

DISCUSSION DOCUMENT

SAFETY ON THE RAILWAY - SHAPING THE FUTURE



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FOREWORD

CHAPTER 1

INTRODUCTION

Why this Discussion Document?

1 This Discussion Document invites views and comments on options to renew and update the main regulatory requirements for safety on the railways in Great Britain. Although the main focus is the mainline railway, metros, heritage railways, trams, monorails and other means of guided transport are also included in so far as they are presently within scope of health and safety legislation enforced by the Health and Safety Executive (HSE).

2 The Discussion Document comes at a key time. A common regulatory framework for safety on the railway network is being established across Europe. The substantial programme of action identified by Lord Cullen in the Ladbroke Grove Rail Inquiry (<http://www.hse.gov.uk/railways/paddrail/lqri2.pdf>) continues to be taken forward, and there are lessons to learn from operation of the existing requirements since privatisation of the railway in 1994. The Health and Safety Commission (HSC) wishes to provide a robust regulatory framework that aligns with the rapidly emerging European regime and which drives the railway industry to maintain, and where reasonably practicable, improve safety.

Safety on the railway

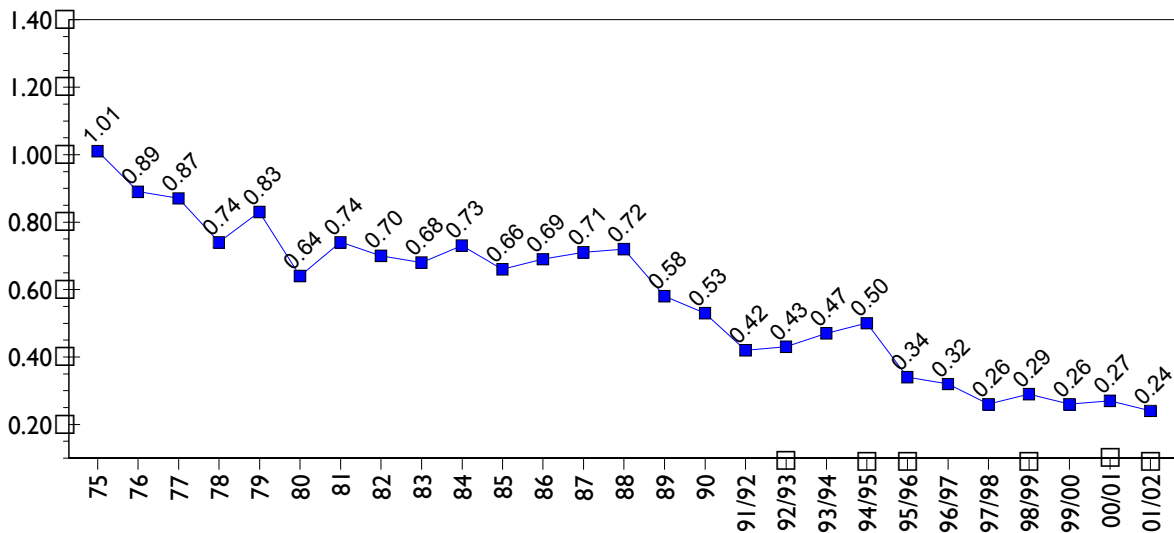
3 As in any industry, managing safety on the railway is part of good business management. The challenge that pervades this Discussion Document is how best to promote better safety management in the railway industry to minimise the risk of serious harm to the many thousands of individuals who travel and work on the railway every day. The measures could include industry arrangements as well as formal legal requirements.

4 In terms of overall statistics the downward trend in significant train accidents apparent prior to privatisation has been maintained (Figure 1), and rail travel continues to be one of the safest forms of transport (Table 1). The statistics in Table 1 bring out well-known differences in, for example, the statistical risks of death during travel by car and by train. Such statistics seem to reflect an underlying acceptance by society of higher levels of fatalities from accidents on the public highway compared to those from railway accidents. This in turn may reflect a feeling that road accidents are, at least to some extent, the price society is prepared to pay for individual freedom to drive on the public highway, and for the mobility on which modern daily life depends.

5 Notwithstanding these statistics, safety on the railway is seldom far from the public eye and consciousness. One explanation is that railway incidents make dramatic and photogenic news – coverage of major accidents is extensive and even minor incidents with few injuries can receive substantial media attention. Another explanation focuses on the public's heightened concern of

rail accidents arising from factors such as the potential for multiple fatalities and the individual's lack of control as a passenger on a train compared with the perceived control of the motorist. In short, high standards of safety are expected as part of payment of a fare. For those living and working in urban areas, this expectation may be exacerbated by lack of any practical alternative to commuting by rail.

Significant train accidents per million train miles 1975 – 2001/2



Significant train accidents covers most collisions and derailments that occur on, or that affect, passenger lines. Source: HSE's Annual Report on the safety record of the railways in Great Britain during 2001/02

Figure 1

Table 1 – Fatality Rates Across Different Modes of Transport

Mode	Passenger fatalities per billion passenger		
	kilometres	journeys	hours
Motor cycle / moped	123	1,910	4,890
Foot	47	43	210
Pedal cycle	35	140	430
Car	2.9	39	120
Rail	0.4	10	21
Bus / coach	0.3	3	7
Air	0.01	23	5

*Notes:
Data for rail and air are 10-year averages 1992-2001; data for bus/coach is 5-year average 1997-2001; other data for 2001*

Source: Rail Safety and Standards Board *Annual safety performance report 2002/3*, quoting unpublished DfT figures updated to 2001
<http://www.rssb.co.uk/pdf/railrepo0203/ASPR02-03.pdf>

6 An alternative explanation recently put forward centres on moral responsibility. In this explanation the starting point is that the public expect state-of-the-art approaches to railway safety (at least in comparison with those in other major countries), and hold the industry morally culpable if these are not provided and maintained (http://www.rspb.co.uk/pdf/policy_risk.pdf). This may help to explain why significant railway accidents live long in the public memory, and why their locations (e.g. Harrow and Wealdstone, Moorgate, Clapham Junction, Southall, Ladbroke Grove, Hatfield, Potters Bar) become etched into public consciousness as places where those responsible for providing a key part of the national infrastructure fell short of the standards expected.

7 Whatever the explanation safety on the railway is important, both for individuals who may be affected and for society as a whole. This is recognised in the existing regulatory arrangements, which aim to secure high levels of railway safety and assuage societal concerns. There is, however, scope for debate on the extent to which the existing arrangements have been successful in both respects.

8 HSC intends that this Discussion Document should contribute to wider public discussion and debate on what constitutes tolerable risk on Britain's railways. Where the judgment is that changes to the regulatory framework are needed the way forward may not be more legislation, but better regulation that is clearer in putting responsibility and accountability on those who create the risk to provide and maintain the necessary controls. HSC is firmly of the view that to build public confidence in railway safety the industry must demonstrate that it has the capability to manage risk competently, consistently and reliably.

Drivers for change

9 In addition to the considerations in paragraphs 3 to 8 above, three drivers prompt review of the existing railway safety requirements:

- Existing and future European legislation intended to establish a single market and a common regulatory framework for railway safety;
- The legacy of recent accidents, and in particular the recommendations for changes to the regulatory system for railway safety set out by Lord Cullen in his Inquiry on the accident at Ladbroke Grove (<http://www.hse.gov.uk/railways/paddrail/lqri2.pdf>); and
- The need to learn from duty holder and regulator experience generally since privatisation of the railways in 1994.

Timing of the review

10 The European legislation and Lord Cullen's public inquiry recommendations generate different, but not incompatible, timescales for action. The timescale for implementation of European requirements reflects a progressive approach to the introduction of a single market and a common

regulatory framework for the European rail system. In the context of this Discussion Document the European approach is broadly three-fold, covering arrangements for:

- a) 'Interoperability' whereby rail sub-systems and components can progressively be used on infrastructure and rolling stock across Europe, and mainline trains can operate across national boundaries. Here the main European Directives were agreed in 1996 and 2001 and there is a growing corpus of European standards for the design, construction and operation of trains and infrastructure. In Great Britain implementing regulations are already in force for much of the high-speed rail network, and should be in force for most of the conventional network in late 2004 or early 2005 [ref DfT's CD expected October]. A further directive will progressively extend interoperability to the whole heavy-rail network when it is implemented (due 2006);
- b) Safety management whereby duties to control risk are imposed on those who provide infrastructure and operate trains. Organisations that wish to undertake such activities have to secure permission from the safety regulator before they do so. Permission is subject to provision of evidence of capability to operate safely and meet relevant standards. Here the Railway Safety Directive (part of the second railway package) is at common position in the European Council and is due to be adopted in early 2004 for implementation in early 2006. The full text of the directive is at <http://register.consilium.eu.int/pdf/en/03/st08/st08557en03.pdf>.
- c) Competence and fitness of railway staff. Here thinking in Europe is at an early stage – the European Commission is presently drawing up proposals for a directive on driver licensing. Such a directive is unlikely to have to be implemented until at least 2007. HSC has already agreed that it would not anticipate European requirements by regulating in advance in Great Britain. However, non-regulatory arrangements developed in response to Lord Cullen's specific recommendation for some form of driver and signaller licensing may enable the UK to influence the directive as it takes shape and is negotiated.

11 In contrast, the timescale for action on Lord Cullen's recommendations extends to September 2004. However, in April 2003 HSC confirmed that the outcomes of an evaluation and review of the present regulations on competence and fitness should be taken forward as a package with the reviews of the other two sets of key regulations, even though this meant that action on Lord Cullen's recommendations would not be complete until spring 2005.

12 In short HSC believes the timing of this review is opportune. It enables HSC to develop and bring forward a single package of measures that would become law in Spring 2005 (with appropriate dates for coming into force and transitional arrangements). The package would:

- Implement the requirements of the Railway Safety Directive on safety management;

- Take account of European developments on interoperability;
- Complete regulatory action on Lord Cullen's recommendations on safety management;
- Take on board the lessons of operational experience since privatisation¹; and
- Prepare the ground for further European developments on competence of railway staff without legislating in advance of a directive.

Better regulation

13 HSC believes that taking these changes together offers significant opportunities to bring greater proportionality and consistency to the existing piecemeal regulatory requirements for health and safety on the railways, and to improve transparency and accountability (<http://www.brtf.gov.uk/index.htm>). In particular it provides an opportunity to look across the key elements of current railway health and safety legislation to:

- Clarify, consolidate and make more coherent duty holder requirements to provide safe railway plant and equipment, to ensure competence of staff and suppliers, and to maintain effective safety management systems;
- Streamline existing requirements which have developed piecemeal, often in response to specific incidents; and
- Minimise burdens on industry that would otherwise arise from sequential changes firstly in response to Lord Cullen's recommendations and then in implementing substantive requirements establishing a common European regulatory framework for safety on the railway.

Objectives and constraints

14 HSC's objectives for the review are to identify and implement the changes that are needed to:

- a) Build public confidence that risks to railway passengers and staff are properly controlled, and that, where reasonably practicable, safety on the railway is continuously improved in line with society's expectations;
- b) Meet European requirements for a common regulatory framework for safety on the railway;
- c) Implement Lord Cullen's recommendations concerning the regulatory system that remain outstanding;

¹ Normally regulations are evaluated and reviewed 5 years after their introduction, in line with Cabinet Office guidelines. However, pressures and priorities following the Southall and Ladbroke Grove accidents forced postponement, and this review marks the first evaluation of the key elements of railway health and safety legislation introduced on privatisation in 1994.

- d) Take account of the wisdom of practical experience of both duty-holders and HSE in operating the existing regulatory requirements since privatisation in 1994;
- e) Secure greater coherence between the key elements of the present regulatory system for railway safety; and
- f) Streamline, so far as possible, processes and requirements and reduce bureaucracy.

15 However, the drivers for change also impose some constraints that limit the extent of the changes that can be made. The main constraints include:

- The European Directives that are progressively creating a single European rail system with common principles for the management, regulation and supervision of railway safety. These Directives are intended to give effect to the establishment of a single market for rail transport services; when implementing Member States may only provide for alternative provisions where the Directives allow. Chapter 3 provides further details of the requirements of the draft Railway Safety Directive and on HSC's proposed approach to implementation.
- The continuation of a permissioning regime for mainline railway operation with prior demonstration of capability to provide and maintain suitable safety management systems. This is not only a requirement of the draft Railway Safety Directive (paragraph 10b) above, it is also a conclusion of Lord Cullen². In addition it is fully consistent with HSC's general policy (<http://www.hse.gov.uk/enforce/permissioning.pdf>) to apply permissioning regimes to high-hazard activities that give rise to societal concerns and where the regime adds proportionate value. This is clearly the case for most rail transport (paragraphs 3 to 7 above).
- Lord Cullen's recommendation that HSE should continue to fulfil the role of the independent safety regulator for the railways³. It follows that safety on the railways will continue to be regulated under the Health and Safety at Work Etc. Act 1974 (HSWA) by regulations made under HSWA powers and enforced by HM Railway Inspectorate (HMRI). Regulations made under HSWA may be goal-setting (like the Act) or set out more detailed requirements. The approach in the forthcoming Railways Safety Directive is consistent with that in HSWA.

16 Three further 'givens' for the purposes of this review are:

- The separation of responsibilities for provision and operation of infrastructure and trains introduced in Great Britain in 1994. The

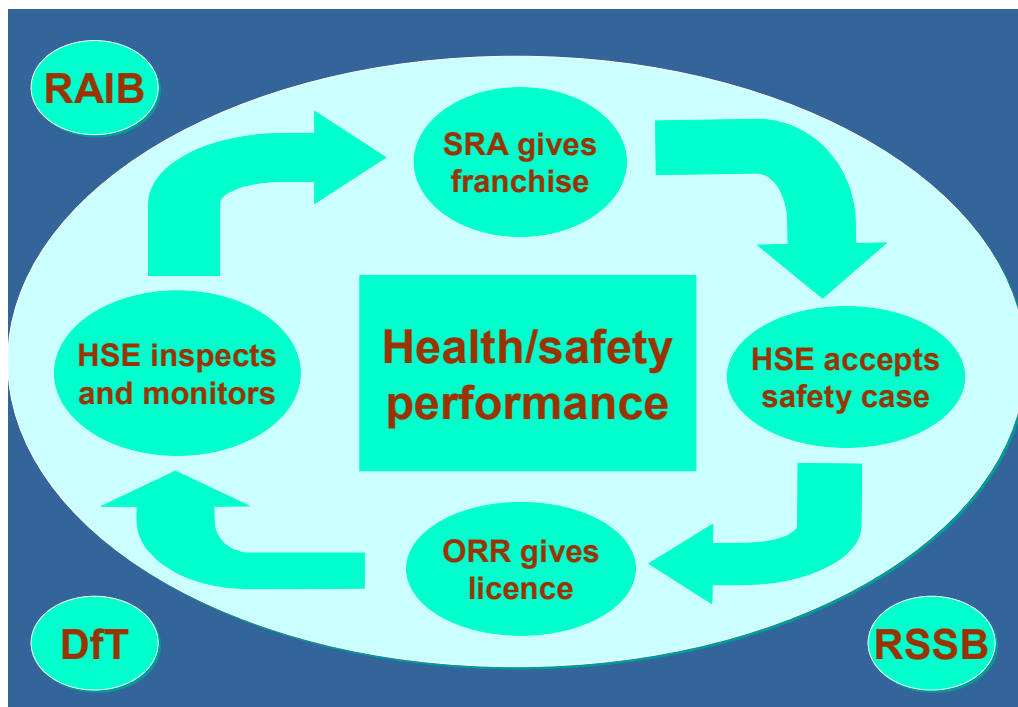
² Lord Cullen endorsed the application of the safety case to Great Britain's railways - recommendation 18 in *The Ladbroke Grove Rail Inquiry, Part 2 Report*, (<http://www.hse.gov.uk/railways/paddrail/lgr2.pdf>)

³ Recommendation 35 in *The Ladbroke Grove Rail Inquiry, Part 2 Report* (<http://www.hse.gov.uk/railways/paddrail/lgr2.pdf>)

principle of such separation is now becoming established across Europe; and

- The roles of others in the regulation of railway health and safety, including the Strategic Rail Authority (SRA, which provides leadership and strategic direction for Britain's railway), the Office of the Rail Regulator (ORR, the economic regulator), and the Rail Accident Investigation Branch (RAIB). Figure 2 gives an overview of the arrangements. HSC/E will continue to work closely with these bodies.
- The role of the Railway Safety and Standards Board (RSSB), which was created in April 2003 to fulfil Lord Cullen's view that the railway industry needed a body to provide health and safety leadership. While not part of the regulatory system RSSB leads the process of creating and reviewing railway group standards.

Regulation of Health and Safety on the Railways in Great Britain



SRA: Strategic Rail Authority **DfT: Department for Transport**
ORR: Office of the Rail Regulator **RSSB: Rail Safety and Standards Board**
RAIB: Rail Accident Investigation Branch

Figure 2

Overview of existing requirements

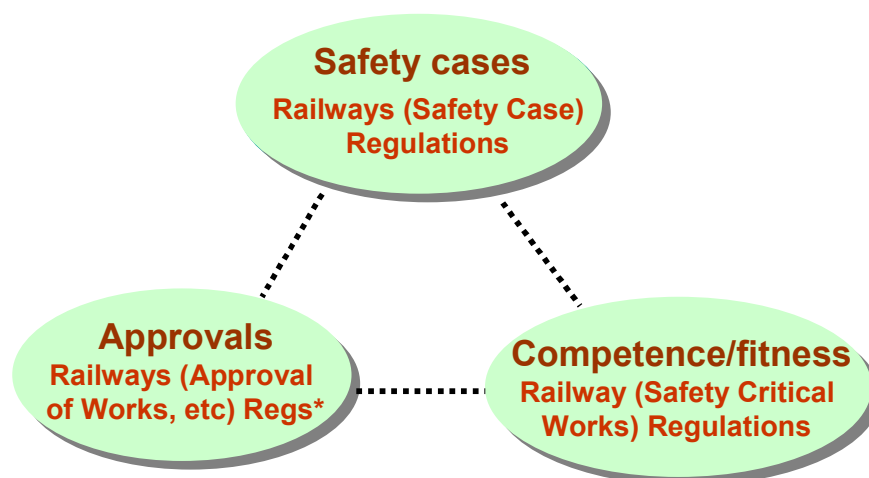
17 The general requirements of the Health and Safety at Work Act apply to rail transport as well as to other work activities. The general duty on employers and the self-employed to ensure, so far as is reasonably practicable, health and safety is developed in regulations made under HSWA. Under the Management of Health and Safety at Work Regulations employers have to make a suitable

and sufficient risk assessment, and to make and give effect to arrangements to plan, organise, control, monitor and review preventive and protective measures.

18 In addition there are specific regulations that apply to railway operations. Figure 3 gives an overview. Broadly there are general requirements on railway operators to:

- a) Prepare a safety case setting out evidence of their health and safety management system and their arrangements to control risk to passengers and staff, and secure HSE's acceptance of their evidence (The Railways (Safety Case) Regulations 2000⁴);
- b) Secure HSE approval before bringing into use new or altered works, plant or equipment capable of materially affecting safe operation (The Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994); and
- c) Ensure the competence and fitness of staff engaged in safety critical work (The Railways (Safety Critical Work) Regulations 1994).

Railway Health and Safety Legislation



* In full – The Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994

Note: This simplified picture does not include legislation on level crossings, or on specifics such as train protection systems, brakes and preventing unauthorised access to railway lines.

