier sites prepare only MAPP, which is not submitted.	Safety case must demonstrate major accident risks evaluated & that measures have been, or will be taken to reduce these ALARP, including QRA for specified major accident hazards. Must submit for acceptance. Must conform to the accepted case. Must keep it up to date & review every 3 years. Must submit for re-acceptance every 3 years & in advance of material change.	Safety case to summarise significant findings of risk assessment & measures taken to prevent & protect against risks. Must submit for acceptance. Must conform to accepted case. Must keep up to date & review every 3 years. Where revision materially different must submit for re-acceptance. Draft Railways (Safety Case) Regulations 2000 (R2000) require a safety case development plan, to include proposals for improving safety case and measures in place.

**Principle 3:** .....within a goal-setting context, 'permissioning' regimes prescribe elements of the management arrangements required....

Key feature	Nuclear	Onshore	Offshore	Railways
- Arrangements for producing, implementing & reviewing safety management systems (SMS)	Implicit. Spectrum of LCs require adequate arrangements, including arrangements for quality assurance of SMS. Safety management prospectus examined before licence granted.	Explicit. SMS must include the part of the general management system relevant for determining & implementing MAPP.	Implicit. Need to demonstrate system is adequate to ensure compliance.	Explicit. 1994 Regs require demonstration of adequate organisation for carrying out policy. Guidance states safety case to indicate how satisfactory design, implementation & monitoring of SMS will be achieved. R2000 will require description of arrangements for : <ul style="list-style-type: none"> <li>• setting objectives;</li> <li>• measuring, reviewing &amp; auditing health &amp; safety performance;</li> <li>• policy implementation;</li> <li>• provision of emergency equipment &amp; arrangements for train evacuation.</li> </ul>
- Aims & principles	Implicit.	Explicit. MAPP to include aim & principles for control of major accident hazards.	Implicit.	Explicit. Policy to include the health & safety objectives.
- Hazard identification & risk assessment arrangements	Explicit. Arrangements required as part of justification of design, construction, manufacture, commissioning, operation & decommissioning.	Explicit. Arrangements for adoption & implementation of procedures for systematically identifying major hazards & for assessment of likelihood & severity.	Implicit. Need to demonstrate system is adequate to ensure compliance.	Implicit. 1994 Regulations require demonstration management system adequate to ensure compliance. R2000 will require process & method used & assumptions made.
- Management of change	Explicit requirement to manage hardware & organisational change.	Explicit requirement to manage hardware & organisational change.	Implicit	Implicit
- Design	Conditions explicitly require justification of the safety of proposed design. NII require preliminary design safety report containing adequate arrangements for the design process, including design philosophy, principles, good practice & QRA.	Before construction & operation of new top tier establishments, demonstration required that all necessary measures taken to prevent or limit major accidents, & that design incorporates adequate safety & reliability.	Requirement to demonstrate risk from major accident hazards is ALARP in relation to design, in both design & operational safety cases. Justification using suitable and sufficient QRA required for specific hazards.	Explicit requirement for description of the design & procurement procedures. Approval required of new or modified works (ROTS). R2000 will require description of arrangements rather than procedures.
- Operational control arrangements	Produce operating rules and operating instructions.	Adopt & implement procedures & instructions for safe operation.	Provide instructions, procedures & permit to work system (MAR).	Procedures or arrangements relating to operations or maintenance.
- Management of contractors	Not specifically mentioned. Overall duty on licensee for all nuclear- related activities, no matter who is carrying them out.	Explicit - general management arrangements in MAPP must cover sub-contractors.	Not specifically mentioned. Overall duties on owner / operator for major hazards, no matter who is carrying out the work.	Duty holders must set out the arrangements for managing work carried out by people not in their employment.

Key feature	Nuclear	Onshore	Offshore	Railways
- Competence arrangements	Implicit. Licensee shall ensure no operations carried out which may affect safety except under the control & supervision of suitably qualified & experienced people.	Implicit. Arrangements to address training needs mentioned.	Implicit.	Explicit. Duty for adequate arrangements to ensure competence. HSE able to approve schemes for the assessment of staff in safety critical jobs. R2000 will require keeping of training & competence records.
- Arrangements for emergencies made & tested	Duty relates to 'on-site emergencies & their effects' on and off site.	On-site & off-site (local authority)	Detailed set of objective driven Regs (PFEER). Require arrangements, setting of performance standards & testing.	Procedures required by 1994 Regulations. Testing in guidance. R2000 will replace 'procedures' with arrangements and require provision of equipment for emergency train evacuation .
- Identification of emergency responsibilities & training needs	Explicit.	Explicit.	Explicit (PFEER).	Explicit.
- Incident investigation	Explicit (Condition 7).	Explicit (under monitoring).	No explicit duty.	1994 Regulations require demonstration of adequate arrangements for investigation. R2000 will also require demonstration of adequate arrangements for identifying the causes of incidents.
- Audit	See quality assurance of SMS.	Explicit.	Explicit.	Explicit.
- Quality Assurance of SMS	Explicit.	No mention.	No mention.	Mentioned in guidance.
- Communication & co-operation	Explicit for emergency response, in relation to those whose assistance is required. Major licensees communicate with the public through local liaison committees and reports.	Explicit in relation to the public and those whose assistance is required for emergency response. Duty holder to make Safety Reports publicly available.	Explicit duty on all parties to co-operate to enable compliance.	Explicit duty to pass on health & safety information. R2000 will require duty holder to make accepted safety cases publicly available.
-Consult work force	Explicit consultation of those whose assistance required in respect of emergency arrangements; practice to consult widely.	Explicit duty.	Explicit duty.	Explicit duty.
- Inhouse & external non-regulator scrutiny	Hardware & procedural changes subject to independent scrutiny by the Nuclear Safety Committee after peer review. Responsibility remains with licensee.	No requirement for independent non-regulator scrutiny.	Independent verification of safety critical elements. The duty holder responsible for system.	No requirement for independent scrutiny in the 1994 Regulations (apart from infrastructure controller acceptance of some safety cases). R2000 will require independent scrutiny of safety cases before submission to HSE, & annual independent audit of operations.

**Principle 4:** .....the involvement of the safety regulator through 'permissioning' should give society an added level of confidence....

Key feature	Nuclear	Onshore	Offshore	Railways
<p>- Safety regulator's involvement</p>	<p>Licence required for operation of nuclear installation. HSE able to impose conditions, revoke or refuse a licence. Can direct licensee to take a particular course of action. Option to approve / freeze aspects of management arrangements. Can specify requirement for consent before proceeding beyond pre-agreed hold points.</p> <p>International obligation through International Convention on Nuclear Safety includes duty to organise adequate system of inspection. Conditions &amp; safety cases may be used as a basis for inspection &amp; audit.</p>	<p>Operators of new top tier site cannot start construction or operation before receiving conclusions of assessment. Existing plants can continue to operate. Regulator power to prohibit operation if insufficient information provided, with independent appeal mechanism.</p> <p>Must prohibit operations if there are serious deficiencies in measures taken. Must organise adequate system of inspections. Must report major accidents to EU. Safety Reports &amp; lower tier site notifications may be used as a basis for inspection &amp; audit.</p>	<p>Offence to:-</p> <ul style="list-style-type: none"> <li>• continue to operate existing installation without an accepted safety case;</li> <li>• start to operate a new installation without an accepted safety case;</li> <li>• operate an installation with an accepted safety case for more than 3 years since it was last accepted.</li> </ul> <p>Safety regulator must make a timely judgement whether or not to accept the submitted case for safety. Duty holders must notify HSE before starting specified activities. Safety case may be used as a basis for inspection &amp; audit.</p>	<p>Offence to operate without an accepted safety case. Train &amp; station operators must submit safety cases to the infrastructure controller for acceptance in relation to risks imported to network. Works that could materially affect safety submitted to HSE for approval (ROTS). HSE powers to approve schemes for assessment of staff in safety critical jobs (RSCW). R2000 will require all duty holders to submit safety case to HSE for acceptance, and gives powers to HSE to require changes to accepted case. HSE to receive copies of assessment body audit reports and reviews of safety cases. Safety case may be used as basis for inspection and audit.</p>