Figure 3

19 These requirements came into effect in 1994. The main purpose of the safety case and safety critical work regulations was to ensure that after

⁴ The Railways (Safety Case) Regulations 2000 updated and replaced regulations introduced in 1994 as an initial response to concerns arising from the train collision and fire at Ladbrooke Grove on 5 October 1999.

privatisation, when responsibilities for track, trains and stations were split between different undertakings, overall levels of safety would be at least maintained. At the same time the approval system for railway works, plant and equipment, which originated in the Victorian era, was updated following the accident at Clapham Junction.

20 The safety case brings together an operator's safety objectives, risk assessment and risk control measures, together with their arrangements for review and audit. Both the safety case and approval systems (paragraphs 18a) and b) above) take the form of permissioning systems, i.e. positive permission is needed from HSE before particular activities can be undertaken. Permissioning regimes demand significant input from the regulator, and are resource intensive. This is reflected in charges on those seeking the permission.

21 The review has focused on these three substantive sets of regulations and on any additional measures needed to implement European requirements and to meet Lord Cullen's recommendations. Subsequent chapters set out in more detail the present requirements, and go on to consider changes and whether additional measures are needed to address weaknesses in other areas.

General issues

22 An underlying theme in this Discussion Document is the need to promote greater responsibility and accountability for health and safety in those who provide and operate railway infrastructure and trains, ie those who create the risks. Within this there are a number of general issues. These include:

- The extent to which the scope of application of the existing requirements on safety management, 'hardware' (ie plant, work and equipment), and competence (Figure 3) should be aligned. This is taken up in Chapter 2.
- The extent to which the existing specific requirements for health and safety on the railways should be either
 - revoked because the general duties under the HSWA and associated legislation of general application are now sufficient; or
 - altered or extended to clarify and strengthen the onus on duty holders in the railway industry to maintain and improve standards.
- The significance for health and safety of terms such as 'approved', 'authorised', 'certificated', 'accredited', 'competent', and 'licensed'; the criteria that must be satisfied before they can be awarded; and the circumstances in which they should be withdrawn.
- The circumstances in which formal permissioning should be replaced by notification of information to the regulator, who can then intervene as appropriate.
- The circumstances in which third parties might play a role in, for example:
 - verifying conformity of railway 'hardware' with safety standards;

- promoting the competence of employees in the rail industry and of suppliers of safety critical products and services to the industry. Where potential circumstances are identified the Discussion Document explores what may be needed so that such schemes (which could be voluntary) are perceived to be independent and add value.

Progress so far

23 This Discussion Document is the outcome of an on-going process of engagement with the railway industry, rail trade unions, passenger groups and other interested parties. The experience and views of stakeholders have been tapped in a series of bilateral meetings and stakeholder workshops. In addition a stakeholder working group has informed the work on competence and fitness. HSC would like to thank all who have given their time to share their experience of the present regulatory requirements and their views on how they can be improved. The information and insights gained have been invaluable.

24 Other inputs have contributed to particular areas of the review. The safety case regime lies at the heart of the present regulatory requirements and its impact in ensuring post privatisation that health and safety standards have been maintained and, so far as is reasonably practicable, improved is the subject of an independent evaluation (Chapter 3). The Chapters on supplier accreditation (5), safety critical work (6), and driver and signaller licensing (7) have also been shaped by an initial steer from the HSC on the future direction likely to be appropriate in these areas.

25 A small steering group comprising representatives of the Strategic Rail Authority, the Office of the Rail Regulator, the Rail Safety and Standards Board, the Rail Passengers Council, the Rail Maritime and Transport Union, and the Department for Transport has provided a strategic steer. HSC's Rail Industry Advisory Committee has also provided strategic input to the review. Both strategic inputs will continue.

What happens next?

26 This Discussion Document continues the process of engagement already in progress. HSC/E will continue to listen to views and comments from all interested parties. As part of the dialogue plans are in hand for open seminars in mid November and early December to share views on key issues arising from this Discussion Document and promote further debate and discussion before the deadline for receipt of comments at the end of this year. In addition the HSE policy team will be pleased to meet stakeholders separately if they wish.

27 Thereafter HSC/E will consider carefully all views and comments expressed, and will draw up proposals for new or amended regulatory controls in a Consultative Document, which we aim to publish in Summer 2004. Views and comments will again be considered, and HSC will then advise Ministers on the legislative and other changes it considers appropriate in early 2005.

28 HSC/E has sought to be open and transparent by publishing its approach to regulating risk from work activities (<http://www.hse.gov.uk/dst/r2p2.pdf>). In considering the issues raised in this Discussion Document readers may wish to take into account the general criteria HSC is likely to apply in assessing options and advising Ministers. These include:

- Impact on the risk to workers and to individual members of the public;
- The extent to which societal concerns are assuaged;
- Compatibility with European and international requirements, and with our national approach of goal-setting legislative requirements supported as necessary by codes, standards and guidance;
- Practicality, robustness and workability of any necessary technology;
- Costs and benefits;
- The industry's track record in addressing risk;
- The 'fit' with HSC and wider Government policies and objectives, including the Government's better regulation principles of proportionality, consistency, targeting, transparency and accountability.

Explanatory Note: HSC, HSE and HMRI

The job of the Health and Safety Commission (HSC) is to ensure that risks from work activities are properly controlled. The Commission advises Ministers on all matters relating to health and safety at work. It conducts and sponsors research, promotes training, provides an information and advisory service, and submits proposals for new or revised regulations and approved codes of practice (<http://www.hse.gov.uk/aboutus/hsc/index.htm>).

The Commission is a multi-partite body chaired by Bill Callaghan. It has nine members with a wide variety of backgrounds and experience, and is supported by a network of industry advisory committees.

The Health and Safety Executive (HSE) is the operational arm of the Health and Safety Commission. It advises the Commission on policy and general operational issues. Its staff include administrators, lawyers, policy makers, inspectors, scientists, engineers, technologists and medical professionals (<http://www.hse.gov.uk/aboutus/hse/index.htm>).

HM Railway Inspectorate (HMRI) is part of HSE. Its operational and technical inspectors focus on the railway industry. They offer guidance, manage the railway permissioning regimes and ensure compliance with the law by inspecting and investigating accidents and complaints.

CHAPTER 2

TRANSPORT SYSTEMS IN SCOPE OF THIS DISCUSSION DOCUMENT

The present position

29 As noted in Chapter 1, paragraph 22, the 'scope' of the regulatory and other proposals in this Discussion Document – that is, which railways and other transport systems they should apply to - is a key issue. If safety controls are to be properly focussed on risk, it is important to get their scope right. This is especially so for permissioning regimes, which are relatively onerous and costly and must, therefore, be directed to activities where if things go wrong very serious consequences may result (typically multiple fatalities to the public).

30 The railways that are subject to some or all of the Regulations currently under review, covering safety cases, approvals and safety critical work, vary considerably, ranging from the national 'heavy rail' network to very small and sometimes relatively low-risk systems. Minor and heritage railways are in themselves a diverse category that ranges from railways that provide timetabled passenger services to those that offer occasional rides on vintage rolling stock, possibly within a museum. There are also railways within or serving industrial premises, or in depots, which do not normally carry passengers. Some of the Regulations under review also apply to tramways and to other guided transport systems. This diversity presents a challenge in terms of ensuring that the controls we develop are proportionate, consistent and targeted to risk.

31 The scope of the three sets of Regulations under review is set out in Table 2, and presents a relatively complicated picture. In particular:

- The Approvals and the Safety Critical Work Regulations differ from the Safety Case Regulations in that they apply to tramways and other guided systems. Whilst the Approvals Regulations apply to all other guided systems of specified types (eg monorails, guided buses), the Safety Critical Work Regulations apply only to five specified systems listed in a Ministerial Order.
- The Safety Case and the Safety Critical Work Regulations contain identical exclusions for certain industrial railways. A dispensation made under the Approvals Regulations in respect of non-passenger carrying private lines and sidings achieves a broadly similar result.
- Whilst the Safety Critical Work Regulations place duties on employers, which include contractors, the Safety Case and Approval Regulations place duties only on railway/transport system operators. This is in line with HSC's policy on permissioning regimes and was endorsed by Lord Cullen in his Part 2 report on Ladbroke Grove (paragraph 7.72 in <http://www.hse.gov.uk/railways/paddrail/lgr2.pdf>).

Table 2 – Systems within Scope of Existing Railway Health and Safety Regulation

	Safety Cases⁵	Approval of Works, etc⁶	Competence/Fitness⁷
Transport systems in scope (subject to the exclusions below)	Railways.	Railways. Tramways. Trolley vehicle systems. Other 'prescribed modes of guided transport', ie systems using: <ul style="list-style-type: none"> • magnetic levitation • monorails • road-based with cable guidance • road-based with rail guidance • road-based with side guidance • track-based with side guidance 	Railways. Tramways. Individual systems specified in the Transport (Guided Systems) Order 1992.
Exclusions	Any part of a railway - <ul style="list-style-type: none"> • within a harbour/harbour area, factory, mine or quarry, unless used for fare-paying passengers • used solely for building operations or works of engineering construction • within a maintenance or goods depot. 	Interoperability constituents and subsystems on the designated high-speed network. ⁸ Vehicles subject to approval provisions of the Channel Tunnel Act 1987 (reg 4(2)(a)). Vehicles that are otherwise subject to design, construction and use requirements under road traffic legislation (reg 4(2)(b)).	Any part of a transport system - <ul style="list-style-type: none"> • within a harbour/harbour area, factory, mine or quarry, unless used for fare-paying passengers • used solely for building operations or works of engineering construction • within a maintenance or goods depot.
Duties placed on	Railway operators, ie infrastructure controllers, train and station operators.	Operators of the transport systems above.	Employers of employees engaged in safety critical work ⁹ in the transport systems above.

⁵ The Railways (Safety Case) Regulations 2000

⁶ The Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994

⁷ The Railways (Safety Critical Work) Regulations 1994

⁸ In due course further exclusions will be added for the conventional network.

⁹ Safety critical work is defined explicitly in terms of specific jobs such as drivers, guards, signalmen; work in a maintenance capacity which could affect the health and safety of persons on a transport system.

32 The scope of the Approvals and Safety Critical Work Regulations is partly defined by reference to a list of types of transport system. A similar approach is present in the Approvals Regulations to define the categories of works, etc which do not require approval and in the Safety Critical Work Regulations to define the work activities that are covered by the Regulations. This prescriptive type of approach can lead to difficulties of omission and legal interpretation of the many terms used, and may become outmoded as new transport systems are developed. It can also make it rather difficult to understand the overall legal 'picture', and to ascertain the legal position in particular cases.

33 The current legal distinction between a 'railway' and a 'tramway', which arises from the Transport and Work Act 1992 and depends on whether the rails are laid wholly or mainly on the street (or other public places), sits uneasily with the development of new light rail systems which often operate in 'railway' mode at some locations and in 'tramway' mode at others. This point affects only the Safety Case Regulations, since the other two sets of Regulations apply to railways and tramways alike. It is explored further in Chapter 3.

34 All three sets of Regulations enable HSE to grant exemptions or dispensations. Exemptions under the Safety Case Regulations tend to apply to specific minor or heritage railways, or to specific charter journeys which meet published HMRI criteria. Under the Approvals Regulations there is a 'general notice' containing a long list of specific types of works, plant or equipment for which approval is not required. In the case of the Safety Critical Work Regulations, the power of exemption has not been used.

Scope – the future

35 In developing the proposals in this document, HSC wishes to introduce greater clarity, simplicity and logic by avoiding unnecessary or inappropriate differences in scope. If a particular type of transport system presents risks that warrant some form of permissioning regime for works, plant and equipment, it may well follow that such systems should also be subject to some or all of the following -

- new requirements for safety certification and authorisation (replacing the existing Safety Case Regulations, see Chapter 3);
- requirements on competence and fitness (amending or replacing the Safety Critical Work Regulations, see Chapter 6); and
- the other arrangements proposed in this document for ensuring staff and supplier competence, including licensing and accreditation.

36 In developing the proposals HSC will look for opportunities to adopt a more 'generic' approach to definitions. This should help to make the legal position clearer and simpler to understand, reduce the need for HSE exemptions, and provide a sound and flexible basis for future developments.

37 HSC also wishes to explore the possibility of establishing a 'risk threshold' below which a transport system would be excluded from future permissioning requirements (that is, requirements on safety certification or authorisation in Chapter 3 and options for third-party assessment and HSE authorisation/approval in Chapter 4), and possibly from industry systems for suppliers and licensing as discussed in later chapters. HSC believes that such a risk threshold, if it could be established, would increase certainty and transparency, reduce greatly the current number of exemptions and dispensations, and help target industry's and HMRI's resources to best effect. A risk threshold might take the form of a number of conditions, some or all of which would have to be met, for example a maximum line speed (possibly 40 kph), segregation from the national network, simplicity of operation (for example the absence of conflicting movements), and limited scale of operation in terms of numbers of vehicle movements and/or passengers.

38 These aims stem from our objectives of securing greater coherence between the elements of the present regulatory system for railway safety, streamlining processes and requirements and reducing bureaucracy. In pursuing them, we will take account of the other objectives set out in Chapter 1 including, in particular, the objective of building public confidence that risks to railway passengers and staff are properly controlled and ensuring that, where reasonably practicable, safety on the railways is continuously improved in line with society's expectations.

Question 1: In responding to the proposals in the following chapters, HSC invites you to bear in mind the potential benefits of a greater commonality of scope. Are there any general points you would like to make on this issue?

Question 2: Do you agree that a risk threshold should be developed below which operators would be excluded from permissioning requirements, and perhaps from other requirements discussed in this document? If so, please suggest what the criteria should be. You may like to use the ideas in paragraph 37 as a starting point.

CHAPTER 3

REVIEW OF THE RAILWAYS (SAFETY CASE) REGULATIONS

OBJECTIVES

39 HSC's objectives in reviewing the Railways (Safety Case) Regulations 2000¹⁰ are:

- To improve the current Regulations, in line with the objectives in paragraph 14, including taking account of Lord Cullen's recommendations on safety cases that have not yet been actioned; and
- To implement relevant parts of the European Railway Safety Directive, taking maximum advantage of the opportunities it presents.

THE PRESENT RAILWAY SAFETY CASE REGIME

40 The Railways (Safety Case) Regulations were first introduced in 1994 to address the potential risks arising from the fragmentation of the industry and the entry of new operators to the industry following privatisation. Their primary purpose was, and remains, to ensure that safety standards are maintained and wherever possible improved. An important secondary purpose is to maintain public confidence in the safe operation of the railway. Despite their origin in privatisation, the Regulations have always applied not only to the main network but also to other railways such as the London Underground, Manchester Metrolink, and heritage railways.

41 The Regulations require railway operators (infrastructure controllers, train operators and station operators) to prepare and gain HSE acceptance of a detailed safety case before being allowed to operate. Safety cases serve two main purposes:

- To demonstrate that the railway operator has the ability, commitment and resources to properly assess and effectively control risks. In the case of train and station operators, this includes giving confidence to the infrastructure controller that they will not import undue risk onto the railway.
- To create a living, comprehensive document against which the operator's management, and HSE, can check that the safety management system and other arrangements described in the accepted safety case have been properly put into place and continue to operate in the way intended.

42 Railway operators are required to follow the procedures and arrangements set out in their safety case; to revise it when appropriate, and to

¹⁰ (SI 2000/2688)

gain HSE acceptance of 'material revisions'. They are required to undertake a thorough review of the safety case every three years, and to obtain an annual external health and safety audit from an independent 'competent body'.

43 In addition, infrastructure controllers are required to:

- scrutinise train and station operators' safety cases, and to recommend to HSE whether they should be accepted;
- obtain commitments from train and station operators to comply with the infrastructure controller's reasonable health and safety requests;
- take reasonable steps to ensure that train or station operators comply with their safety cases; and
- report serious non-compliance, and any failure to comply with reasonable health and safety requests, to HSE.

These additional duties are consistent with the infrastructure controller's wide-ranging duties under the Health and Safety at Work Act 1974, which involve ensuring that train and station operators do not import undue risk onto the railway.

44 The Regulations have been amended three times since their introduction in 1994. The most extensive changes were made in 2000 in response to the Ladbroke Grove disaster. Previously, the infrastructure controller accepted train and station operators' safety cases, and the infrastructure controller's safety case was accepted by HSE. However, under the Railways (Safety Case) Regulations 2000 all safety cases are now accepted by HSE. A brief history of the Regulations is at Annex 1.

45 HSE's formal guidance, Railway (Safety Case) Regulations 2000 – Guidance on Regulations (L52) reproduces and explains the legal requirements, and gives guidance on the content of safety cases.

46 The Regulations are administered by Her Majesty's Railway Inspectorate (HMRI), which is part of HSE. HMRI maintains a safety case assessment manual, published to support its staff and for use by railway operators. The manual describes the assessment process and includes extensive 'safety case assessment criteria' detailing the kind of evidence the Inspectorate requires in a safety case. The current version can be found at <http://www.hse.gov.uk/railways/rsc.htm>.

47 HMRI is required to recover from operators the costs of assessment and acceptance of safety cases and of any subsequent material revisions.

Experience of operating the current Regulations

48 Currently there are some 110 safety cases. About 20-30 'material revisions' are assessed annually. About 100 individual small or heritage

railways are exempted from the requirements. These exemptions are generally subject to conditions, including the submission of safety documentation, and to periodic review. In addition, about 70 exemptions, subject to conditions, are issued annually to permit individual passenger charter journeys into areas which do not generally require a safety case but where the carriage of passengers triggers the Regulations.

49 HSE's assessment of a safety case can be a lengthy and complicated process, involving the application of published assessment criteria and the exercise of professional judgment on the adequacy and credibility of the safety case. Many months may elapse between the start of the process and final acceptance, especially if the initial submission is incomplete or of poor quality or if complex issues arise. During that time, the safety case is examined by several HSE assessors, issues are logged and gradually resolved, and the safety case usually undergoes redrafting and refinement. 'Material revisions' are handled in a similar way.

50 After acceptance, the safety case becomes an important driver of proactive audit and inspection. For each railway operator, HMRI has a three-year 'intervention plan' reflecting its inspection priorities in relation to that operator. As part of the intervention plan HMRI checks the operator's progress in meeting its own 'development plan' (a required element of every safety case, containing time-bound commitments for improvement).

51 Problems and difficulties with the present safety case regime include:

- a) Public confidence in railway safety management remains relatively weak. The recurrence of serious incidents raises expectations for change, even though the statistical trends in railway safety are positive overall.
- b) HSE's 'hands-on' role in assessing the detail of operators' (often very lengthy) safety cases can undermine railway operators' ownership of their arrangements and their responsibility for managing risk.
- c) A lack of impetus to continuously improve health and safety. Contributing factors include:
 - i) an emphasis only on compliance with the safety case once accepted;
 - ii) the absence of a requirement to resubmit a safety case periodically – in effect once a safety case has been accepted, it cannot be 'unaccepted';
 - iii) although the safety case has to include a development plan setting out operators' commitments to further action, there is little incentive to do more; and
 - iv) the requirement to gain HSE's acceptance before making material revisions to the safety case (see below) has tended to discourage improvements as safety enhancements may amount to material revisions.