## LEGAL REQUIREMENTS - SOME KEY POINTS

### The Health and Safety Work etc. Act 1974 (HSWA)

- The Health and Safety at Work etc. Act lays down a framework of duties for ensuring health and safety.
- Section 2 of the Act sets out the wide-ranging general duties of employers to their employees. It requires employers to ensure, so far as is reasonably practicable, the health, safety and welfare at work of their employees. It specifies some of the matters to which that duty extends, including:
  - preparation of a written health and safety policy statement, including the organisation and arrangements for dealing with foreseeable risks;
  - provision of a safe working environment;
  - provision of safe systems of work;
  - provision of information, instruction, training and supervision.
- Section 3 of the Act places a duty on employers to ensure, so far as is reasonably practicable, that people who are not employed by them, but who may be affected by the way they conduct their business, are not exposed to risks to their health or safety.

### The Management of Health and Safety at Work Regulations 1999 (MHSWR)

- The Management of Health and Safety at Work Regulations 1999 are aimed at improving health and safety management, and make more explicit what is required of employers under the Health and Safety at Work etc. Act. They lay down a framework of duties requiring a systematic approach to the management of health and safety, based on risk assessment. Such an approach must include the following elements;
  - assessment of risks to the health and safety of employees and others to identify the preventive and protective measures required by law;
  - arrangements for management, planning, organisation, control, monitoring and review of the measures identified in the assessment;
  - appointment of competent people;
  - provision of adequate health and safety training;
  - provision of appropriate health surveillance;
  - provision of information for employees, for example on risks and preventative or protective measures;
  - setting up emergency procedures.

### The Construction (Design and Management) Regulations 1994 (CDM)

The CDM Regulations are intended to protect the health and safety of people working in construction, and others who may be affected by their activities, by ensuring good management of construction projects, from concept to completion and eventual demolition. Everyone in the construction supply chain is included. The regulations require:

- appointment of competent and adequately resourced duty holders eg designers and contractors, to safely undertake the project;

- communication, co-operation and co-ordination between all duty holders;
- early assessment of the hazards arising from the entire project, including the construction of the design, its maintenance and demolition, with a view to eliminating or reducing them;
- planning and management of the work to control risks;
- training and involvement of the work force;
- recording of significant information needed for the safety of future work.

### **Railways and Other Transport Systems (Approvals of Works, Plant and Equipment) Regulations 1994 - (ROTS)**

These Regulations require operators to gain approval from HSE Inspectorate before bringing into force any new and altered railway works, plant and equipment which might materially affect safe operation. Of particular relevance to this discussion are Regulation 4(1) which defines approvals and Regulation 4(4) which defines when 'bringing into use' occurs.

*Reg 4(1) Subject to the following provisions of these regulations the approval of the Secretary of State shall be obtained before;*

- a) any new works, plant or equipment*
- b) any altered works, plant or equipment*

*which are capable of materially affecting the safe operation of a relevant transport system are first brought into use for the purposes of that system.*

*Reg 4(4) in ascertaining the time when any new works, plant or equipment or altered works, plant or equipment are first brought into use subject to any requirement of the Secretary of State under reg 11(1) no regard shall be had to any period during which such new works, plant or equipment or altered works, plant or equipment are*

- a) necessarily used in order to avoid interruption to the operation of existing transport services before sufficient information is available for a decision to be made on an application for approval.*
- b) with the prior written consent of the Secretary of State used for the purposes of*
  - i) any testing or trials provided that the testing or trials are conducted with the terms of such consent or*
  - ii) obtaining information to prove their satisfactory performance in connection with an application for approval.*

["Other transport systems" includes tramways or rapid transit systems. "Works, plant and equipment" includes general works (eg embankments, fencing), permanent way (eg track layouts and junctions), stations and other stopping places, bridges, level crossings, signaling, electrical equipment, rail mounted vehicles, and other plant and equipment (e.g. production models for type approval or some components).