- d) The requirement to submit all material revisions for assessment and acceptance has been problematic because:
- i) it tends to 'freeze' the safety case by discouraging and delaying change, even when the change would improve health and safety;
 - ii) identifying when a revision is 'material' is not always easy;
 - iii) it incurs additional cost for the operator; and
 - iv) operators may have a sense, albeit erroneous in law, that their safety responsibilities are in some way shared or reduced by HSE's continuing say in the detail of the safety case.
- e) The very dominant position of the infrastructure controller, although somewhat diluted in the 2000 and 2003 amendments (Annex 1) may no longer be appropriate. While the infrastructure controller retains a key role and an overall responsibility, risk on today's railways has to be managed in active partnership. There is an increasing recognition of the risks that the activities of the infrastructure controller can pose to train operation. The present safety case regime could be said to downplay these risks compared to the risks that train operators can import onto the railway.

Stakeholder views so far

52 HSE officials have met 19 railway organisations informally to listen to their views on the current Regulations. A productive one-day 'stakeholder workshop' was also held in May 2003. A wide of support was expressed for the current regime, but also some criticisms, largely reflecting the difficulties referred to above. There was a wish for -

- a less detailed, more high-level safety case, not only to reduce bureaucracy but also to strengthen the position of HSE in holding operators responsible for their assessment and management of risk;
- clarity about what constitutes a 'material revision' of a safety case;
- recognition that the infrastructure manager's activities can bring risk to train and station operations, as well as vice versa; and
- greater alignment of the transport systems and operators that are required to have safety cases with the scope of the regulations on the approval of new/altered works and on safety critical work (see paragraphs 35 and 83-90).

Impact evaluation of the Safety Case Regulations

53 HSE commissioned new research to evaluate the impact of the Railways (Safety Case) Regulations. The work was undertaken by BOMEL

Limited, with economic support from National Economic Research Associates (NERA).

54 The nine-month research project commenced in January 2003. It included a stakeholder workshop, a large number of questionnaires, a number of face-to-face structured interviews and extensive reviews of safety cases and associated documentation to collect the required evidence with sufficient triangulation of data. Some of the key findings from the evaluation are summarised in Annex 2. These confirm that the Regulations have represented 'value for money'. In particular, the preparation of safety cases has been found to benefit railway operators, and the Regulations have stimulated a more pro-active use of risk assessment. These and other findings confirm the value of the current regime in maintaining and improving safety and in providing a basis from which new Regulations implementing the Railway Safety Directive can be prepared.

THE RAILWAY SAFETY DIRECTIVE

55 HSE's review of the Safety Case Regulations has to take full account of the European Railway Safety Directive. The Directive is at an advanced draft stage and is expected to be adopted by Spring 2004. Member states will then have two years to implement it. In HSE's view the 'common position' text of the Directive, which can be found at <http://register.consilium.eu.int/pdf/en/03/st08/st08557en03.pdf>, represents a positive outcome for the UK. Those parts of the Directive with greatest immediate relevance to this review are shown at Annex 3.

56 The aim of the Directive is to harmonise railway safety regimes across the EU, so that safety cannot be used as a barrier to access to a liberalised European railway market. The Directive puts in place general principles of railway safety management and a safety permissioning regime based on requirements to obtain a safety certificate or authorisation. The current safety case regime will therefore need to be amended to give effect to the requirements of the Directive, and this chapter considers how that might be achieved.

57 The Directive also puts in place a mechanism for introducing Common Safety Indicators (CSIs), Common Safety Methods (CSMs) and Common Safety Targets (CSTs) which will in time replace current national arrangements, and makes a number of other provisions.

General principles in the Directive

58 Article 4 of the Directive contains a number of general principles:

- Article 4.1 states: 'Member States shall ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Community legislation and technical and scientific progress and giving priority to

the prevention of serious accidents.’ This principle is supported by a requirement, in the Directive’s Annex III, for railway operators to show how they will ensure that their safety management systems are continuously improved.

- Article 4.2 requires that responsibility be placed on ‘railway undertakings’ (passenger and freight train operators) and ‘infrastructure managers’ (infrastructure controllers) to ‘implement necessary risk control measures, where appropriate in co-operation with each other, to apply national safety rules and standards, and to establish safety management systems in accordance with this Directive’.
- Article 4.2 also requires that ‘each infrastructure manager and railway undertaking shall be made responsible for its part of the system and its safe operation, including supply of material and contracting of services, vis-à-vis users, customers and third parties’.

In HSC’s view these principles are of central importance. They are fully in line with safety management philosophy and law in the UK.

Safety certificates and safety authorisations

59 The Directive requires (Article 10) railway undertakings to hold a safety certificate issued by the safety authority in the Member State where they were first established before being allowed access to infrastructure. Infrastructure managers are required (Article 11) to hold a safety authorisation issued in the Member State where they are established. Responsibility for issuing certificates and authorisations rests with the ‘safety authority’, which in Great Britain will be HSE.

60 Certificates and authorisations will be in two parts:

- Part A confirming acceptance of the applicant’s safety management system. In the case of a railway undertaking (but not an infrastructure manager), the Part A certificate will be valid throughout the EU for ‘equivalent rail transport operations’. The information to be provided in support of the application will therefore be about arrangements which would apply regardless of where they are conducted. ‘Equivalent rail transport operations’ is not defined in the Directive, but in HSE’s view reflects the type and extent of the operation for which the Part A certificate was issued. This could be based on, for example, criteria such as passenger or freight operation on high speed or conventional lines.
- Part B confirming acceptance of the applicant’s arrangements for meeting network-specific requirements. Part B certificates and authorisations will be valid only in the country of issue. A railway undertaking proposing to operate across borders will therefore need to obtain a Part B certificate in each member state where it proposes to operate.

61 The requirements for gaining a Part A certificate or authorisation are in Articles 9-11 and Annex III of the Directive. Article 9 contains a number of general requirements:

- Article 9.1 requires infrastructure managers and railway undertakings to 'establish their safety management systems to ensure that the railway system can achieve at least the CSTs, is in conformity with the national safety rules described in Article 8 and Annex II and with the safety requirements laid down in the Technical Standards for Interoperability (TSIs), and that the relevant parts of the CSMs are applied'.
- Article 9.2 requires the safety management system to meet the requirements and contain the elements in Annex III, 'adapted to the character, extent and other conditions of the activity pursued'. It should 'ensure the control of all risks associated with the activity of the infrastructure manager or railway undertaking, including the supply of maintenance and material and the use of contractors'.
- Article 9.3 requires: 'The safety management system of any infrastructure manager shall take into account the effects of operations by different railway undertakings on the network and make provisions to allow all railway undertakings to operate in accordance with TSIs and national safety rules and with conditions laid down in their safety certificate. It shall furthermore be developed with the aim of coordinating the emergency procedures of the infrastructure manager with all railway undertakings that operate on its infrastructure.'

Railway undertakings and infrastructure managers will need to show that their safety management systems meet these requirements when they apply for a safety certificate or authorisation.

62 More specific requirements and what are termed by the Directive as 'basic elements' of a safety management system are set out in Annex III of the Directive. These are broadly similar in effect to Schedule 1 of the current Safety Case Regulations, which sets out the requirements for a safety case.

63 The network-specific requirements for a Part B certificate are in Articles 10.2(b) and Annex IV of the Directive. Railway undertakings must provide documentation on the national requirements which they will meet, and on how their safety management system will ensure compliance with those requirements. This provides a link between the requirements of the Part A certificate and those of the Part B certificate. Information is to be provided on relevant TSIs (this can be in summary form); national safety rules, including regulations and industry rules; and other rules covering operations, staff and rolling stock. Information is also required on the categories of staff and rolling stock used, including evidence that they meet the requirements of TSIs or national rules and have been 'certified'. 'Certified' in this context would include how staff are assessed as competent and fit, including any requirements for specific certificates, qualifications, permits or licences, and

the acceptance and authorisation of rolling stock by the infrastructure manager and safety authority.

64 For infrastructure managers, the requirements for a Part B authorisation are in more general terms. Article 11(1)(b) describes the authorisation as ‘confirming acceptance of the provisions of the infrastructure manager to meet specific requirements necessary for the safe design, maintenance and operation of the railway infrastructure including, where appropriate, the maintenance and operation of the traffic control and signalling system’.

65 Railway undertakings must notify HSE ‘without delay’ of ‘all major changes in the conditions of the relevant part of the safety certificate’, and ‘whenever new categories of staff or new types of rolling stock are introduced’ (Article 10.5). There is no requirement for any of these changes to be accepted by HSE, or to be notified in advance.

66 Certain changes, however, require an updating of the certificate or authorisation, implying that application should be made to HSE in advance of the change. Safety certificates must be ‘wholly or partly updated whenever the type or extent of the operation is substantially altered’ (Article 10.5). Authorisations must be “wholly or partly updated whenever substantial changes are made to the infrastructure, signalling or energy supply or to the principles of its operation and maintenance” (Article 11.2). In many cases, changes which require an updated certificate or authorisation will arise from renewal or upgrading projects which require (under Interoperability Directives) authorisation following a third-party assessment by a notified body; having authorised the project under interoperability requirements the safety authority would issue an updated safety certificate or authorisation, provided the safety management system and network-specific arrangements remain satisfactory.

67 The Directive puts in place a process for achieving further harmonisation. A new European Railway Agency for Safety and Interoperability is to make recommendations within five years for migrating towards a common EU-wide safety certificate (Article 10.7). In addition, decisions are to be taken on common harmonised requirements for the Part B certificate within five years (Article 15).

68 The preamble to the Directive (recital 16) recognises that Member States will continue to operate some national safety rules for the foreseeable future. The Directive also provides for the Annexes to be ‘adapted to technical and scientific progress’ in future (Article 26).

Common safety indicators, methods and targets

69 Articles 5-7 of the Directive provide for the development of –

- Common Safety Indicators (such as signals passed at danger and broken rails);

- Common Safety Methods (for example risk assessment methods, and acceptance criteria for safety certificates and authorisations); and
- Common Safety Targets which 'define the safety levels that must be reached by different parts of the railway system and by the system as a whole in each Member State', expressed in terms of risk acceptance criteria for both individual and societal risk.

70 Common Safety Methods and Targets will be developed by the new European Railway Agency and agreed at European level. A first set of Targets, taking account of existing national targets, will be produced in 2009, leading to a definitive set in 2011. There will be a supporting statement of costs and benefits. Member States will not be required to reduce existing safety standards, and may introduce rules requiring safety levels which exceed the Common Safety Targets provided there is no disguised market restriction and certain notification and consultation requirements in Article 8 are followed. The achievement of Common Safety Targets is one of the aims, specified in Article 9.1 of the Directive, for the safety management system.

71 The Directive's aim of developing Common Safety Indicators, Methods and Targets is facilitated by requirements for annual reports from both railway operators and safety authorities. Railway undertakings and infrastructure managers are required by Article 9.4 to submit annual safety reports to the safety authority containing information on how corporate safety targets are met, and the results of safety plans the development of national safety indicators and Common Safety Indicators; the results of internal safety auditing; and 'observations on deficiencies and malfunctions of railway operations and infrastructure management that might be relevant to the safety authority'. The safety authority is required by Article 18 to publish an annual report of its activities containing information on the development of railway safety including aggregated information on Common Safety Indicators, important changes in railway safety legislation, the development of safety certification and safety authorisation, and results and experience of the safety authority's supervision of railway undertakings and infrastructure managers.

Other provisions

72 The Directive also covers a number of other issues, including access to training facilities (Article 13) and the establishment of independent accident investigation bodies (Articles 19-25), which are or will be implemented by other legislation or arrangements. A Rail Accident Investigation Branch has, for example, already been established through primary legislation, and is part of the Department for Transport.

Differences from the Safety Case Regulations

73 HSE considers that the Railway Safety Directive is in line with the approach in the Health and Safety at Work Act. There are however some significant differences of emphasis, procedure and detail from the present Safety Case Regulations. Two key differences are:

- a) The Directive has an explicit framework of general duties: to maintain and where reasonably practicable improve railway safety (giving priority to serious accidents), to establish safety management systems, to implement risk control measures, to apply national safety rules and standards. It also provides for the establishment of Common Safety Targets (CSTs) that must be reached by different parts of the railway system and by the system as a whole.
- b) Under the Directive, once a safety certificate and authorisation has been issued a railway undertaking or infrastructure manager does not have to secure the agreement of the safety authority before making changes to its safety management system or safety documentation (ie in future railway operators will not have to submit material revisions to HSE for acceptance). However, HSE will have to be notified of major changes, and will be able to check that the safety management system has been followed - for example, that the risks of change have been evaluated and risk control measures implemented as required by paragraph 2(d) of Annex III of the Directive.

74 Other differences are identified and considered under 'Issues for Discussion' below.

Advantages of the Directive's approach

75 HSC believes that the Safety Directive provides a good opportunity to address the difficulties or shortcomings associated with the present safety case regime (paragraph 51). Implementing its requirements should result in:

- a) Greater clarity of railway undertakings' and infrastructure managers' responsibilities for controlling risk and of their accountability. Once a certificate or authorisation has been issued it will be for railway operators to decide on any changes they should make to their safety arrangements (since there will be no requirement to seek HSE's agreement in advance), and operators will have to send annual reports on their safety performance to HSE.
- b) A sharper focus on railway operators' obligations to maintain and continuously improve safety and to control risk. The principles in Article 4 (paragraph 58) provide a framework of duties within which all must operate.
- c) A more dynamic regime, as operators will be able to make changes without having to wait for HSE to assess and accept them. At the same time, the requirement to notify HSE of major changes provides a safety net.
- d) Additional ability for HSE to monitor and intervene. Railway operators will have to notify major changes in their safety arrangements to HSE, and will have to apply for an updated certificate if they propose a

substantial alteration to the type or extent of their operation. Railway operators will have to re-apply for a safety certificate or authorisation every five years, and HSE will be able to revoke a certificate or authorisation.

- e) A more streamlined system. The current arrangements will be simplified, and delays in the system reduced, by removing the current requirement to gain HSE acceptance of material revisions. The present three-yearly review will be replaced by a less frequent five-yearly re-assessment. Operators based abroad who wish to operate in Britain will already have a valid Part A certificate from their own safety authority.
- f) A more equal position as between infrastructure managers and railway undertakings, resulting from the removal of the infrastructure managers' duties in paragraph 43.

76 Notwithstanding these advantages, some may consider that the introduction of more 'clear water' between HSE and infrastructure managers/railway undertakings could lead to an increase in risk. In particular, the ability to make major changes without gaining HSE's agreement might be considered a relaxation of control. The issue here is, in essence, whether sustainable safety improvement is best promoted by giving HSE a stronger 'hands-on' role in controlling the day-to-day actions of duty holders, or by putting responsibilities clearly and firmly on the duty holder and holding them accountable for their acts and omissions. HSC's view is that a more hands-on role is neither appropriate nor sustainable – in effect it would mean that HSE taking more responsibility for the running of the duty holder's undertaking. HSC believes the way forward is clarity of responsibility on the duty holder, backed by active inspection by an Inspectorate with the capability to challenge duty holders and hold them accountable. The changes in legislation will be accompanied by a review of how HMRI should work under the new regime.

77 Overall HSC believes that giving effect to the Safety Directive offers significant advantages in comparison with the present Safety Case Regulations.

Question 3: Do you agree with our assessment of the potential advantages of the Directive?

Implementing the Directive

78 New Regulations on the management of railway safety will be needed, which will implement the Directive and replace existing Safety Case Regulations. They will cover general principles for railway safety, and requirements for safety certificates and authorisations.

RECOMMENDATIONS FROM INQUIRIES AND INVESTIGATIONS

79 In preparing proposals for future consultation, HSC also wishes to take account of a number of recommendations which are outstanding from public inquiries and HSE investigations.

Lord Cullen's recommendations

80 Lord Cullen's Part 2 Report of the Ladbroke Grove public inquiry (insert link) includes a broad endorsement of the railway safety case regime. However it made a number of recommendations for change. Some of these have already been implemented through the Railways (Safety Case) (Amendment) Regulations 2003. The remainder are reproduced in Annex 4 and will be taken into account in implementing the Railway Safety Directive, either in the new Regulations or by supporting administrative arrangements. Proposals in response to specific recommendations by Lord Cullen are discussed below.

Potter's Bar

81 HSE's final progress report on the Potter's Bar derailment, published in May 2003 (<http://www.hse.gov.uk/railways/pottersbar/may03progrep.pdf>), recommended that HSE review its safety case assessment arrangements to see whether they can be more closely aligned to the prevention of catastrophic events. It is HSE view that this is consistent with Article 4.1 of the Railway Safety Directive (paragraph 58 above), and its implementation is taken up under 'Issues for Discussion' below.

ISSUES FOR DISCUSSION

82 The framework of future Regulations is reasonably clear from the Safety Directive. However, there are a number of issues affecting the Regulations and the operation of a new permissioning regime on which we would particularly welcome your comments and suggestions.

Scope of new Regulations

83 The Directive (Article 2) permits Member States to exclude:

- “ a) metros, trams and other light rail systems;
- b) networks that are functionally separate from the rest of the railway system and intended only for the operation of local, urban or suburban passenger services, as well as railway undertakings operating solely on these networks; and
- c) privately owned railway infrastructure that exists solely for use by the infrastructure owner for its own freight operations.”

84 Equally, the Directive does not prevent Member States from applying some or all of its provisions to any or all of the above systems. The current Safety Case Regulations apply to the systems in a) and b) above with the exception of tramways; but (broadly) not to those within c) above. (The definition of 'railway' in the Regulations excludes railways or parts of railways within factories, mines, quarries, harbours, harbour areas – unless fare-paying passengers are carried – and maintenance and goods depots.) It would, therefore, be possible to apply the new Regulations to all the railways that are subject to the current Safety Case Regulations, and also to make adjustments to the scope if appropriate (a number of possible adjustments are discussed below). In setting out their scope, the new Regulations may draw on the definitions of 'railway system', 'railway undertaking' and 'infrastructure manager' in Article 3 of the Directive, which in effect define the 'interoperable' European railway system, and then extend their scope to other railways and transport systems.

Infrastructure maintenance contractors

85 There are currently about 25 infrastructure maintenance companies (IMCs) that operate trains ('train' being widely defined to include road-rail vehicles), of which about 20 operate solely within possessions. All are subject to the Safety Case Regulations. They operate under contractual arrangements which require the preparation and acceptance by Network Rail or other client of an 'assurance case'. This is similar to a safety case, but non-statutory and not accepted by HSE. Network Rail as infrastructure manager has overall responsibility for the safety of maintenance and renewal work on its infrastructure, and must provide evidence on how it will discharge these responsibilities, including how it will manage the work of its contractors. HSC believes that the Directive is not intended to require IMCs to obtain a safety certificate or authorisation.

86 The safety cases of the existing 20 or so operators of road-rail vehicles operating solely within possessions largely duplicate their contractual assurance cases, and add an unnecessary and possibly confusing layer of documentation and control. The activity is essentially construction work and very different from normal freight or passenger operation. The experience of both HMRI and industry stakeholders consulted so far is that the railway safety case regime is not appropriate to infrastructure maintenance undertaken solely within possessions. The five or so IMCs that are permitted to operate trains outside possessions, in order for example to transport materials to a possession or for other maintenance or purposes, are in a somewhat different category; since their train operations on the running line pose risks that are, in principle, similar to those posed by passenger and goods trains operators. However, these IMCs are Network Rail's contractors and are required to comply with an assurance case. It could be argued that requiring them to comply, in addition, with a statutory permissioning regime adds little value, and that greater clarity of responsibility would be achieved by removing them from scope and placing reliance on Network Rail's duty to manage the safety of contractors' activities as described in its safety case (and in future in its evidence for a safety authorisation).