## RISK RELATED TERMS

1. The terms *so far as is reasonably practicable* (SFAIRP) and *as low as is reasonably practicable* (ALARP), as used in health and safety provisions, are not explicitly defined in law. Interpretation of SFAIRP by the courts indicates that judgements about reasonable practicability involve taking account of the degree of risk on one hand and, on the other, the costs (in money, time or trouble) of averting it. Unless it can be shown that there is a 'gross disproportion' between these, with the risk insignificant in comparison to the cost, the duty holder must take the measures to reduce the risk. An individual duty holder's ability to afford the measures is not relevant to the judgement.

2. HSE looks for demonstration that risks have been reduced ALARP in the safety cases submitted under the offshore and nuclear legislation. Under railways legislation, HSE looks for risks to have been reduced SFAIRP. Under COMAH the duty holder is required to take all necessary measures to prevent major accidents, and to limit their consequences to people and the environment. The wording was drawn from the Seveso II Directive. By requiring measures for prevention and mitigation, it recognises that risk cannot be completely eliminated. This in turn implies proportionality between the risks and the measures to control them. Under COMAH therefore, prevention should be considered in a hierarchy based on the principles of eliminating hazard and then reducing ALARP.

3. To demonstrate they have reduced risks ALARP, or taken measures SFAIRP, duty holders need to show that they have, as a minimum, applied relevant standards of authoritative good practice, and then reduced the remaining risk ALARP. This involves assessing the reduction in the level of risk achieved by particular measures; assessing the cost; and comparing the two. Where relevant and appropriate, the ALARP demonstration needs to take account of society's concerns.

4. Following the Public Inquiry into the Sizewell B nuclear power station, HSE developed the Tolerability of Risk (TOR) framework to explain its philosophy of risk control for nuclear power stations. This has since been further developed, to apply to all hazards/risks within HSE's remit. Its most recent development is in the HSE Discussion Document *Reducing Risks - Protecting People*<sup>31</sup>.

5. The approach described in *Reducing Risks - Protecting People* is summarised in the diagram on the next page. The triangle represents an increasing level of 'risk' (measured by the individual risk and the related societal concerns). In the upper region of the triangle, the risks are considered intolerable, regardless of potential benefits. At the opposite end of the spectrum is the area where the risks are considered insignificant: comparable to those we regard as trivial in our everyday lives, giving little thought to their adverse consequences. Between the two is the region where the risk is tolerable only if it has been reduced to a level that is ALARP. In this region the risk is not to be ignored, but kept under review and reduced still further, as and when possible.

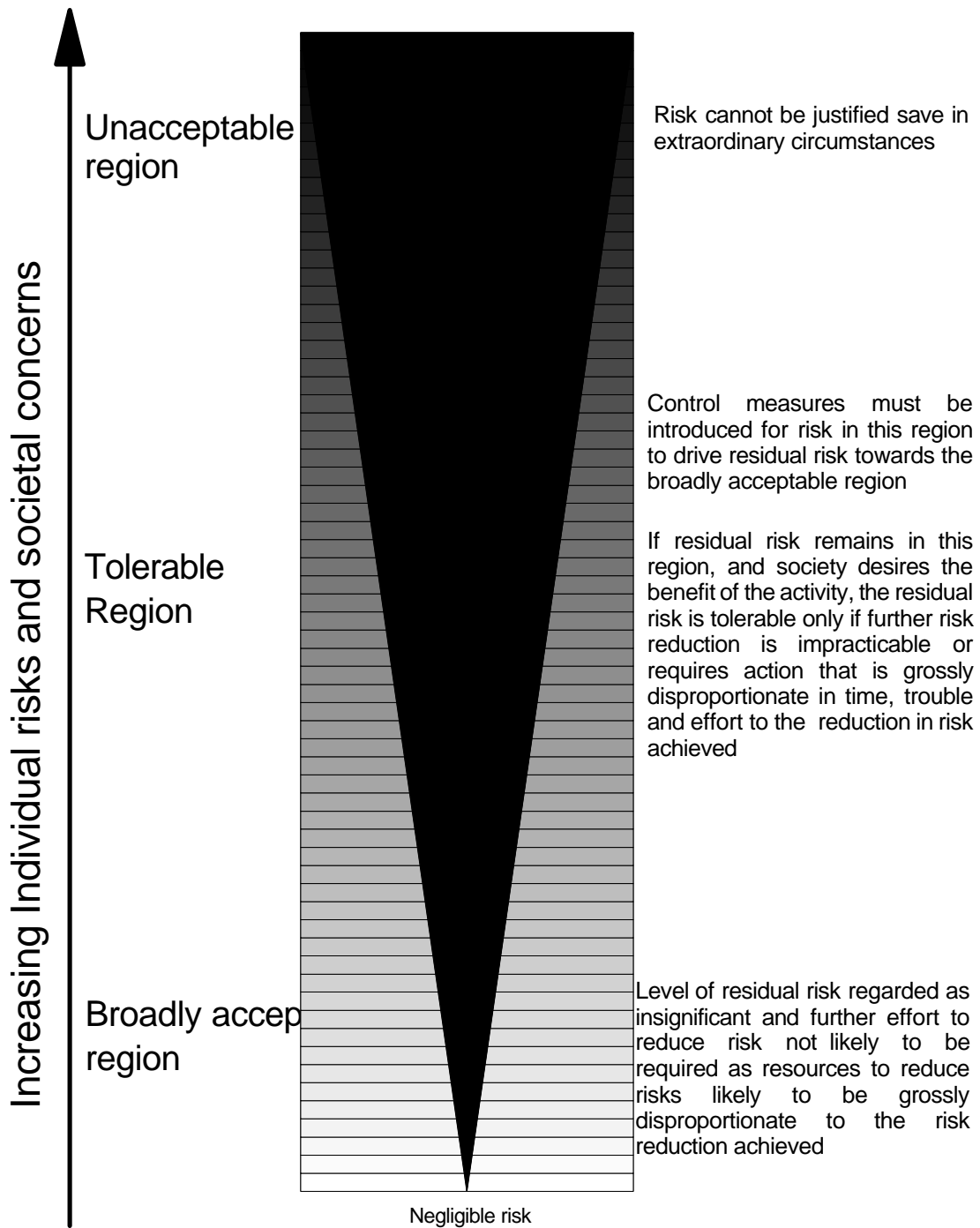


Figure 1. HSE criteria for the tolerability of risk

## ABBREVIATIONS USED IN THIS DOCUMENT

## ANNEX 4

ALARP	As low as is reasonably practicable
CDM	Construction Design and Management Regulations 1994
CIMAH	1984 regulations for control of major chemical sites that preceded COMAH
COMAH	Control of Major Accident Hazards Regulations 1999 - regulates major onshore installations e.g. chemical factories
DCR	Offshore Installations (Design and Construction) Regulations
DETR	The Department of Transport, Environment and the Regions
HMRI	Her Majesty's Railway Inspectorate
HSC	The Health and Safety Commission
HSE	The Health and Safety Executive
HSWA	The Health and Safety at Work etc Act 1974
LC	Licence Condition
LGRI	Ladbroke Grove Railway Inquiry - chaired by Lord Cullen
MAPP	Major Accident Prevention Policy
MAR	Offshore Installations (Management and Administration) Regulations 1995
NII	Nuclear Installations Inspectorate
PFEER	Offshore Installations (Prevention of Fire Explosion and Emergency Response) Regulations 1995
QRA	Quantified Risk Assessment
R2000	Proposed Railway (Safety Case) Regulations 2000
ROTS	The Railways and Other Transport Systems (Approvals of Works, Plant and Equipment) Regulations 1994
RSCW	Railway (Safety Critical Work) Regulations 1994
SCR	Offshore Installations (Safety Case) Regulations 1992
SFAIRP	so far as is reasonably practicable
SMS	Safety Management System