87 HSC proposes, therefore, not to apply the new Regulations to infrastructure maintenance companies. However their activities, both in terms of their maintenance and renewal activities and their operation of trains, will continue to be subject to scrutiny under the new Regulations via the safety authorisation of the infrastructure manager.

Note: paragraphs 86 and 87 are subject to legal advice as to application of the Directive to IMCs. If changes need to be made we will report them to the Commission orally.

Tramways

88 Tramways are outside the scope of the Safety Case Regulations. However, currently there is some arbitrariness in how the Regulations apply to transport systems that operate partly on the street and partly on a segregated track like a conventional railway. The whole of such a 'mixed' system is defined as either a 'tramway' or a 'railway', depending on whether the greater part of the track is laid on the street (or other public place) or not. Moreover, since new transport systems may be extended from time to time, it is possible for a mixed system to be a 'railway' at one time and a 'tramway' at another, falling in or out of the scope of the Regulations through the passage of time.

89 One approach would be to exclude from scope those parts of a tramway or railway that run in the street or other public place. However, this would run counter to developments in urban transport in which 'mixed' train and tram systems are increasingly considered as a single system. An alternative approach would be to bring tramways fully within scope of the new Regulations. As tramways are not part of the single European rail system we could then choose either to apply the requirements of the Directive in full or in part, or to establish our own national requirements. If we chose to apply the requirements of the Directive, we could take advantage of some in-built flexibility for the safety management system which can be 'adapted to the character, extent and other conditions of the activity pursued' (Article 9(2)). Tramways are considered further in Chapter 4.

Other guided systems

90 Other transport systems such as monorails and guided people movers that are outside scope of the single European rail system could also be brought into the new regulations. As in the case of tramways, we could choose either to apply the provisions of the Directive or to establish national requirements, but even if we applied the the requirements of the Directive it would be possible to set different or adjusted assessment criteria for them. Other guided transport systems are outside the scope of the Safety Case Regulations; however they are subject to the Approvals Regulations (in relation to which future options are discussed in Chapter 4).

A 'risk threshold'

91 Chapter 2 invited comment on the possibility of establishing a 'risk threshold' below which a transport system would be excluded from some or all of the regulations and proposals discussed in this document. This is a separate issue from the points of scope on which we are seeking your views below. If a particular type of transport were, in principle, brought (or retained) in scope of the current Regulations, specific systems of that type might still be excluded on the ground that they fall below the 'risk threshold'.

Question 4: Your views are invited on the scope of the new regulations for safety management, and in particular on:

- a) **The proposal to exclude operators of vehicles solely within possessions from scope of new Regulations (paragraph 86)**
- b) **Whether infrastructure maintenance companies operating outside possessions should be within or outside the scope of the new Regulations (paragraph 87).**
- c) **The two options for tramways in paragraph 50. Do you prefer either of them to the option of retaining the present position described in paragraph 88?**
- d) **Whether other guided transport systems (as discussed in Chapter 4) should be brought in scope (paragraph 90).**

Risk assessment

92 One of the basic elements of a safety management system required by the Railway Safety Directive is "procedures and methods for carrying out a risk evaluation and implementing risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or operations" (Annex III paragraph 2(d) of the Safety Directive – see Annex 3 of this document). This aligns well with HMRI's recent emphasis in operating the present Safety Case Regulations on effective change management based on assessment and management of risk.

93 The Railway Safety Directive is clear that railway undertakings and infrastructure managers must control risks arising from their activities (eg Articles 4.2 and 9.2). The Directive also provides for the future development of Common Safety Targets, expressed in risk acceptance criteria, that must be reached by different parts of the rail system and by the system as a whole (Articles 3(e) and 7), and Common Safety Methods that include common 'risk evaluation and assessment methods' (Article 6). HSE believes that these, and other parts of the Directive, make clear that railway undertakings and infrastructure managers must assess risks arising from their operations, and ensure that the outcome of the risk assessment is translated into appropriate risk controls. However, there is no requirement in the Directive for operators

to send their risk assessments to the safety authority as part of their application for a safety certificate or authorisation, or for the safety authority to examine the assessment in detail and check that for each identified hazard appropriate risk controls have been introduced. This is in line with the approach in the Directive whereby issue of a certificate or authorisation indicates that the safety authority is satisfied that the operator has the capability to control risks, but puts the responsibility for doing so firmly on the operator and makes them accountable for their safety performance.

94 One option for the future would be to rely on the existing duty on all employers in the Management of Health and Safety Regulations 1999 (which will implement the EU Framework Directive 89/931) to make a suitable and sufficient assessment of –

- a) the risks to the health and safety of his employees to which they are exposed whilst they are at work; and
- b) the risks to the health and safety of persons not in his employment arising out of or in connection with the conduct by him of his undertaking,

for the purpose of identifying the measures he needs to take to comply with the requirements and prohibitions imposed on him by or under the relevant statutory provisions'. ('Relevant statutory provisions' is a wide term covering the Health and Safety at Work Act and all regulations made under it.) The Management Regulations also include requirements to review the assessment and to cooperate with other employers who share the workplace.

95 Another option would be to include in the new regulations a specific requirement for railway undertakings and infrastructure managers to undertake a risk assessment of their railway operations, which would amplify the requirements of the Management Regulations by, for example, drawing on the existing requirements in paragraphs 4(a), (b) and (c) of Schedule 1 of the Safety Case Regulations to specify more about what should be covered and recorded in the risk assessment.

96 Under either option, in line with the Directive the risk assessment would not form part of the application for a safety certificate or authorisation under the new Regulations, but HMRI will be able to view it and if necessary challenge its suitability and sufficiency in the course of inspection.

Question 5: What approach should be taken to risk assessment in the new regulations? Do you have any alternative options to those in paragraphs 94 and 95 that are compatible with European requirements?

Standards

97 The Railway Safety Directive requires Member States to 'establish binding national safety rules and ensure that they are published and made available' (Article 8(1)). Such national safety rules include legislation, approved codes of practice and standards. The standards include Railway Group Standards under a system managed by the Railway Safety and Standards Board (RSSB). Operators within the Railway Group agree to follow railway group standards. This agreement is formalised in the terms of their licences issued by the Office of the Rail Regulator (ORR), which allow the Rail Regulator, after consulting HSE, to revoke a licence on the grounds of a serious breach of the Safety Case Regulations.

98 The architecture of health and safety legislation in Great Britain provides flexibility for progressive safety improvement by setting general legal duties supported by codes and standards. Railway Group Standards do not generally have the force of law, but a failure to meet a standard may provide evidence of a breach of law, such as the general duties of the Health and Safety at Work Act 1974.

99 Lord Cullen recommended that duty holders should be under a statutory duty to comply with Railway Group Standards in so far as they relate to matters of health and safety (Recommendation 21 in Annex 3). Railway Group Standards are the industry's own rules, and many are written in a way that inextricably links safety with technical reliability, efficiency and economic purposes. Furthermore the Group Standards system provides for indefinite or time-limited derogations (currently about 450 in number). In HSC's view, these points suggest that it would be inappropriate to give Group Standards the force of law.

100 However the picture on standards in the railway industry is changing. The emerging European Standards for railways (the Technical Specifications for Interoperability or TSIs) have been developed within a different framework and do have the force of law. Over time the TSIs will largely replace Railway Group Standards,

Stations

101 Under the present Safety Case Regulations, the infrastructure controller's safety case covers the track and electrical equipment at stations, but platform and wider station safety issues are subject to a separate station operator's safety case. This reflects the position in Great Britain where the station operator is generally separate from the infrastructure controller. By contrast, the Directive views station platforms and the means of access to them as part of railway infrastructure. Station operators in Britain are, therefore, 'infrastructure managers' in the Directive's terms, and will be required to obtain a safety authorisation from HSE in respect of platforms and passenger access ways. Although other parts of stations are outside the Directive's scope, the new Regulations could be applied to stations in entirety, in the same way as the Safety Case Regulations. The rationale for doing so

would be that controlling access to and from platforms depends on the layout and arrangements of the station as a whole, and that concourses and other station areas can in themselves present significant congestion and evacuation hazards. HSE believes we can go beyond the directive's requirements in this respect because such a national requirement would not interfere with the operation of the single European rail system or single market in rail products and services.

Question 6: Do you agree that new Regulations should apply to the whole of stations, as in the present Safety Case Regulations?

Health

102 The Directive refers only to safety, not health. However, occupational health and medical fitness issues such as fatigue have the potential to affect railway safety; and will therefore need to be considered within a safety management system. However, the terms of the Directive may mean that it is not possible to refer explicitly to health in the text of the new Regulations. Duty holders will still be bound by the general duties in the Health and Safety at Work Act and the Management of Health and Safety at Work Regulations to assess health risks and provide adequate controls. It is and will continue to be HSC's policy to promote greater attention to, and the improvement of, occupational health across all sectors, including transport.

Audit

103 One of the basic elements of the safety management system in Annex III of the Directive is 'provisions for recurrent internal auditing of the safety management system'. This is very similar to a requirement of Schedule 1, paragraph 5(d) of the present Safety Case Regulations. The Directive also requires railway operators to include the results of internal auditing in their annual report to the safety authority (see paragraph 71). This provision will replace current requirements to send audit reports to other affected railway operators and to HSE. It will enable HSE to review audit findings, request to see the full audit report if necessary, check that any necessary remedial action is being taken, and consider whether there are issues that should be drawn to the attention of other operators. HMRI inspectors may of course also ask to see audit reports in the course of inspections.

104 As the Safety Directive refers to internal audit only, HSE considers that it will not be possible to retain the existing additional requirement for annual external audit in regulation 9 of the current Regulations. However, the objectivity and integrity of audits is important, and HSC proposes to retain in some form the existing requirement that audits should be conducted by persons are sufficiently independent of the safety management system to ensure that the audit is objective, even though they may work in the same company. Operators would be free, and encouraged, to introduce an external perspective in their audit arrangements. To promote accountability HSC considers that there may be merit in requiring operators to make summaries of audit reports (or perhaps the full reports) available for public inspection.

Such a requirement would operate in a similar way to the existing duty under the Safety Case Regulations for operators to make available for public inspection their accepted safety case.

Question 7: Do you see any particular difficulties, or advantages, arising from the Directive's approach to audit? Do you consider that operators should be required to make summaries of their safety audit reports, or the full reports, available for public inspection?

Revocation

105 The Directive requires the safety authority to revoke part A or B of a safety certificate if it 'finds that the holder no longer satisfies the conditions for a certification which it has issued' (Article 10(5)). Similarly, an authorisation must be revoked 'if an authorised infrastructure manager no longer satisfies the conditions for a safety authorisation' (Article 11(2)).

106 Revocation on safety grounds means that the operator will no longer be able to conduct its business, and is therefore a major step. HSE believes the intention of the Directive is that revocation should follow where the safety authority is satisfied that the operator no longer has the capability to meet the minimum standards in the Directive. HSE will develop and publish procedures and criteria for revocation, and is discussing with the Rail Regulator and the Strategic Rail Authority how best to put this part of the Directive into effect. HMRI inspectors will continue to be able to use their existing powers to serve improvement or prohibition notices or to initiate legal proceedings.

Question 8: Do you have any views on the criteria for revocation, or on the process that should be followed?

Exemptions

107 As noted in paragraph 48 above, HMRI issues a significant number of exemptions from the Safety Case Regulations. Broadly these fall into two groups. The first is exemption for many small heritage railways, and other minor railways such as cliff railways and railways in working museums, where the requirement to have a safety case and the other provisions of the regulations can be out of proportion to the hazards and risks. About 100 such exemptions have been granted. Exemption is given subject to conditions such as operation at a line speed below 25 mph, and is subject the provision of acceptable safety documentation to HSE. The second group is exemptions for individual passenger charter journeys to areas which are normally excluded from scope, but where the carriage of fare paying passengers triggers the Regulations. About 70 such exemptions are issued annually. Before granting an exemption, HMRI considers the safety arrangements proposed for the journey and imposes conditions as appropriate. In terms of impact on risk, the current arrangements are not a particularly good use of HMRI's resources.

108 As indicated in Chapter 2, HSC would like to reduce the need for frequent exemptions from the future Regulations. If a 'risk threshold' can be established, as proposed in Chapter 2, below which the new Regulations would not apply, it would eliminate the need for many of the existing exemptions for self-contained heritage and minor railways to have a safety authorisation. In relation to individual charter journey exemptions, one possible approach would be to require the infrastructure managers of railways which normally only carry goods to apply for a safety authorisation if they wish to permit passenger charter operators onto its infrastructure. The charter operator would also have to possess a safety certificate which permitted such journeys. The flexibility in Article 9 to adapt the safety management system to 'the character, extent and conditions of the activity pursued' will help to maintain proportionality to risk. Once a new or amended certificate or authorisation is issued, individual applications for exemptions would no longer be necessary.

Question 9: Do you agree with the suggested approach to exemptions in paragraphs 107 to 108? If not, what do you consider would be an appropriate way forward that is consistent with European requirements?

Current provisions to be retained in new Regulations

109 HSC suggests that the new Regulations should include a number of additional provisions which are not explicit in the Safety Directive. They are similar to existing provisions in the Safety Case Regulations, and should be reflected in the new regulations:

- a) A requirement to consult employee representatives on the preparation of applications (including the supporting evidence) for a safety certificate or authorisation (existing regulation 14(8)-(9)).
- b) A requirement to make applications open for public inspection (existing regulation 14(1)(c)).
- c) Requirements to keep documentation, including audit reports, for set periods (existing regulation 14(5)).
- d) A right of appeal from a decision to refuse, or to revoke, a safety certificate or authorisation (existing regulation 15).
- e) A power for HSE to grant exemptions with or without limit of time and conditions, provided it is satisfied that an exemption would not prejudice safety. Exemptions should be few in number if a 'risk threshold' can be established and if individual charter journey exemptions can be eliminated. Any decision to grant an exemption would be based on HSE's assessment of risk. It would not be possible to grant exemptions in respect of the European rail system covered by the Directive.

Question 10: Do you agree that provisions on the above lines should be included in the new Regulations? Are there any other current provisions which you would like to see included? Please feel free to make more detailed suggestions on their content.

How the new permissioning regime might operate

Application

110 Under new Regulations, railway operators would apply to HMRI for a safety certificate or, in the case of an infrastructure manager, a safety authorisation, submitting the required evidence. HMRI will, as required by Article 12 of the Directive, publish an application guidance document explaining the requirements and the documentation that should be submitted. In due course common assessment criteria will be developed by the European Railway Agency for use by safety authorities throughout the EU (Article 6.3(b) of the Directive). HSE will seek to ensure that HMRI's experience in operating the current scheme in Great Britain will contribute to the development of the future EU common assessment criteria. In the meantime HMRI will review its safety case acceptance criteria in the light of the Directive and publish suitable criteria and guidance to accompany the new Regulations.

111 Safety certificates and authorisations will be valid for a maximum of five years after which the operator must reapply.

Assessment

112 As now, assessment of documentary evidence will remain a key part of the process which, for successful applicants, will result in the issue of a certificate or authorisation. However, there are several requirements in the Directive that will necessitate changes to the process of assessment which HMRI operates at present. For example the Directive requires HSE to reach a decision within four months of receiving all of the information required, including any supplementary information, it may request (Article 12). This contrasts with the present position in which it can take many months for a safety case, or even a substantial revision, to be accepted. Other indicators of change from the present process include the different approach to risk assessment to that currently taken (paragraphs 92 to 93); the priority that the Directive gives to the prevention of serious accidents (paragraph 58); and the fact that the Part A certificate is valid throughout the EU (suggesting that it should cover higher -level safety management arrangements rather than detailed precautions).

113 The Directive therefore signals a shift away from detailed safety cases and favours instead higher-level documents that demonstrate capability to operate safely based on the establishment of a safety management system that includes the necessary procedures, methods and arrangements. This approach is consistent with Lord Cullen's observation that safety cases have tended to become bureaucratic (recommendation 19 reproduced in Annex 4).

Lord Cullen also noted that the process of safety case acceptance should include a check that a system as described in the safety case is actually in place, and that the audit system should check that it is working in practice to ensure and improve safety (recommendation 22). It is also consistent with the view that a more optimal balance of HMRI resource allocation may involve a modest shift away from office-based assessment and acceptance of safety cases towards inspection 'on the ground', including activities such as pre- and post-acceptance inspection and audit (recommendation 22).

114 Although infrastructure managers retain a key role (Article 9.3 of the Directive), there are no explicit provisions in the Directive that they should scrutinise the safety documentation that train operators submit in support of an application for a safety certificate (cf paragraph 43 above). This is consistent with Lord Cullen's recommendation that HSE should no longer be dependent on the infrastructure controller for a recommendation on whether the safety case of a train operator should be accepted (recommendation 28 in Annex 4). However, HSC recognises that infrastructure managers have a proper interest in seeing the evidence for safe operation submitted by railway undertakings in support of application for a certificate.

115 HSC proposes that Lord Cullen's recommendation that infrastructure controllers should have the opportunity to make representations to HSE on train and station operators safety cases (recommendation 28) should be met by introducing administrative arrangements whereby, in future, HSE would forward the documentation received from a railway undertaking in support of their application for a safety certificate to the infrastructure manager with a request to send any observations to HSE in a timescale that is consistent with the 4 month period in which HSE has to come to a decision.

116 Similarly, in line with Lord Cullen's recommendations 28 and 30 (Annex 4), HSC also proposes that railway undertakings should have the opportunity to comment on the safety management system of the infrastructure manager and of other railway undertakings that could affect their operation. HSC proposes that these should also be met administratively, and would welcome your views on appropriate, workable arrangements – for example, on whether the infrastructure manager's application for a new or updated safety authorisation (and supporting evidence) should be sent to all train operators operating on its infrastructure or to a narrower group of railway undertakings selected by, for example, the Association of Train Operating Companies (ATOC).

117 The process of assessment is considered above, but a separate question is who should make the assessment. Although a safety certificate or authorisation can only be issued by the safety authority (Article 16(2)(e)) it is HSE's view that the process of assessment of the submitted safety documentation on the operator's safety management system could be undertaken by other appropriate bodies, particularly where there are standards against which the material submitted could be judged – the certification however would still be issued by HSE. An international standard for occupational health and safety systems in all work activities already exists

(OHSAS 18001: 1999), and there are plans to prepare at European level criteria for safety management systems for the European rail industry. In the future this could be adopted as a European standard. This opens up the possibility of adopting for the 'software' of safety management systems the same approach as has already started to operate for 'hardware', whereby notified bodies assess railway sub-systems and components against recognised standards. HSE authorisation would then follow if it received a report of compliance with and was satisfied that the proper procedures had been followed. Such an approach could release some HMRI resource which could be applied to inspection and monitoring. It may however result in some additional cost to industry.

Operation

118 As noted earlier, railway operators would have to:

- undertake risk assessments and document and maintain those assessments ;
- maintain safety and, where reasonably practicable, continuously improve it;
- maintain and improve their safety management systems;
- implement risk control measures, in cooperation with other operators as appropriate;
- apply national safety rules and European and national standards;
- meet the Common Safety Targets;
- notify major changes to HSE without delay; and
- report annually to HSE on their safety performance.

119 After issuing a certificate or authorisation HSE would, as under the existing safety case regime, be responsible for checking that the conditions and requirements are met and that railway operators comply with their legal requirements. On being notified of changes to a railway undertaking's or infrastructure manager's safety arrangements, HSE would take note of the changes, or make inquiries and advise the undertaking/manager, or take other action as it considers appropriate. HMRI would continue to inspect and audit railway operators' activities, and may use its general powers to enforce compliance with the law.

Question 11: Have you any comments on any of the issues raised under application, assessment and operation in paragraphs 110 to 119 above? In particular, do you agree that:

- a) Documentation on safety management systems should be less detailed than those submitted now under the safety case regulations? (paragraphs 112 and 113)
- b) Administrative procedures should be introduced to allow infrastructure managers and railway undertakings to make representations on each others safety management systems, and if so do you have any views on how such processes should operate? (paragraphs 114 to 116)
- c) The role of assessor of safety management systems should be undertaken by suitable notified bodies and that HSE's role should be to issue a final 'authorisation' (paragraph 117)? If yes, when should such a change be introduced, eg when specific standards for railway safety management systems have been adopted at European level, or more quickly?

Question 12: Do you wish to make any other points on how the new permissioning regime may operate?

Transitional arrangements

120 For railway operators with an existing accepted safety case, HSE will consider suitable arrangements to secure an orderly transition to the new regime. The new Regulations could require existing operators to obtain a safety certificate or authorisation by a certain date but, to avoid HMRI having to deal with a large number of applications at the same time, that date could be staggered for different operators. Such an approach was adopted in the transitional provisions of the existing Safety Case Regulations (regulation 16), where the deadline was linked to the date of each operator's three-yearly safety case review. The existing safety case could form a basis from which applicants would prepare the evidence supporting their application, but some changes would be needed to reflect the Directive's requirements and the need to obtain separate Parts A and B certificates. This may involve some reconfiguring of existing material and perhaps the preparation of a some new material. As noted above, in certain areas it may well be possible to submit rather less detailed information than in the existing safety case regime.

Question 13: At this stage do you have any particular views on transitional arrangements?

OTHER ISSUES

Question 14: Are there any other concerns which you would like to raise about the approach to implementing the Railway Safety Directive?

REGULATORY IMPACT ASSESSMENT

Question 15: An initial regulatory impact assessment is at Annex 5. Are there any comments you wish to make on it?

CHAPTER 4

REVIEW OF THE RAILWAYS AND OTHER TRANSPORT SYSTEMS (APPROVAL OF WORKS, PLANT AND EQUIPMENT) REGULATIONS 1994

OBJECTIVE

121 A regime that will ensure that risks arising from the introduction of new/altered works, plant and equipment on 'relevant transport systems' continue to be properly controlled.

HISTORY AND BACKGROUND

122 There has been an approvals regime for bringing new works into use on the railways since 1840. The Road and Rail Traffic Act 1933 extended approval to altered works in order to bring re-signalling and electrification works in scope and in 1994, following the Hidden Report into the Clapham incident, the approvals regime was further extended to cover new rolling stock. The current Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994 (ROTS) were made under the Transport and Works Act 1992. Originally, the authority to approve was vested in the Secretary of State for Transport and delegated to the Chief Inspector of Railways, but the Railways (Miscellaneous Provisions) Regulations 1997 transferred the power of approval to HSE.

Current requirements

123 The ROTs Regulations require operators of railways and other 'relevant transport systems' to obtain approval from HSE before bringing into use any new or altered works, plant and equipment that are capable of 'materially affecting' the safe operation of the system (reg. 4(1)). The term 'relevant transport systems', as defined under the Transport and Works Act, comprises:

- railways (including heritage and metro systems);
- tramways;
- trolley vehicle systems;
- prescribed modes of guided transport (defined in Schedule 1 of ROTs).

Definitions of these transport systems are provided at Annex 1.

124 The requirements in the Regulations do not depend on degree of risk. However, HSE may grant dispensation from the requirements of the Regulations for lower risk works, etc. by means of a General Notice, and also operates simplified, self-certification procedures (referred to in paragraph 29 of HSE's published guide to the Regulations) for an agreed list of minor works. HSE is in the process of preparing a new General Notice that will extend the

original list of dispensations in Appendix 1 of the HSE guidance to include other works such as Train Protection and Warning System installations, footbridges and minor alterations to platforms, where the risks are low and where formal approval adds little value to other existing requirements and standards. The Regulations also permit 'type' approval for some equipment such as rolling stock, signalling and other plant and equipment that will be manufactured in quantity.

125 The Regulations do not prescribe the process to be followed between initial submission of a proposal and the final approval, apart from the documentation to accompany a submission which is prescribed in Schedule 2 of the Regulations. However, procedures are set out in the guidance to the Regulations.

126 The scheme operator usually submits an outline design early in the planning stage. Depending on the scale of the scheme, meetings may begin several years before work actually commences and continue on a regular basis. This may include site visits and inspections until the works are completed to a satisfactory standard and formal approval is given. Her Majesty's Railway Inspectorate (HMRI) issues a 'letter of no objection' at key stages of the project to indicate that the works, if completed satisfactorily, are likely to be approved, although this does not guarantee approval. Normally approval can only be given for completed works but, exceptionally, duty holders may invoke Regulation 4(4)(a) to bring new works into use prior to approval where this is necessary to avoid interruption to existing services.

127 HMRI assesses proposals against the 'Railway Safety Principles and Guidance' (HS(G)153) suite of documents which incorporates high level principles (and some detailed guidance) dealing with railways and tramways, as well as against other health and safety legislation and British, European and industry standards.

128 New schemes submitted for approval may range in size from a proposal for a food kiosk on a station to a major new scheme such as the West Coast Route modernisation. In 2001/2 HMRI granted 406 approvals in total, the vast majority relating to stations, bridges, rolling stock, signalling and level crossings (ROTS applies to a small number of private level crossings which are not covered by an individual statutory order under the Level Crossings Act 1983 and to modifications to those level crossings).

DRIVERS FOR CHANGE

129 A number of factors have contributed towards the HSC's decision to review the approvals regime.

Interoperability

130 New requirements for an 'interoperable', trans-European railway system are gradually overtaking the national scheme in ROTs which HSE considers is incompatible with the establishment of a single European rail system and a single market in rail sub-systems and components. The Railways (Interoperability) (High Speed) Regulations 2002¹¹ disappplied ROTs from all high speed lines and regulations expected to come into force in late 2004 or early 2005¹² are expected to disapply ROTs from most of the conventional railway network, apart from some local lines. A proposed Directive in the Second Railways Package is expected to amend the Interoperability Directives to progressively extend requirements to all of the conventional railway system. These developments should mean that, by 2006, ROTs will have effectively ceased to apply to the mainline railway in Great Britain. The management and supervision of the interfaces between sub-systems on the mainline railway will be dealt with in the revised safety management regulations (see chapter 3).

131 However, ROTs will continue to apply to the other relevant transport systems. The 'remainder' of ROTs comprises:

- metros;
- heritage railways;
- tramways;
- trolleybuses;
- prescribed modes of guided transport systems (grouped for the purpose of this paper into the following categories: Maglevs, monorails, guided buses, people-movers, novel systems).

The proposals in this chapter are concerned solely with these transport systems (the 'remainder' of ROTs)

132 This is a significant and expanding group of transport systems and includes London Underground (LUL) (which carries more passengers than the entire national railway), other large, metropolitan metro systems such as the Tyne and Wear Metro and an increasing number of trams and guided buses.

HSC Statement on Approvals

133 The Health and Safety Commission (HSC) has stated [<http://www.hse.gov.uk/spd/spdca.htm>] that HSE will not directly approve goods and services where there is an adequate system of conformity (or third party) assessment in place. ROTs is one of the few direct approvals schemes still operated by HSE and must therefore be reviewed in the light of the HSC's stated policy and the move away from approval initiated by the interoperability requirements.

¹¹ Implementing Directive 96/48/EC

¹² Implementing Directive 2001/16/EC

Experience of operating the current Regulations

134 Experience of operating the regulations in practice has identified some problems with the current regime. At a fundamental level, there is an issue about the meaning of 'approval'. The guidance to the Regulations makes it clear that the responsibility for the safety of new/alterd works rests with the operator. However, HSE's role in approving new works may lead to differences in interpretation, particularly when new/alterd works that have been approved by HSE are implicated in a transport accident.

135 There are also difficulties with the use of regulation 4(4)(a) which was intended to be invoked in exceptional circumstances, but in practice is being used more frequently, to bring new works into use prior to approval. This may undermine the principle of 'approval' and suggests that the current approvals regime sometimes lacks the flexibility to meet the operational needs of modern transport systems.

136 Experience of the regulations in practice has also highlighted the need for closer integration of the approvals regime and railway safety case regimes. The demarcation between bringing new works into use and operational safety is not clear-cut and the 'grey' area at the interface between the two regimes can be confusing for duty holders.

Stakeholder Views

137 During March/April 2003 HSE conducted an informal consultation, seeking the views of key stakeholders, including representatives from the mainline railway, heritage railways, operators of trams and guided buses, trades unions and passenger groups. This was followed by a stakeholder workshop that provided a forum for stakeholders to discuss the future shape of the approvals regime.

138 In general, the views expressed reflected the issues outlined in paragraphs 134-136 as well as the following points:

- The approvals process and HMRI's input to new schemes is generally seen as adding value, particularly by smaller duty holders. Added value is greatest for higher risk and novel schemes.
- There is more ambivalence about the value of the approval itself. It is useful commercially in that it provides assurance to financial backers and gives added leverage over contractors, but has little intrinsic value.
- 'Letters of no objection' provide the green light to proceed to the next stage of the project and are commercially useful, but do not provide a

positive endorsement of key stages of a project or guarantee approval. In some cases they have remained in place for several years with no approval being given. Most stakeholders would prefer staged approval of new works.

- Stakeholders would like to see closer integration between the approvals and the safety case regimes.
- The approvals process can be lengthy and time-consuming. Duty holders are charged for approval, but may also incur financial penalties from financial backers for delays in delivering a new scheme.

Some Issues for consideration

Works, plant and equipment

139 It is important that any future permissioning regime for the 'remainder of ROTS' focuses on areas of highest risk. The list of works excluded from the approvals requirements has recently been extended to cover other low risk schemes such as footbridges. However, it could be argued that there is little added value in approving other small schemes such as small, commercial developments on stations. There is also a provision for certain minor works to be approved through a simplified, self-certification procedure, but again it is debatable whether these should be in scope at all. The consensus emerging from HSE's consultation so far is that the approvals process adds most value to large, complex schemes such as the Jubilee Line Extension and should not apply to minor works.

Question 16: HSC would welcome your views on the type of scheme that should fall within scope of any future permissioning regime for the introduction of new/altered works.

The railways safety management regime

140 Some of the transport systems which will remain in scope of ROTS post interoperability are also subject to the railways safety case permissioning regime. The Railways (Safety Case) Regulations cover all aspects of a railway operator's health and safety management system including arrangements to meet technical specifications for plant and equipment and for the design and procurement of new premises and plant¹³. The regulations are currently being reviewed in the light of the European Railway Safety Directive and Lord Cullen's specific recommendations on the safety case regime, although the continuance of a safety management regime for the railways is assured (see Chapter 3).

141 Feedback from our initial dialogue with industry stakeholders and experience of operating the two regimes in practice suggests that there is a need for greater integration between the ROTS approvals process and the

¹³ RSCR Schedule 1 (6) and (7)

assessment and acceptance of railway safety cases. Certainly there are areas of overlap and the boundary between 'bringing into use' and 'operations' is not always clear. For example, Schedule 1 of the Railways (Safety Case) Regulations deals with some initial integrity issues such as technical specifications and the procurement and design of new premises and plant. Similarly the approvals process includes consideration of some installation and operational issues in relation to bringing new works, plant and equipment into use. The review of ROTS and other railway legislation is an opportunity to inject greater clarity and coherence in order to achieve a better 'fit' between the two processes.

142 However, it could be argued that the safety case regime alone is sufficient to address societal concern about the safe operation of the railway, including risks arising from the introduction of new/altered works, plant and equipment. The majority of transport systems within the 'remainder of ROTS' are currently outside the scope of the safety case regulations and in fact only metro systems and heritage railways are in scope (and the majority of heritage railways hold exemptions). However, as discussed in Chapter 3, the new safety management regime could be extended to some of the other modes of transport within the 'remainder of ROTS'.

Safety critical goods and services

143 Chapter 5 discusses proposals for the development of an industry wide scheme for the accreditation of suppliers of safety critical goods and services. This would help to control risks at the point of supply thereby allowing for less stringent controls at the end of the supply chain, but it will only apply to goods defined as 'safety critical' the precise scope of which has yet to be agreed.

'Approvals' processes in Europe

144 A UK survey of members of the International Liaison Group of Government Railway Inspectors¹⁴ found that there are procedures for Government approval of rolling stock and infrastructure in all member countries, except Belgium where this responsibility currently lies with the Infrastructure Manager. The scope of approval regimes varies widely, both in terms of transport systems and types of works, plant and equipment captured. Some countries extend their approvals regime beyond the mainline railway to include trams, guided transport, etc. whereas others specifically exclude trams and other local transport.

145 There is also a wide disparity in the extent of the regulator's involvement in assessing new schemes. France, for instance, employs only two inspectors, whereas Germany employs six hundred staff. In general, countries that require or allow independent third party assessment are likely to devote less resource to approvals work, although there are some exceptions.

¹⁴ Members include Finland, Netherlands, Germany, Denmark, Portugal, Italy, Austria, Ireland, Switzerland, Belgium, France, Norway.

Value for money

146 We also need to consider whether a permissioning regime delivers value for money by considering costs (to industry and HSE) and comparing them with the benefits, both in terms of risk reduction and, more widely, in providing reassurance to passengers and society as a whole. The initial Regulatory Impact Assessment at Annex 7 sets out estimated costs and benefits of each option described.

IS A PERMISSIONING REGIME NECESSARY FOR THE INTRODUCTION OF NEW/ALTERED WORKS?

147 The general risks arising from the introduction of new works, etc. in other industries such as construction and manufacturing are considered to be adequately controlled by provisions in the Health and Safety at Work Act 1974 (particularly section 6 which deals with the design, manufacture, import and supply of articles for use at work) and secondary legislation made under the Act such as the Provision and Use of Equipment Regulations 1998 (equipment to be safe and suitable) and the Construction (Design and Management) Regulations 1994. However, these regulations are intended to address generic, rather than specific transport-related, risks and concentrate to a greater extent on risks to employees rather than the public. For instance, the Construction (Design and Management) Regulations 1994 focus on risks arising during construction and on ensuring that new structures can be safely cleaned and maintained, rather than designing out risks to the public. In contrast, the approvals regime addresses specific risks to passengers arising from the design of a structure, e.g. in relation to overcrowding or emergency evacuations at stations.

148 Transport systems in the remainder of ROTS are also subject to the Transport and Works Act 1992 (except in certain circumstances) which requires developers to apply to the Secretary of State for Transport for an Order to commence operations. Applications under the Act must address a wide range of issues including impacts and benefits in relation to safety. However, the main purpose of the Act is to address environmental concerns and to provide successful applicants with certain powers, e.g. to purchase land or close roads. Safety is a relatively minor element and in practice, applicants tend to focus on the safety benefits of a modal shift from private to public transport, rather than the integral safety of the proposed transport system.

149 The approvals regulations provide an additional layer of regulatory control for relevant transport systems which sits above these general requirements. Therefore one purpose of this review is to establish whether the continuation of a 'permissioning' type of regime for new work, etc. is necessary at all to ensure that current standards of safety are maintained. And, if such a regime is considered necessary, what form it should take?

Criteria for permissioning regimes

150 The HSC's recent policy statement on permissioning regimes (<http://www.hse.gov.uk/enforce/permissioning.pdf>) states that permissioning regimes will be introduced for industries or activities where:

- there is a high level of societal concern/aversion; and/or
- there is significant risk of multiple fatalities from a single/linked series of events; and
- the proposed regime adds proportionate value in terms of risk control and/or allows specific activities (with clear benefits to society) to proceed.

151 There is also an underlying presumption that a permissioning regime will be introduced for novel technologies in order to reassure the public that risks have been thoroughly identified and appropriate measures taken before the technology is brought into use.

152 The mainline railway industry satisfies all the criteria for a permissioning regime. However, the position in relation to the transport systems within the remainder of ROTs is more complex because they are so diverse. It is not possible therefore to apply a 'one size fits all' solution. Instead we need to consider the different transport systems against the criteria above and decide, in each case, whether the continuation of some form of permissioning regime is justified.

Metro systems

153 Metro systems are 'railways' as defined in the Transport and Works Act 1992. There are currently four metro railways - Glasgow Underground, Tyne and Wear Metro, the Docklands Light Railway and LUL and further extensions are planned. All other urban transit systems, e.g. Manchester Metrolink, are classed as tramways because they operate wholly or mainly on the road (see paragraph 158).

154 Metro systems share the same risks as the mainline railway, e.g. collision, derailment, etc and give rise to similar levels of societal concerns particularly where they operate underground. This may be due in part to the high profile Kings Cross disaster in 1987, when an escalator fire resulted in 30 fatalities. There have been no multiple fatality incidents on metro systems since Kings Cross, but a combination of recent incidents such as the Central Line derailment in January this year which led to 35 people being injured, and public disquiet about the changes in organisation and ownership which may put pressure on the management of safety, is likely to have contributed to societal concerns.

155 Major operators such as LUL have well-developed internal standards for the introduction of new works and, as safety case holders, they are required to describe in the safety case their arrangements for ensuring safety in relation to the design and procurement of premises and plant.

In these circumstances, an additional permissioning regime to the safety management one may not add greatly to risk control, but is likely to be justified in terms of assuaging societal concerns.

Question 17: HSC would welcome your views on whether a permissioning regime is necessary for the introduction of new/altered works, etc on metro systems.

Heritage railways

156 There are approximately 100 heritage railways operating in the UK with numerous schemes for extension and development. The total route length for all heritage systems is 687 km, greater than the London Underground [<http://ukhrail.uel.ac.uk/>]

157 Heritage railways are also 'railways' as defined in the Transport and Works Act, but the majority are entirely self-contained systems and only a few have track linked to the mainline railway. Heritage railways are often described as low risk because the majority operate at low speeds (i.e less than 40kmph). However, some larger companies such as the North Yorkshire Moors Railway, carry significant numbers of people, including a high proportion of children, particularly in holiday periods, and operate over significant lengths of track. All railways have the potential for a major incident from, for example, derailment, collision with motor vehicles at level crossings and, in the case of steam trains, boiler explosions. Chapter 18 of HMRI's Annual Report for 2001/02 describes four minor derailments, a buffer collision and a 'near miss' on a level crossing involving heritage railways.

158 Heritage railways are often small operations staffed largely by volunteers. They do not have the resources available to larger railway companies and therefore rely to a greater extent on the current approvals process to provide assurance and specialist advice. The only relevant, modern standards for heritage railways are in a draft section H of the Railway Safety Principles and Guidance. Heritage railways are within scope of the Safety Case Regulations, but the majority hold the exemptions. A permissioning regime for 'hardware' may add proportionate value in terms of risk control, particularly for larger, higher risk heritage railways.

(Note: Also included in this category are heritage tramways. These are generally tramways that operate heritage vehicles or replicas of them. Most operate in museums and as such do not entirely share the risks of modern street running light rail systems, though some share interfaces).

Question 18: HSC would welcome your views on whether a permissioning regime is necessary for the introduction of new/altered works, etc on some or all heritage railways.