## ANNEX 5

## References

1. *The Public Inquiry into the Piper Alpha Disaster* by the Hon Lord Cullen (2 vols) ISBN 0-10-113102 (HMSO)
2. *Ensuring Safety on Britain's Railways*. A report submitted to the Secretary of State for Transport by the Health and Safety Commission developing proposals for assuring safety following the liberalisation of access to and privatisation of British Railways. January 1993. Published by the Department of Transport, 2 Marsham Street, London SW1P 3EB.
3. *Revitalising Health and Safety Strategy Statement* June 2000. Published by Department of the Environment, Transport and the Regions, Free Literature Service Product Code OSCSG0390 ([www.detr.gov.uk/hsw/index.htm](http://www.detr.gov.uk/hsw/index.htm))
4. *Proposals for the Railway (Safety Case) Regulations 2000*; HSE consultative document CD160
5. *Nuclear Installations Act 1965* (as amended) (1965 C.57)
6. *Health and Safety at Work etc. Act 1974* (as amended) (1974 C.37)
7. *The Management of Health and Safety at Work Regulations 1999* (SI 1999/3242)
8. *The Construction (Design and Management) Regulations 1994* (SI 1994/3140)
9. *Control of Major Accident Hazards Regulations 1999* (SI 1999/743 as amended)
10. *Report of the Committee appointed by the Prime Minister to examine the organisation for control of Health and Safety in the UKAEA*. Published by HMSO 1958 Cmnd 342 (The Fleck Report)
11. *Nuclear site licences under the Nuclear Installations Act 1965 (as amended) - notes for applicants* HS(G) 120 ISBN 0-7176-0795
12. *Safety assessment principles for nuclear plants 1992* ISBN 0118820435
13. *Nuclear Licence Condition 36* ([www.hse.gov.uk/nsd/cond36.htm](http://www.hse.gov.uk/nsd/cond36.htm))
14. *Council Directive 96/82/EC* (known as the Seveso II Directive) this replaced *The Directive on the Major Accident Hazards of Certain Industrial Activities* (82/501/EEC) 1982 as amended by (87/216/EEC) and (88/610/EEC) (known as Seveso I Directive)
15. *COMAH safety report assessment manual* ([www.hse.uk/chid/comah2](http://www.hse.uk/chid/comah2))
16. *Control of Industrial Major Accident Hazard Regulations 1984* (SI 1984 / 1902 as amended)
17. *Pipeline Safety Regulations 1996* (SI 1996/825)
18. *Offshore Installations (Safety Case) Regulations 1992* (SI 1992/2885)
19. *Offshore Installations and Pipeline Works (Management and Administration) Regulations 1995* (SI 1995/738)
20. *Offshore Installations (Prevention of Fire and Explosion, and Emergency Response) Regulations 1995* (SI 1995/743)
21. *Offshore Installations and Wells (Design and Construction etc.) Regulations 1996* (SI 1996/913)
22. *Assessment principles for offshore safety cases 1998* HSG 181 ISBN 0-7176-1238-4
23. *Railways (Safety Case) Regulations 1994* (SI 1994/237)
24. *Railway Safety Principles and Guidance* ISBN 0-7176-0712-7
25. *Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994* (SI 1994/157)

26. *High Speed Trains Directive (96/48/EC)*
27. *Communication from the Commission to the Council and other the European Parliament on the interoperability of the trans-European conventional rail systems COM (1999)617*
28. *HSE Internal Inquiry Report - Ladbroke Grove rail accident on 5th October 1999 (www.hse.gov.uk/railway/paddrail/inquiry.htm)*
29. *Guide to the approval of railway works, plant and equipment ISBN 7-0776-0741-0*
30. *The Southall Rail Accident Inquiry Report by Professor John Uff QC FREng ISBN 0-7176-1757-2*
31. *Reducing Risks, Protecting People: HSE Discussion Document DDE11 C150*

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We would like you to give us your views on any aspect of the material set out in this Discussion Document, in particular an indication of whether or not you are generally in favour of the approach suggested, and any alternative solutions or problems that you wish to put forward. Some of the specific issues are summarised in the following questionnaire but please feel free to comment on any aspect.

**For each of the specific issues, we have given you the paragraph references in the CD commentary which explain the reasoning behind the proposals. You will want to read these paragraphs before commenting.**

For those who would like to use it, a detachable form is included as a convenient way to respond. You may, of course, attach additional pages where insufficient space is available for your response, or send us your comments in a different form.

All responses will be analysed and taken into account in future recommendations to HSC. Any initial responses received **by 1 December 2000** may be fed into the Inquiry into the train collision at Ladbroke Grove. You should tell us if you object to this. Any proposals to change current regulations produced as a result of this Discussion Document will be published as a Consultation Document in the usual way, giving detailed explanations of the course chosen, and including a Regulatory Impact Assessment.

The Health and Safety Executive tries to make its consultation procedures as thorough and open as possible. After the close of the consultation period, responses to this document will be lodged in the Health and Safety Executive's Information Centres, where they can be inspected by members of the public or copied to them on payment of the appropriate fee to cover costs.

Responses to this Discussion Document are invited on the basis that anyone submitting them agrees to their being dealt with in this way. Responses, or parts of them, will be withheld from the Information Centres only at the express request of the person making them. In such cases a note will be put in the index to the responses identifying those who have commented and have asked that their views, or part of them, be treated as confidential. Many business e-mail systems now automatically append a paragraph stating the message is confidential. If you are sending your comments by e-mail and are content for your response to be made publicly available please state clearly in the body of your response that you do not wish any standard confidentiality statement to apply.

If you are not satisfied with the way in which this consultation exercise has been conducted you can complain by writing to **Anne Sharp** at the address given below.

**Please return your comments to:**

Lila Tait

Safety Policy Directorate C

Health and Safety Executive, Rose Court, 2 Southwark Bridge, London SE1 9HS.

telephone: 0207 717 6861

fax: 0207 717 6908

e-mail: lila.tait@hse.gsi.gov.uk

**By 28 January 2001**

(Responses received by **1 December 2000** may also be fed into to the Ladbroke Grove Inquiry)





**Q 2:** HSE would welcome your views on whether this basis for the application of 'permissioning' regimes is appropriate (paras 15 -19).

Yes	No	Your comments

**Q3:** HSE would welcome your views on whether principle 2 properly reflects the responsibilities and demands which should be placed on duty holders (paras 20 - 26).

Yes	No	Your comments

**Q4:** HSE would welcome your views on what more could be done to help safety cases to become living documents of practical relevance to the daily operation of sites (paras 20-26).

Your comments

**Q5:** In relation to all or any of the regimes, HSE would welcome your views on whether the current balance between goal-setting and prescription is appropriate (paras 27 - 33).

Yes	No	Your comments

**Q 6:** For any or all of the regimes, HSE would welcome your views on the extent to which principle 3 adequately describes the place of the safety regulator in 'permissioning' (paras 34 - 44).

Your comments

**Q 7:** For any or all of the regimes, HSE would welcome your views on whether safety regulator intervention is currently pitched correctly, bearing in mind that more activity requires more resource (paras 34 - 44).