Tramways

159 A 'tramway' is defined in the Transport and Works Act 1992 as a system of transport used wholly or mainly for the carriage of passengers and employing parallel rails which:

- a) provide support and guidance for vehicles carried on flanged wheels and
- b) are laid **wholly or mainly** along a street or in any other place to which the public has access (including a place to which the public has access only on making a payment).

160 Apart from a number of small heritage tramways operating as a visitor attraction, often within a museum, there are currently five tramways in operation (the Blackpool Tramway, Manchester Metrolink, Sheffield Supertram, Midland Metro, and Croydon Tramlink). There are also more than eight others either in construction or at some stage of planning, including extensions to existing systems. Tramways operate differently to railways because they are driven by 'line of sight' rather than signalling. This relies on the tram driver controlling the speed of the tram so that it can stop in the distance that can be seen ahead (line of sight). This mode of operation is common to both the street running and the segregated sections of tramway (except sections of the Manchester Metrolink which uses railway signalling). Operating speeds are usually about 50km/hour on the street and about 80km per hour on the segregated sections.

161 As explained in paragraph 4 of the Introduction, the public appears to have an underlying acceptance of accidents on the public highway compared with those on rail. This acceptance appears to extend to guided transport systems that run wholly or mainly on the road such as trams. Evidence from public consultations on new systems, such as the proposed West London Tram (<http://www.tfl.gov.uk/trams/initiatives/westlondon/wl-information.shtml>) suggests that public disquiet focuses on the potential for accidents to individuals – drivers, pedestrians, cyclists, etc. - rather than the possibility of a multiple fatality incident. This view is supported by the accident statistics. For instance, although there are an average of 200 tramway incidents per year, the majority involved road vehicles colliding with trams, or pedestrians crossing the tramway and none have resulted in multiple fatalities [<http://www.hse.gov.uk/railways/railwaysafety0102.pdf>].

162 However, trams share the usual railway risks such as collision (although this may be with other vehicles on the street running sections) and derailment and so there is the potential for a serious accident, particularly as the number of tramways increases. Certainly there have been a small number of multiple fatality incidents involving tramways in other countries¹⁵

¹⁵ Gothenburg, March 12 1992: 42 injured, 13 fatalities. Cologne, August 1999: 7 major injuries, 60 minor injuries.

and, if such an accident was to occur in Great Britain, public disquiet might increase considerably and change its focus to major accidents.

163 The construction of new tramways on the public highway is subject to appropriate elements of road traffic legislation, but trams are exempt from the requirements in the Road Vehicle (Construction and Use) Regulations. In the absence of any common national or international standards, the guidance set out in section G of HMRI's Railway Safety Principles and Guidance is considered by the tram industry to be the benchmark of safety.

164 The distinction between a 'railway' and a 'tramway' is becoming less relevant as local authorities develop integrated, urban transport systems incorporating elements of both modes of transport (see chapter 3, paragraph 88). Given that tramways share the usual railway risks and have the potential for a multiple fatality accident, HSC considers that there is a case for a permissioning regime for the introduction of new/altered works on tramways to help control risk and provide reassurance to the public.

Question 19: HSC would welcome your views on whether there should be a permissioning regime for the introduction of new/altered works on tramway systems.

Trolleybuses

165 A 'trolleybus' is a normal highway bus that is powered by an electric motor instead of diesel or petrol. The electrical energy is transmitted to the vehicles through overhead wiring similar to that for tramways, though of a more complex nature. Although trolley buses run along a fixed route, the overhead connections allow for limited steering.

166 At present there are no public service trolleybus systems in Britain, though there are a small number of museum-based systems. Trolleybus systems are largely in competition with tramways in the public transport market so there is a possibility that public systems could be constructed in the future as the economics of the market change. Although they are 'unguided', trolleybuses have required approval in the past because of the particular hazard presented by the overhead electrification in public areas. However, it could be argued that these hazards are now adequately controlled by provisions in the Electricity at Work Regulations 1989 and the Electricity, Safety, Quality and Continuity Regulations 2002. As a road based transport system, trolleybuses are also expected to benefit from the greater public tolerance of road traffic accidents described earlier. HSC therefore considers that a case for a permissioning regime is not justified for any future trolley vehicle systems.

Question 20: HSC would welcome your views on whether there should be a permissioning regime for the introduction of new/altered works on any future trolley vehicle systems.

Magnetic Levitation systems (Maglev)

167 A 'Maglev' is a transport system, which runs using high powered magnets to raise vehicles above the track and also to propel and brake them. With friction almost eliminated, Maglevs can be propelled forwards at speeds of up to 400 km/hour for very high speed train services.

168 There are no 'Maglev' systems currently operating in Great Britain, although there used to be a small system linking Birmingham airport and the adjacent railway station which has now been closed. HSE is not aware of plans for any further Maglevs but this may change as the technology improves and certainly, prototype systems have been developed in China, Germany and Japan. As Maglev systems have the potential to operate at high speed, the risks and consequences of collision are comparable with other railways. In addition, as this is an emerging and novel form of technology, some form of permissioning regime may be necessary to reassure the public that risks have been thoroughly identified and appropriate measures taken before they are brought into use. Therefore HSC considers that a permissioning system is likely to be needed.

Question 21: HSC would welcome your views on whether there should be a permissioning regime for the introduction of new/altered works on Maglevs.

Monorails

169 A monorail is a single rail serving as a track for passenger or freight vehicles. In most cases the rail is elevated, but monorails can run at ground level or below ground. Vehicles are either suspended from, or straddle, a narrow guideway.

170 The five monorail systems operating currently in Great Britain are located in amusement parks and zoos (e.g. Chester Zoo). These systems can carry large numbers of people. There was a collision in 1996 on a (now defunct) system at Butlins in Minehead resulting in 7 minor injuries. However, there are proposals for three new monorails that would operate as urban transport systems in Portsmouth, Hull and London. The Portsmouth proposal for a large-scale public transport monorail is fairly well advanced and the Hull scheme has been under discussion for a number of years.

171 There are specific risks associated with monorails, particularly elevated systems where there are obvious hazards in relation to derailment, evacuation in an emergency and road vehicles colliding with the support structure. All types of monorail also share the usual railway risks such as collision. There have not been any multiple fatality incidents in this country, but there have been serious incidents on monorail systems in other countries. For example, there was a serious incident in Germany in 1999 when a derailment on the Schwebbahn suspended monorail caused one of the vehicles to fall into the river Wupper resulting in four fatalities.

172 Urban monorails are very new to GB and, as each system is built to an individual prototype there are currently no common standards across the monorail industry. HSC considers that this increases the need for some form of permissioning regime to reassure the public that appropriate expertise and sound professional judgement have been applied in the assessment and management of risk.

Question 22: HSC would welcome your views on whether there should be a permissioning regime for the introduction of new/altered works on monorails.

Guided buses

173 Guided buses are normal buses that are capable of operating on a road, but are guided for all, or part of their route along concrete bus 'corridors'. So far those constructed in Britain have been of a type which uses two parallel raised kerbs, where the buses are equipped with a set of guide wheels, located at the front wheels, that extend outwards against the raised kerbs to guide the bus along the corridor. Other types of systems where the buses are guided by buried cables or by a central rail or slot exist, but have not so far been built in Britain.

174 HSE is currently aware of three guided bus systems in operation with a further eleven planned or under construction. Guided buses, like trams, benefit from the public's greater acceptance of accidents on the public highway. This is supported by a very low risk profile of only 0.3 passenger fatalities per billion passenger km (see Chapter 1, Table 1).

175 The operation of guided buses on the public highway is subject to various Road Traffic Acts. In addition, the design and construction of guided buses is closely regulated by the Road Vehicles (Construction and Use) Regulations 1996. The approvals process currently adds value only in relation to the 'guided' elements of the bus systems which are not covered by other standards or regulations. In HSC's view a permissioning regime for just this part of a guided bus system adds little value.

176 There are proposals for systems that will have significant sections of 'cross country' running well away from highways. In all cases these are along old railway formations, with sections of unguided, on-street running at the ends where they re-enter the normal traffic systems. The status of these proposed systems in relation to transport legislation is uncertain as the cross-country sections may not be deemed to be public highways as defined. Nevertheless these will still be guided bus systems, albeit operating in a different environment and as such HSC considers that a permissioning regime will add little value for the reasons outlined above.

Question 23: HSC would welcome your views on whether there should be a permissioning regime for the introduction of new/altered works on guided buses.

People-movers

177 People-movers typically run along a single track and are guided wholly or mainly by wheels that bear outwards against fixed apparatus. They are most commonly used in airports to transfer passengers from one terminal to another, e.g. at Gatwick airport. HSE is aware of four of these systems operating currently and a further two are planned. They are usually quite small, typically carrying up to 30 people per car at one time, and run short distances along fixed routes at low speed. All the current systems are fully automated which means that consideration of safety at the design stage is important to ensure that the system will 'fail safe' in the event of a breakdown.

178 In the absence of UK standards in these areas, the high level principles in the Railway Safety Principles and Guidance, part 1 usually guide the development of new systems. HSC considers that a permissioning regime may be justified for people movers to ensure that risks arising from automation are properly addressed at the design stage.

Question 24: HSC would welcome your views on whether there should be a permissioning regime for the introduction of new/altered works on people-movers.

Novel transport systems

179 Local Authorities are generally receptive to new modes of transport that may encourage modal shift from private to public transport. One recent example of a new form of transport using novel technology is the 'Ultra' personal rapid transit system which may be piloted at a demonstration site in Cardiff. The Ultra is an automatically controlled personal taxi system running on its own guideway. It is intended to bridge the gap between private and public transport by providing individual transport in a public transport context. (<http://www.atstld.co.uk/>). It is uncertain whether the Ultra will progress beyond the pilot stage, but this is an area of transport where new technologies are encouraged and will emerge in future.

180 As explained earlier, there is a presumption that a permissioning regime will be introduced for novel, potentially hazardous, technologies in order to reassure the public that risks have been properly identified and appropriate control measures identified. For this reason it is important that the scope of any future permissioning regime for the introduction of new/altered works is defined so that it can capture novel schemes.

Question 25: HSC would welcome your views on whether there should be a permissioning regime for the introduction of new/altered works on novel forms of transport such as the Ultra.

PERMISSIONING REGIMES- DIFFERENT MODELS

181 ROTS is one type of permissioning regime which involves HSE directly in the approval of new works, but it is also useful to look across at other models which could be applied.

The 'interoperable' model

182 Interoperability is effectively introducing an alternative model for the introduction of new works, plant and equipment that will run concurrently with ROTS for a short while. Under the new procedures for a European interoperable railway, the railway is divided into broad 'sub-systems', e.g. infrastructure, signalling, etc. Each sub-system is subject to agreed European standards – the technical specifications for interoperability (TSIs) - which, when met, deliver the essential requirements for interoperability. Detailed checking of new subsystems against the relevant technical standards for interoperability is carried out by third party 'notified bodies' appointed by the Strategic Rail Authority and accredited by the United Kingdom Accreditation Service. HSE/HMRI's role is restricted to screening applications to check that they are in scope of the interoperability regulations and 'authorising' new schemes at key stages. Essentially this involves checking that the notified bodies have done their job and due process has been followed. In this model HSE is one step removed from direct involvement in the assessment of schemes, but is still responsible for authorising new/altered works.

183 As it is likely that at least a few local lines on the mainline railway will remain in scope of ROTS until 2006 when the Interoperability (Amendment) Directive is required to be implemented, some railway operators will find that they have to follow two different processes depending on whether a line is 'interoperable' or not. It is also possible that the principles of interoperability will eventually be extended to some of the other transport systems in the remainder of ROTS through proposals at European Union level. For instance, the European Commission is funding a study project¹⁶ to look at the feasibility of developing harmonising European standards for trams. As the interoperable system becomes more established it may become harder to justify retention of the current approvals regime. We therefore need to consider whether some degree of 'convergence' with the interoperable system is desirable.

The 'lifecycle' model

184 This model addresses the whole 'lifecycle' of new processes from concept/design to revocation/decommissioning, under a single permissioning regime. The nuclear industry, the onshore chemical industry and the offshore gas and oil industries all follow the 'lifecycle' approach, although the procedures may differ.

¹⁶ The Light Rail Thematic Network (LibeRTIN)

185 All these regimes include a requirement for some form of early notification of design details, as follows:

- major hazard chemical sites onshore - notify basic details 'within a reasonable period of time prior to construction of an establishment';
- offshore oil and gas installations - submit a 'design safety case' for all new installations;
- nuclear installations - prepare a 'Preliminary Safety Case' at the design stage followed by a 'Pre-commencement' (construction) safety case.

186 In all cases, HSE assesses the information provided and may produce recommendations for consideration by the operator. Some regimes require HSE to formally accept or authorise new designs. In others any outstanding issues are resolved at later stages in the 'lifecycle' of the process through assessment and/or inspection. For instance, in the offshore regime, any recommendations that have not been adopted by the operator will be identified and resolved in the operational safety case which must be accepted before operations can commence.

187 This model may also include an element of independent third party assessment. The offshore safety case regime, for example, includes legal requirements for independent, third party verification of design/operational issues from the pre-design stage onwards. Verification Bodies such as Lloyds Register give assurance to the operator that they have met their stated performance standards, but also exercise a challenge function by encouraging operators to raise standards. Nuclear licensees are also strongly advised to seek peer review of safety cases by suitably qualified, experienced and independent assessors who may be internal or external.

188 The 'lifecycle' model offers an holistic approach to safety which avoids any artificial distinctions between design and operational safety and is flexible enough to incorporate some degree of third party assessment. It is also very much in line with thinking on railway safety at a European level. For example, Annex III of the draft Railway Safety Directive, which sets out the basic elements of a safety management system, refers to 'procedures to ensure compliance with standards and other prescriptive conditions throughout the life-cycle of equipment and operations'. In this model, HSE 'accepts' the operator's overall safety management system, including arrangements for managing the introduction of new works, but does not necessarily have to approve or authorise design details. The lifecycle approach places the responsibility for the safe introduction of new/altered works firmly on the operator.

Question 26: HSC would welcome your views on which model (interoperability or lifestyle) of permissioning regime might be

appropriate for the transport systems identified in the second section of this chapter (4)

OPTIONS

(1) No change

189 Under this option HSE would retain ROTS in its current form with no further amendment (apart, of course, from the changes introduced by interoperability which are implemented by the relevant regulations).

190 This would involve the least disruption to the stakeholders in scope of ROTS in that stakeholders would not need to come to terms with a new set of requirements. It would also be cost neutral. As discussed earlier, interoperability will gradually take the entire mainline railway out of scope of ROTS during the next few years. In the medium term, it is likely that the principles of interoperability will be extended to other transport systems such as trams and metros and this will reduce the scope of ROTS still further until it gradually withers away over time. It may also be that, as procedures and awareness improve, other types of minor works can gradually be taken out of scope by means of further General Notices. This will improve the targeting of resource on higher risk schemes, reduce costs to stakeholders and go some way to address doubts about the need for HSE approval of minor works.

191 However, taking no action at this point will fail to address most of the key issues already identified such as the justification for a permissioning/approvals regime, the meaning of approval, value for money, targeting of HSE resources to high risk schemes, fit with other legislation, and concerns about process. To do nothing would also leave ROTS largely outwith the HSC's policy on approvals (see paragraph 133).

192 Further dispensations may satisfy stakeholders in the short term, but there is bound to be pressure to take other small developments out of scope, e.g. commercial concessions on railway stations. Other railway legislation will move forward and develop out of step with the approvals regime. In the medium to long term, the retention of ROTS in its present form will become increasingly anomalous and difficult to justify as the principles of interoperability are extended to other forms of transport and HSC/E withdraws further from direct approval schemes.

(2) Amendment

193 Under this option HSE would retain the regulations, but amend them to move to a risk based philosophy, addressing some of the key issues above. Possible revisions include:

- narrowing the scope to remove some of the 'other transport' systems, e.g. trolley/guided buses, which could be controlled solely under road transport and not a mixture of legislative regimes as now;

- narrowing the scope to focus on complex, high risk schemes and/or giving HMRI a formal 'screening' power, similar to that used for the high speed interoperable railway, which would allow them to screen out lower risk schemes (this is already done to a certain extent);
- providing for 'fast tracking' of proposals which have been independently assessed by a third party.

194 This option would have several advantages. In common with option 1 (no change) it would involve minimal adjustments for stakeholders who would not need to come to terms with a new set of requirements. A focus on high risk transport systems and schemes would provide better justification for the retention of a permissioning regime, improve the targeting of HSE resource on high risk schemes, reduce costs to stakeholders and deliver better value for money overall. The option for third party independent assessment would provide an alternative and probably quicker route to approval with reduced input from HMRI and achieve some degree of convergence with the European system for interoperability. Stakeholders would incur costs for procuring independent assessment, but these would be balanced, at least in part, by a corresponding reduction in HSE charges.

195 Other improvements could perhaps be achieved by improving the guidance to the Regulations and associated procedures, e.g. to provide more clarity on the relationship between the approvals and safety case regimes.

196 However, this option would not address key issues in the review such as whether a permissioning regime is justified for new/altered works, etc. and whether HSE should continue to be involved in direct approval schemes. It would also fail to address fully the interface between ROTS and the safety case regime and would be out of step with procedures for the interoperable railway.

(3) Revocation/'interoperable' approach

197 This would involve revoking ROTS completely and replacing it with new regulations to introduce a system of third party assessment for higher risk transport systems and schemes, with final 'authorisation' by HSE. Although the transport systems in scope would not be 'interoperable' in the European sense, they would be assessed to common standards.

198 The main advantage of this approach is that it allows HSE to withdraw from the direct approval of new works and to adopt a more detached 'authorisation' role consistent with the European interoperable system for the mainline railway. It would also release HMRI resource for other priorities.

199 However, there are several disadvantages in adopting this approach. On a practical level, it would take time to develop and agree standards for the different transport systems in scope of ROTS, although the Railway Safety Principles and Guidance could form a useful starting point for some transport

systems such as tramways and heritage railways and design specifications could be used as a starting point for the development of standards for other systems such as monorails. It would also take time to identify (and accredit if necessary) independent third party assessment bodies. Given the diversity of transport systems within the remainder of ROTS, it might be necessary to have different sets of standards with different notified bodies for each mode of transport. There is some doubt about whether the industry has the capacity to provide independent third party assessment in all areas but, where they exist, industry associations might be willing to take on this role.

200 It has also been suggested that a system of third party independent assessment may not provide sufficient assurance to operators and the public that new schemes are safe. For instance, some stakeholders believe that third party assessors operating for profit would lack HSE's independence and objectivity. However, third party assessment works well in other industries and in principle there is nothing to prevent it operating equally well in the railway industry.

201 At a more fundamental level, it may be difficult to justify requiring the industry to pay for an interoperable/authorisation model that does not deliver any benefits in terms of interoperability across Europe. The majority of heritage railways and some people movers in particular would incur new costs as they are currently exempt from charging under the approvals regime (see initial Regulatory Impact Assessment at Annex 7).

(4) Revocation/lifecycle approach

202 This option would involve revoking ROTS and developing a 'lifecycle' approach to safety on railways and other relevant transport systems within the new safety management permissioning regime which will replace the Safety Case Regulations (see Chapter 3). In practice this would mean:

- building a design notification requirement for major new works and modifications into the new regulations; and
- extending the new regulations to transport systems in the remainder of ROTS that satisfy the criteria for permissioning regimes.

(Note: The European Railway Safety Directive will introduce common EU wide requirements for safety certificates and will restrict the extent to which the UK can diverge from the European norm in domestic safety management regulations for the mainline railway (see chapter 3). However, Article 2 of the Directive gives Member States discretion to apply their own national requirements to light rail, tramways, etc. There is no single EU system for these modes.)

203 This option could also include a requirement for independent third party, or conformity, assessment. The interoperable model offers a structured system of third party assessment based on accredited notified bodies, but there are other types of conformity assessment. In some industries, for

instance, dutyholders are required to select a 'competent body', which may be internal or external as long as it has sufficient independence to carry out an objective assessment.

204 The advantage of the lifecycle model is that it addresses risks arising from the introduction of new works within the context of overall operational safety and focuses resource on the design stage when intervention can be most effective. This would be a change in emphasis from the current focus on bringing new works into use.

205 If this option is taken forward, HSE will need to consider whether it should formally 'authorise' or 'accept' designs of new/altered works or not. The advantage of the offshore model (see paragraph 186) where HSE does not accept design details, is that it firmly places responsibility for safety of design on the operator. However, there are risks if HSE's recommendations are ignored and/or the design is altered during construction. It is much more difficult for HSE to intervene effectively when money has been invested and systems are nearly complete as this may have major cost implications for the operator.

206 The lifecycle option has a number of attractions. Firstly, it would allow HSE to withdraw from direct approval of hardware whilst retaining some control over the introduction of major new schemes on transport systems within the remainder of ROTS. It would focus HMRI effort on higher risk transport systems and schemes and preserve those elements of the approvals process that stakeholders feel add the most value for money (e.g. the 'challenge' function). It would also integrate the approvals and safety case regimes, allowing for a more holistic approach to safety on the transport systems in scope. A requirement for third party assessment would also be consistent with procedures for the interoperable railway and provide added reassurance to the public.

207 However, there are some difficulties with this approach. As stated previously, most of the transport systems within the remainder of ROTS, with the exception of metros and heritage railways, are currently outside the scope of the Safety Case Regulations. In order for the new requirements to apply, all transport systems that satisfy the criteria for permissioning regimes would need to be brought within scope. This would clearly involve some extra costs to new duty holders who would have to commit resource to developing safety cases, although many operators will already have a written health and safety management system. New dutyholders will also be charged for assessment and acceptance of safety cases, except those operating at low speeds, such as the majority of heritage railways, which will continue to be exempt from charging.

208 A requirement for third party assessment is also likely to increase costs to industry, particularly the majority of heritage railways and some people-movers which are not currently charged for approvals work. However, a system that allows duty holders to use internal assessors with sufficient independence from day-to-day safety management to ensure objectivity, or

the provision of services by industry associations, may provide less expensive routes to compliance.

(5) Revoke ROTS/no replacement

209 The final option is to revoke ROTS and not replace it at all, relying instead on general health and safety requirements, the railways safety management regime (for metros and heritage railways), other legislation and standards to control the risks arising from the introduction of new/altered works, plant and equipment.

210 The main advantages of this option are that HSE would withdraw from direct approval, transferring responsibility for the safe introduction of new/altered works, plant and equipment from HSE to stakeholders in line with the approach taken in other industries. It would also reduce costs to industry significantly and align wholly with current HSC policy.

211 However, there are several disadvantages to this approach. Unlike construction and manufacturing, the railway industry attracts significant societal concern. This may be less relevant to transport systems such as guided buses, but HSE believes the public expects some form of regulatory intervention in the design and installation of transport systems that convey significant numbers of passengers, e.g. metro systems. It might also be argued that the current patchwork of legislative requirements and standards is not sufficient to support the safe introduction of new works, plant and equipment (see paragraphs 147 and 148). Other regulatory options also allow HSE to withdraw from direct approval, but to retain some control over safety either through authorisation or through acceptance of the safety case, providing reassurance to the public and to some of the smaller operators who may find it difficult to cope with the complete withdrawal of HSE involvement in new schemes. Finally it would be difficult to justify this option in view of the restrictions and controls placed on the introduction of new/altered works, plant and equipment on the national railway by the interoperable model.

Question 27: HSC would welcome your views on which option should be taken forward and whether there are any other options that should also be considered.

THE WAY FORWARD

212 No options have been discarded, but at this stage HSC considers that option 4 may represent the best way forward, i.e. revoking ROTS and incorporating a design notification requirement into the revised railway safety management regime. HSE also suggests that the new safety management regulations should be extended beyond railways to include transport systems that meet the criteria for permissioning regimes. HSC invites discussion on whether, if this model is adopted:

- HSE should accept or authorise designs;

- operators should be required to procure third party assessment of new/altered works by a competent body.

213 HSC considers that this option would meet the main objective of the review by ensuring that risks arising from the introduction of new/altered works on relevant transport systems continue to be properly controlled through a combination of independent, third party assessment and HSE assessment/acceptance of design details. This option would also deliver the specific objectives of the review in that it would:

- allow HSE to withdraw from direct approval in line with HSC's statement (see paragraph 133), whilst ensuring that an appropriate system of conformity assessment is in place to control risk;
- retain the 'added value' of the ROTS process within a framework of safety management;
- ensure consistency with HSC's criteria for permissioning regimes;
- target HSE resource at higher risk schemes;
- fully integrate the approvals and the current safety case regime by incorporating a design notification requirement into the revised safety management system.

Question 28: HSC would welcome your views on whether designs should be formally accepted/authorised by HSE if this model is adopted.

Question 29: HSC would welcome your views on whether operators should be required to procure independent third party assessment of design if this model is adopted.

Implementation

214 If taken forward, the 'lifecycle' option would be implemented by revoking ROTS and incorporating new requirements into the new safety management regulations.

215 The requirement to notify design details would only apply to transport systems outside the scope of the Interoperability Directives. Until 2006, when the Second Railway Package comes into force, this category will also include certain local lines on the conventional railway.

216 If the decision is taken to require some form of third party assessment, a transitional period may be required before the new arrangements come into force in order to allow the identification/development of common standards and appropriate third party assessment bodies and to allow new dutyholders to develop their safety cases. During the transitional period, HMRI would

continue to assess and accept proposals for new/altered works to ensure that risks are properly controlled.

Regulatory Impact Assessment

Question 30: An initial regulatory impact assessment is at Annex 7. Are there any comments you wish to make on it?

CHAPTER 5

IMPROVING THE MANAGEMENT OF THE SUPPLY CHAIN THROUGH CERTIFICATION OF SUPPLIERS OF SAFETY- CRITICAL PRODUCTS AND SERVICES

OBJECTIVES

217 To undertake a study into the independent certification of suppliers of safety-critical products and services with a view to suggesting improvements in the management of the supply chain for the railway industry, as recommended by Lord Cullen in the Ladbroke Rail Inquiry Part 2 Report (Recommendation 24).

BACKGROUND

218 Recommendation 24 (Annex 4 reproduces the relevant Cullen recommendations) arose from a wider discussion and evidence presented to Lord Cullen on the safety case regime on the railways. While explicitly rejecting the extension of the safety case regime to contractors, he recommended that some system for quality control of companies who supply to the industry should be explored. In particular, Lord Cullen had in mind that a company is 'accredited' if an external body, i.e. an independent third party assessment, had determined it had suitable processes for controlling the safety of products and services it provides, in particular where they are safety-critical.

219 Lord Cullen tasked HSC as the action holder for Recommendation 24, and the Rail Regulator for Recommendation 47, as part of the future functions for the new RISB, now the Rail Safety and Standards Board (RSSB), and provided a three-year timescale from the publication of the report in which to implement both recommendations.

CURRENT LEGAL REQUIREMENTS

220 While there are requirements in health and safety law require some products and services to be assessed by a third party (e.g. regulations relating to certain types of machinery), there is currently no comprehensive voluntary or mandatory national scheme for the railway industry of the sort envisaged by Lord Cullen. However, there are a number of assessment or registration schemes operated by companies or groups of companies as in-house schemes and some of these offer extensive coverage across the railway industry.

221 Duty holders do, however, have a legal obligation to comply with:

- duties under Section 6 of the Health and Safety at Work Act 1974 (HSWA) which, among other things, makes it the duty (among other things) of any person who designs, manufacturers or imports or supplies any article for use at work, to ensure so far as is reasonably practicable that the article is so designed and constructed that it will be safe and without risks to health at all times when it is being used by a person at work, and to carry out/arrange for the carrying out of any necessary testing of the article to ensure this;
- the Railways (Safety Case) Regulations 2000, which relate to railway safety case holders' arrangements for ensuring the safety, and managing the work carried out by their contractors, and for controlling the risks from the procurement of plant (see Chapter 3);
- the Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994, which relates to the role of HSE in ensuring, among other things, the safety of certain safety critical products (see Chapter 4);
- the Railways (Safety Critical Work) Regulations 1994 (RSCWR) which relate to controls on the provision of key safety critical workers in the rail industry (see Chapter 6);
- the regime under the EU Interoperability Directives, which relate to, among other things, 'independent' notified bodies assessing certain interoperable constituents and subsystems.

222 At this stage of considering the implications of the EU Interoperability Directives, HSE is minded that the verification and conformity assessment procedures required by these Directives are unlikely to fully meet the objective of Lord Cullen's recommendations on accreditation / certification of suppliers. These Directives require, among other things, interoperable constituents and subsystems (infrastructure, rolling stock etc) to be assessed by 'notified bodies' against European standards, and, where there are gaps in the European standards, against notified national standards, to ensure the interoperability of the European Railways.

223 The EU Interoperability Directives are aimed at providing technical harmonisation of certain products ('interoperability constituents') and subsystems for initial use only, and not at delivering further certification for the systems and components used by suppliers eg. in heavy maintenance etc. While assessment procedures required by these Directives provide for some scrutiny of manufacturers, it may be unlikely that we will be able to fully rely on the Interoperability Directives to deliver the broader objectives envisaged by Lord Cullen.

RELEVANT RAILWAY GROUP STANDARDS

224 The Railway Group Standards apply to all companies in the Railway Group (i.e. Network Rail and companies who use its infrastructure). There is a standard in place that requires all safety critical engineering products and services to be procured from 'qualified' suppliers, and which sets out minimum requirements for the process of qualifying those companies¹⁷. While this Railway Group Standard sets out objectives for compliance, it does not indicate how compliance should be achieved, and in particular it does not provide guidance in the competence assessment of suppliers. As this Railway Group Standard does not include a requirement for independent third party assessment, it does not fulfil the type of system envisaged by Lord Cullen.

BENEFITS OF ACCREDITATION / CERTIFICATION OF SUPPLIERS

225 It may be useful at this stage to clarify the distinction between 'accreditation' and 'certification', which are terms often used interchangeably and prone to cause misunderstanding. European Standard, Standardisation and Related Activities – General Vocabulary BS EN 45020:1998 defines:

'accreditation' as *'a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks'* (i.e. certification), and:

'certification' as *'a procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements'*.

226 HSE considers the sort of accreditation sought by Lord Cullen would entail the accreditation of organisation(s) by, say, the United Kingdom Accreditation Service¹⁸ (UKAS), to certify suppliers of products and services to specified requirements. This element, therefore, of any potential supplier management scheme is the key to ensuring the fundamental spirit of Recommendation 24 is met and appropriately implemented.

227 To that end, the purpose of a supplier accreditation / certification scheme should achieve the following benefits:

- a degree of safety assurance of products and services, based on an **independent and impartial assessment**;
- increased confidence that suppliers have adequate processes in place which demonstrates they understand the safety-criticality of products and services. Such processes might include;
 - production of documentary evidence to validate product approval, conformity to standards etc;

¹⁷ 'Qualification of Suppliers of Safety Critical Engineering Products and Services' RGS GM/RT 2450.

¹⁸ UKAS is the sole accreditation body recognised by government to assess, against internationally recognised standards, organisations that provide certification, testing and inspection services.

- assessment systems to ensure workers are competent to carry out the tasks for which they are supplied;
- effective systems in place to manage sub-contractors to ensure traceability;
- safety performance monitoring taking place across the supply chain.

228 Overall, HSE considers that an effective accreditation / certification for suppliers scheme could lead to a lowering of risks on the railway system and a reduction in the number of rail-related accidents.

229 There should also be an economic benefit in that such a system leads to better designed and manufactured products, improved quality of services, which in turn leads to a more reliable and safe railway.

230 Using an independent accredited / certifying route has the advantage of a single transparent and repeatable approach. Over time, it aims to improve consistency in standards of supplier management, resulting in overall better risk management.

DEVELOPING POLICY

231 The first phase of developing policy to implement Lord Cullen's recommendations on accreditation involved identifying a network of key stakeholders. A productive stakeholder meeting was held in September 02 to engage stakeholders and take views. Participants included representatives from Infrastructure Controllers (Network Rail, London Underground Ltd, Heritage, Light Rail), Freight Operating Companies, Infrastructure Maintenance Companies, Rolling Stock Leasing Companies, the Railway Industry Association, ASLEF, RMT, and Railway Safety (now RSSB). Stakeholders agreed for the need to take a practical and collaborative approach to the issue of supplier management across the industry. Further stakeholder bi-laterals have also been held to explore issues in more detail.

232 HSE carried out a review of existing supplier management schemes in operation across the industry to understand trends, common themes etc. The review indicated many parts of the industry operated a form of supplier 'accreditation', or made use of other schemes. For example, Network Rail's 'Link Up' and 'Proof' Schemes. 'Link Up' is a registration scheme for suppliers of non-impact products and services to the railway industry, 'Proof' is a safety critical supplier verification scheme which uses agreed protocols to assess supplier's application for qualification. These schemes are used more widely than just Network Rail. The Association of Train Operating Companies (ATOC) has produced a Code of Practice, 'National Railway Materials and Services Supply Accreditation Scheme' which sets out principles for Train Operating Companies (TOCs) to procure safety critical materials and services from suppliers who have been 'accredited' by the TOC in accordance with guidance in the code. Suppliers to a company called Railpart undergo a qualification assessment under the 'Railpart Technical Dossier', a certifying

body (in this case Det Norske Veritas (DNV)) provides a further assessment at the specified product level, providing a third party independent assurance. It is also worth noting that ATOC, in collaboration with the Railway Industry Association (RIA), and others have also produced a useful summary of industry supplier management initiatives as a source of reference and a means of sharing information across the industry, 'Supply Chain Initiatives in UK Rail Industry' (<http://www.riagb.org.uk/sci.htm>).

233 However, not all parts of the industry are covered by these schemes. As there is not one national scheme, observance of existing schemes by parts of the industry may not be uniform, and could lead to variable standards. Crucially, not all industry schemes have the element of independent third party assessment, which should be a key feature of accreditation / certification (as discussed in paragraphs 225-230), and therefore providing assurance that consistent standards are achieved.

SYNERGIES WITH OTHER INDUSTRIES

234 HSE's review of accreditation and/or certifying approaches in other industries highlighted the following:

- The nuclear industry is licensed by HSE under the Nuclear Installations Act 1965. The licence conditions are framed in a goal setting context, and there are no regulations or licence conditions that require any defined 'accreditation'.
- The offshore industry is required by the Offshore Installations (Safety Case) Regulations 1992 to identify safety critical elements for each installation which are subject to a verification scheme. The prescribed means of verification is third party assessment by an Independent Competent Person (ICP). This may include examination and testing of safety critical elements, scrutiny of relevant documents and examination of works in progress. The role of the ICP could be carried out by a Certification Body such as Lloyds Register or DNV.
- the gas industry has an accredited assessment and registration scheme for gas installers of domestic and commercial premises, operated independently by the Council for Registered Gas Installers (CORGI) required by the Gas Safety (Installation and Use) Regulations 1998. In addition, a nationally Accredited Certification Scheme (ACS) requires individual gas fitting operatives to have their competence assessed at five-yearly intervals by a certification body accredited by UKAS.
- The Control of Asbestos at Work Regulations 2002 requires employers who commission laboratories to carry out air measurements to ensure the laboratories are accredited by UKAS.

- The aviation industry complies to a stringent licensing and approvals regime required and undertaken by the Civil Aviation Authority which includes aircraft component designers and manufacturers; operators and maintenance companies; infrastructure, including aerodromes and air traffic control; personnel, including provision of training and training providers.

235 It may be worth noting the above review drew out a number of mandatory requirements in other sectors in relation to approvals or the need to include the element of independent third party assessment.

236 While HSC is not minded at present to introduce similar mandatory requirements to the railway industry (see para 238), the added dimension of an independent assessment of a supplier's management system would ensure quality assurance, encourage continuous improvement, and may lead to greater public confidence in the industry, as well as the delivery of potential economic benefits.

OPTIONS

237 In striving to achieve the spirit of recommendation 24, the following options have been considered:

- No change required
 - Taking no further action if reliance on existing industry schemes suggests that the management of suppliers is already being adequately addressed.
- Voluntary means
 - Facilitating the development of an industry-owned, industry-wide accreditation / certification supplier management scheme, with the element of an independent third party assessment.
- Regulatory means
 - Introducing a duty to use certified suppliers via regulation.

HSC VIEWS

238 The above options were put forward to HSC in April 2003 for its early view on a preferred route for further exploration and policy development (<http://www.hse.gov.uk/aboutus/hsc/meetings/2003/080403/c07.pdf>) HSC agreed to the following:

- It did not consider existing industry schemes, at present, to achieve implementation of Recommendation 24 and, therefore, provide an adequate assurance in the rail industry's ability to manage suppliers of safety critical products and services.

- HSC was not minded, at present, to propose regulation in this area.
- HSC wanted HSE to facilitate the development of an industry owned, industry wide accreditation / certification scheme for suppliers, with the recently established Rail Safety & Standards Board (RSSB) taking an important role in such a scheme.
- How involvement of independent third parties in such an accreditation / certification scheme needed to be explored and HSE should investigate the involvement of the United Kingdom Accreditation Service (UKAS).
- The accreditation / certification scheme should apply to the whole of the rail industry, with the initial focus being the establishment of the system on Network Rail Controlled Infrastructure (NRCI).

ROLE OF THE RAILWAY SAFETY AND STANDARDS BOARD (RSSB) AND ADMINISTRATION OF A SUPPLIER MANAGEMENT SCHEME

239 Recommendation 47 of the Ladbroke Grove Train Inquiry Part 2 Report placed the responsibility for the 'accreditation' of suppliers of safety-critical products and services with RSSB. Discussions with RSSB have indicated, at this stage, it is not minded to seek a significant role in setting up and operating a national accreditation / certification scheme for suppliers. Such a role would have significant financial and resourcing implications for RSSB. The Rail Industry Safety Body Development Group under the chairmanship of the Office of the Rail Regulator (ORR) did not consider such a role as falling within the new organisation's core functions, although the RSSB's constitution agreement does not prevent it from doing such work if its members wish it to do so.

240 Currently, RSSB consider that commercial administration of this type of scheme is more appropriate, and that HSE should seek to drive forward in this direction, or encourage duty holders to manage and subsequently seek independent third party assessment of their own schemes.

SCOPE OF AN ACCREDITATION / CERTIFICATION SCHEME FOR SUPPLIERS

241 Chapter 2 discusses the scope of railway and other transport systems which are caught by railway health and safety requirements. It asks whether there should be one common application of requirements to the same railway and related transport systems, or whether there is a need to limit the application in proportion to risks a particular railway or related transport system may pose.