Yes	No	Your comments

**Q 8:** For any or all of the regimes, HSE would welcome your views on the likely consequences of greater disclosure of safety cases and the safety regulator's reports (paras 34 - 44).

Your comments

**'PERMISSIONING' REGIMES**

**(Chapter 3)**

**Q 9:** In relation to the principles, and to any or all of the regimes covered in Chapter 3, HSE would welcome your views on whether the description of the key features matches your understanding of them.

Yes	No	Your comments

**Q 10:** In relation to the principles, and to any or all of the regimes covered in Chapter 3, HSE would welcome your views on: the extent to which the differences between the 'permissioning' regimes are necessary and appropriate.

Your comments

**Q11:** In relation to the principles, and to any or all of the regimes covered in this Chapter 3, HSE would welcome your views on the role and value of external non-regulator scrutiny in a 'permissioning' regime (for example, as set out in paragraph 94).

Your comments

## RAILWAY APPROVALS

### Chapter 4

**Q12:** HSE would welcome your views on the extent to which a system of approvals is still relevant to the regulation of the railway industry, where safety cases are now an established procedure. If it is, how should it be delivered? (para 116 - 125)

Your comments and any views on costs involved

**Q 13:** HSE would welcome your views on how the development of Notified Bodies will affect the approvals regime, and what the role of the safety regulator should be (para 119 - 121).

Your comments and any views on costs involved

**Q 14:** HSE would welcome your views on the role of external non-regulatory scrutiny in all proposals for works on the railway, and on the place for conformity assessment schemes (para 128 - 132).

Your comments and any views on costs involved

**Q15:** HSE would welcome your views on:

- extending the contents of the application;

- requiring it in the form of a written plan;
- the elements that should be included in such a plan (para 133 - 136).

Your comments and any views on costs involved

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**Q16:** HSE would welcome your views on a prioritisation approach using 2 or 3 categories and what it might be appropriate to include in the definition of each (para 137 - 144).

Your comments and any views on costs involved

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**Q17:** HSE would welcome your views on the need to introduce additional controls on operators before final approval, and how this might best be achieved (para 145 - 147).

Your comments and any views on costs involved

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**Q18:** HSE would welcome your views on turning approvals into a consent regime as outlined (paras 149 - 153).

Your comments and any views on costs involved

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**Q 19:** HSE would welcome your views on introducing a safety regulator scrutiny point at the design stage for major works, before the detailed development of the Plan, and whether this should be statutory or voluntary (paras 149 - 153).

Your comments and any views on costs involved
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**Q 20:** HSE would welcome your views on enabling HSE to impose conditions on the operator either during or following the completion of the works (paras 149 - 153).

Your comments and any views on costs involved
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**Q 21:** HSE would welcome your views on placing a duty on operators to notify the safety regulator if works were significantly delayed or cancelled (paras 149 - 153).

Your comments and any views on costs involved
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**Q 22:** HSE would welcome your views on whether there is a need for a more explicit statement of where the primary duty lies (para 154 - 157).

Yes	No	Your comments and any views on costs involved

**Q 23:** HSE would be grateful for any further information you wish to provide on the economic impact of the various discussion points set out in Chapter 4 (para 159 - 160).

Your comments

**Q 24:** Are there any other comments you wish to make on these issues?

Yes	No	Your comments

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**Q 25:** In your view how well does this Discussion Document represent the different policy issues?

Please tick one box:

Very well

Well

Not well

Poorly

**Q 26:** Is there anything you particularly liked or disliked about this consultation exercise?  
*Please add extra sheets if you wish.*

**Please return your comments to:**

Lila Tait,

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fax: 0207 717 6908

e-mail: lila.tait@hse.gsi.gov.uk

**By 28 January 2001**

(Responses received by Friday 1 December may also be fed in to Lord Cullen's Inquiry into the train collision at Ladbroke Grove)

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# DISCUSSION DOCUMENT

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The full text of this and other Discussion Documents can be viewed  
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