242 In considering all options to implement recommendation 24, HSE has taken a wide view, and has been considering management of suppliers of safety critical products and services for Network Rail controlled infrastructure

(NRCI), London Underground controlled infrastructure, the light rail industry, metro and heritage rail sectors.

243 HSE has also been exploring whether it would be possible to apply a supplier accreditation / certification system only to those parts of the industry where the risks were deemed to be significant. This would mean that some parts of the rail sector might be excluded from the scheme, whether voluntary or mandatory, because their rail operations could be deemed to be of low risk.

244 HSC's views in relation to the scope of any proposed scheme indicated that it should apply to the whole of the rail industry, with the initial focus being the establishment of the system on the NRCI, and that any exceptions to the scheme should be considered on the basis of risk.

Question 31: Which parts of the industry do you think should be specifically included, and / or excluded from the scope of an accreditation / certification scheme for suppliers, and why?

PROPOSED MODEL FOR THE ACCREDITATION / CERTIFICATION OF SUPPLIERS OF SAFETY CRITICAL PRODUCTS AND SERVICES

245 Annex 8 sets out a proposed model to manage an accreditation / certification framework for suppliers, which takes into account the steer provided by HSC, and RSSB's current position on its limited involvement. As far as possible, industry best practice will be enhanced and harnessed, with the aim of introducing an element of third party assessment.

246 HSE would facilitate the setting up of a key stakeholder Steering Group to develop and oversee the accreditation / certification framework. The Group may be guided by HSE, and use the advisory function provided by UKAS to establish its terms of reference, role, remit and development of a framework of appropriate criteria for certification. This collaborative approach would ensure a potential scheme is appropriately industry-owned and industry-wide. The work of the steering group could also consider the proposal to establish an accredited national licensing system for drivers and signallers (Chapter 7).

247 The Steering Group could explore the appointment of a Certification Body (ies) to certify suppliers according to the specified criteria. Advice on the remit and function of a Certification Body would be provided by UKAS. A proposed Certification Body would then be assessed by UKAS, and if it satisfied the relevant assessment, accreditation would be granted for it to carry out the certification of suppliers role.

248 See Annex 9, which sets out an Initial Regulatory Impact Assessment for the above proposal, and identifies broad costs at this stage. Please note the inclusion of this document aims to provide costs and benefits of the proposal to industry albeit it being voluntary and not mandatory. Please feel free to comment on the RIA.

Question 32: What are your views on the proposed model, and why?

Question 33: What are your views on the role of the Steering Group, in particular its scope and membership?

FEATURES OF A SUPPLIER ACCREDITATION / CERTIFICATION SCHEME

249 In developing a robust yet practical framework for a supplier management scheme, HSC welcomes your views and comments in the following areas:

- the definition of categories of suppliers of safety critical products and services which should be subject to the system:

Question 34: how far do you think the development of a framework criteria would assist duty holders in assessing which suppliers should be certified (i.e. depending on the safety criticality of the products and services they are supplying)?

Question 35: do you think duty holders should make their own assessments, as part of their overall risk assessment, according to the risks they create, if so why?

Question 36: how far do you think the definition of a safety-critical service should be aligned with the definition contained in the Railways (Safety Critical Work) Regulations 1994 (Chapter 6)?

Question 37: Are different approaches needed for suppliers of products as opposed to suppliers of services? If so, why or why not?

Question 38: What merits certification? i.e. what would suppliers need to demonstrate to gain certification, and what criteria for granting or refusing certification should be used?;

Question 39: How should accreditation/certification be kept under review after it is granted?

250 Views and comments from consultees will be considered and used as a basis for further development as part of the role of the proposed Steering Group.

251 You may wish to note that HSE is also considering how appropriately to tie in the part of Lord Cullen's Recommendation 25, which relates to the accreditation of training providers (Para xx of Chapter 7, Development of a Licensing Scheme for Train Drivers and Signallers); and whether there is also a need to certify suppliers of railway medical practitioners as highlighted in the review of the RSCWR (Para xx of Chapter 6). HSE intends to raise both of

these issues for discussion and consideration as part of the creation and development of the respective Steering Groups.

Question 40: In the meantime, what are your views on how the issue of the accreditation of training providers and suppliers of medical practitioners should be linked, if at all, to a proposed supplier management accreditation/certification scheme?

Question 41: Are there any other issues that HSE should take into account when facilitating the development of an accreditation / certification scheme for suppliers to the railway industry?

CHAPTER 6

IMPROVING THE MANAGEMENT OF COMPETENCE, FITNESS AND FATIGUE OF SAFETY CRITICAL WORKERS IN THE RAIL INDUSTRY

OBJECTIVE OF REVIEW

252 HSC is undertaking the review of the Railways (Safety Critical Work) Regulations 1994 Regulations to ensure there is a clear regulatory framework to ensure dutyholders adequately manage competence, fitness and fatigue of safety critical workers in the rail industry.

BACKGROUND/HISTORY

Origins of Regulations

253 The Railways (Safety Critical Work) Regulations 1994 (RSCW Regulations) arose from a study the Government asked HSC to carry out in 1992 on the health and safety implications of the Government's proposals to secure greater private sector involvement in British Rail. The findings of the study were published in the HSC Report '*Ensuring safety on Britain's railways*' (ESORB). Among the conclusions, the study found that although existing duty holders had strict regimes for controlling competence of their employees, there were no specific statutory controls in place to ensure that new duty holders would have similarly robust systems following privatisation.

254 The report recommended that the setting of standards and assessing competence for train drivers (and possibly other key staff undertaking key safety critical tasks) should be subject to regulatory control beyond the existing general requirements of the Health and Safety at Work etc Act 1974 and relevant statutory provisions. In addition, consideration needed to be given to imposing some control on the hours of permitted work and rest of train drivers.

255 The RSCW Regulations took on board the recommendations arising from the HSC Report and dealt with issues of competence, fitness and hours of work for safety critical workers.

Requirements of the Regulations

256 The intention of the RSCW Regulations were to ensure that competence and fitness standards relating to employees with the greatest safety responsibilities would be maintained post privatisation and that measures would be put in place to avoid fatigue that could cause risks to passengers and others on the railway. The Regulations apply to railways, tramways, metros and monorails.

257 The Regulations include a definition of the type of work which is safety critical e.g. work as a train driver, signaller, work by a person in a maintenance capacity or as a supervisor of people working in a maintenance capacity. On the whole, the definition describes work activities by reference to job titles (e.g. driver or guard) rather than by explaining what the work entails or the functions, which need to be carried out to enable the work to be done.

258 The Regulations:

- effectively require employers to ensure employees are competent and fit if they undertake safety critical work;
- require adequate records of the assessment of employees' competence and fitness to be kept by the employer and the findings made available to railway safety case holders;
- require those undertaking safety critical work to carry identity cards or other means of identification;
- require employers not to allow so far as reasonably practicable safety critical workers to work such hours as could cause fatigue which could endanger safety;
- give HSE powers to approve competence and fitness assessments of safety critical workers, and if these are in place, require industry to follow them; and
- give HSE a power to grant exemptions from some or all of the requirements of the RSCW Regulations.¹⁹

259 The Regulations therefore have four different elements: competence, fitness, hours of work and means of identification. The RSCW Regulations are supported by guidance and an approved code of practice on the hours of work of workers undertaking safety critical work on the railways.

260 The RSCW Regulations do not require dutyholders to have a competence management system, but there is a prohibition against safety critical work being carried out unless the worker is competent and fit. A dutyholder may have to take the same steps in relation to such workers to meet the requirements of Management of Health and Safety at Work Regulations 1999 (MHSW Regulations).

261 The MHSW Regulations require employers to undertake a risk assessment and identify measures that will ensure compliance with the RSCW Regulations. The RSC Regulations require, amongst other things, that certain railway dutyholders should describe in a railway safety case the arrangements they have in place for ensuring the competence of their employees, and for managing the work undertaken by contractors. The adequacy of the dutyholder's arrangements for developing and maintaining staff competence is assessed during HSE's assessment process for safety cases. The current RSC Regulations are reviewed in Chapter 3.

¹⁹ None have been granted to date.

DEVELOPMENT OF POLICY

Links with other railway policy work

262 Work on the quinquennial review of the RSCW Regulations began in 1999, but was delayed by the investigation and Lord Cullen's public inquiry into the Ladbroke Grove rail accident. In reviewing these Regulations consideration of Lord Cullen's recommendations 25 and 26, which stipulated the need for drivers and signallers to be licensed is needed. He also advised that common standards of competence needed to be established. One of the key objectives in introducing a national licensing scheme is to ensure that driver and signaller competence can be readily identified. Exploration of a licensing system is documented in Chapter 7. Licensing has been considered in relation to the development of safety critical ID cards, which is outlined in paragraph 317.

263 In addition, the review of these Regulations will need to take account of the proposed EC Directive on driver licensing (working document EC-DG-TREN-E2) discussed in more detail in Chapter 7. However, key issues relevant to the review of the Regulations are proposals to have:

- an assessment of the drivers ability to drive to be done by bodies/experts accredited by the competent authorities;
- standards to be developed for accreditation of doctors, psychologists, trainers and evaluators;
- on going monitoring of competence and medical fitness for railway undertakings and reassessment and periodic intervals;
- applicants to provide proof of their physical/mental fitness by passing an examination by a doctor of medicine/psychologist recognised by the competent authority.

264 In addition, the EC approach for a licence/certificate is that it would consist of a smart card where a worker's photo and details and employer details are printed on the card and other information e.g. records of competence and fitness are stored in a microchip.

265 Lord Cullen's recommendation 24 on accreditation of suppliers of safety critical products and services is another area, which needs consideration. Suppliers of safety critical services would include training providers, medical practitioners, on track labour suppliers and track examiners. In achieving accreditation through an external body, an independent assessment would look at the processes and systems of the service provider and certify them competent to provide that service. The scheme is envisaged to be a voluntary one and the underlying process for accreditation/certification and benefits for such a scheme are explored in detail in Chapter 5. This scheme has been used as a model for the basis of certifying medical practitioners, which is discussed in paragraph 286.

266 HSE's review of the RSCW Regulations will also consider the Hatfield Interim Recommendations 1.1 on track maintenance employees to have the necessary technical and managerial competence (See Annex 4).

267 [An Evaluation study](#)¹ conducted by Business Strategy Group seeking Stakeholders views on their experience of the Regulations indicated:

- That the Regulations provide focus and framework for industry to work to by placing a legal requirement on employers;
- Majority felt the Regulations should not be revoked;
- Many stakeholders considered the requirements of the Regulations should not be subsumed into the Railway Safety Case Regulations
- Sub-contractor and labour suppliers were problematic areas.
- There was ambiguity in the definition of safety critical work;
- Fatigue was a major area of concern;
- Medical fitness standards needed to be reviewed in light of medical advances; and
- Identification cards were seen to be burdensome, as proliferations of cards are used in industry.

Consultation

268 HSE has also set up a Safety Critical Stakeholder Working Group²⁰ (SCSWG) to assist in reviewing the Regulations. Key stakeholders, HSC and the Rail Industry Advisory Committee (RIAC) have been consulted in this review.

269 The wide ranging discussions with stakeholders and, in particular, the discussions and views of the Safety Critical Stakeholder Working Group have been reflected in HSC03/09 paper <http://www.hse.gov.uk/aboutus/hsc/meetings/2003/080403/c09.pdf> which was presented at the HSC's meeting in April 2003, HSC agreed that HSE should explore a variety of issues given that HSC was minded to retain these Regulations. These issues are that:

- the Regulations should be updated and modernised;
- HSE should seek clarity in the definition of safety critical work;
- more emphasis on competence management systems should be explored;
- HSE should explore with industry how competence and medical fitness standards could be set;
- HSE should explore the usefulness of a national body to approve medical practitioners and standards;

¹ Evaluation of the Railways (Safety Critical Work) Regulations 1994

²⁰ Membership of the group includes Rail Safety and Standards Board, Network Rail, London Underground, Heritage Railway Association, infrastructure maintenance contractors, suppliers, freight trains operators, rolling stock companies, Association of Train Operating Companies, RMT and ASLEF.

- the provision on hours of work should have more emphasis on fatigue management; and
- HSE should explore the provision for an effective means of identification.

Which dutyholders should be in scope?

270 General issues relating to a future scope for regulatory and industry schemes in the rail industry are described in Chapter 2 which raises the question of whether there should be a common scope for future arrangements for regulatory or industry schemes and whether there should be a threshold below which the requirements do not apply.

271 In relation to competence, fitness and fatigue the present scope of the RSCW Regulations is not consistent with the current railway permissioning regime, in particular the limited scope of RSC Regulations. As the RSCW Regulations adopt the definition and application to transport systems from the Transport and Works Act 1992, the present scope covers railways, tramways, metros, Heritage rail and specified systems of guided transport as specified in an Order made by the Secretary of State.

272 When HSC considered the scope of the RSCW Regulations in April 2003. HSC's view is that any exemptions from the Regulations should be on the basis of risk.

Question 42: HSC would welcome your views on which dutyholders should fall within the scope of the any future regulatory requirements for competence, fitness and fatigue for safety critical workers and why?

Question 43: How could we determine this threshold?

Definition of Safety Critical Work

273 Overall the aim of these Regulations is to ensure the competence, fitness and prevention of fatigue for workers whose activities have a significant effect on operational, occupational and public safety. The definition in the Regulations uses job titles, whereas the [HSC RIAC guidance²¹](#) uses activities. There are some important activities not currently covered by the definition e.g. operation/ maintenance of passenger lifts and escalators in underground stations, activities like installation, commissioning and inspections. Also, the current definition is broad and covers some supervisory /management activities and some work within a depot which can affect the health and safety on a transport system (many stakeholders have pointed out the guidance is ambiguous on this point). This has been reflected in the evaluation study where stakeholders thought that RIAC guidance on what is

²¹ HSC RIAC guidance on the definition of activities regarded as safety critical under the Railways (Safety Critical Work) Regulations 1994.

safety critical arrived too late and duty holders had been left to interpret the Regulations themselves.

274 Given that HSC wanted to try to achieve greater clarity in the definition of what is safety critical work, HSE have looked at the definition to better define those activities, which have most impact on the health and safety of persons on the transport system. The options are:

- (a) amend the definition of safety critical work; or
- (b) dutyholders define safety critical work from a risk assessment.

275 The first option (a) is for safety critical workers to be defined in the Regulations by placing more emphasis on activities rather than job titles. The RIAC guidance could be revisited and used as the basis for determining the criteria to be inserted in the definition, with supporting information in an ACoP and guidance. This option could address those activities that are not currently covered and would ensure consistency in terminology and applicability across the rail industry. The disadvantage is that the definition may become outdated with changes in terminology and working practices; significant activities could have been missed; and, the regulator would be responsible for deciding who is safety critical rather than the dutyholder deciding for its own undertaking. HSE would, though, define safety critical work in consultation with stakeholders.

276 Option (b) is for a goal setting requirement in the Regulations for the dutyholder to undertake a risk assessment to identify which activities are safety critical (eg *work which could affect the health and safety of persons on a transport system*). Such a definition would not become constrained by future changes in terminology and working practices. In addition it should mean that the dutyholder could best decide what is appropriate for its specific undertaking. The downside is that there is likely to be considerable inconsistency between dutyholders in the application and interpretation on what is safety critical or not and the terminology used. A supporting ACoP and guidance along the line of the RIAC guidance on safety critical activities might go some way towards overcoming this.

277 The SCSWG were in favour of option (a) as they felt the goal setting approach would not deliver adequate consistency in the application of the Regulations.

Question 44: Do you think greater clarity can be achieved for the definition of safety critical work through option (a) or (b)? And why?

Competence management system

278 The majority of stakeholders were not convinced that the railway safety case alone would ensure the delivery of competent performance through managing competence, fitness and fatigue for all safety critical workers in the rail industry. In particular, there was concern about maintenance workers who

are often not directly employed by railway safety case holders (key finding of the evaluation study).

279 HSC agreed in April that a specific requirement for a railway competence management system was required to best ensure that dutyholders adequately manage the competence, fitness and fatigue of safety critical workers. This would support more general duties under the MHSW and RSC Regulations. HSE believes there may be merit in the CMS not only ensuring competence but also providing a system for managing fitness and fatigue. A general requirement for a CMS could be in the Regulations, with the principles from HSE's Railway Safety Principles and Guidance, Part 3, Section A incorporated into a supporting ACoP.

280 The SCSWG acknowledged the significance of a CMS and fully supported a requirement for CMS. They also recognised the importance of managing fitness and fatigue, but felt the systems for these needed to be kept separate. This is discussed in more detail in paragraphs 282 and 303.

Question 45: HSC would welcome your views on whether a specific requirement for a railway CMS is required? And why?

Question 46: If so, should the CMS also cover fitness and fatigue? Or should these issues be dealt with separately? And why? Please state your reasons.

Fitness

281 An important element in determining overall competence is to establish an individual's fitness. By 'fitness' HSE means the interrelated areas of physical, mental and medical fitness.

Medical fitness

282 Many stakeholders consider the present system to be unsatisfactory as there has been a general fragmentation of railway occupational health expertise and experience and an overall dilution of railway-specific medical knowledge. There is a perception that this has led to inconsistency in fitness assessments by medical practitioners from non-railway backgrounds carrying out assessments on safety critical workers in the railway industry. This was evident in HMRI's study into assessing medical fitness standards within train operating companies in Railtrack's Southern Zone. HMRI found insufficient medicals and railway medical expertise within duty holders. The study also found inconsistent assessment of medical fitness as duty holders had to use doctors with no specific railway expertise. The evaluation report found that under the current regime, there is no appeal if workers fail their medicals.

283 Current medical fitness standards are minimum standards and rely on those medical practitioners implementing them, having sufficient expertise and knowledge of the specific work. These standards require regular updating in light of changing medical advances and changing working practices within industry. Such maintenance of the standards requires ongoing specialist

input. The absence of an appeal mechanism may raise Human Rights Act issues which dutyholders should be aware of.

284 All modes of transport other than rail have open and common standards for medical fitness, with formal delegation of responsibilities to a government department or approved doctors and to a greater or lesser extent audit of the doctors' performance. The aim of assessments of medical fitness is to minimise risks to others caused by perceived limitations or sudden loss of capability of the safety critical worker. The assessments need to be uniform so that the medical standards can stand scrutiny in the event of fitness being questioned in the aftermath of an accident.

285 HSE consider that medicals or assessments carried out by medical practitioners are a safety critical service and therefore, in line with Cullen Recommendation 24, any supplier of medicals / assessments would need to be certified by an independent body. Consideration of options for meeting Cullen recommendation 24 are in Chapter 5, and options for meeting Cullen recommendation 25 and 26 are discussed in Chapter 7.

286 When HSC initially considered these issues, HSE was asked to explore how a national body to administer medical fitness standards and assessments might work. HSE is looking at ways by which consistency in medical fitness assessments can be assured. For this, medical fitness standards need to be set and reviewed taking into account current scientific evidence as well as that medical practitioners carrying out assessments against these standards must be competent to do so. With this in mind, HSE has explored three options:

Option (a)-Regulatory means-Independent body to approve medical practitioners

287 HSE could approve an independent body under a specific provision in the Regulations to take responsibility for setting medical fitness standards and to run a scheme to certify medical practitioners.

288 HSE in collaboration with UKAS and a steering group would develop and oversee a framework under which accredited independent bodies are appointed. This would certify that the service the independent body provides would ensure the use of competent medical practitioners. Any development of this model would need to include dialogue with representatives from the Association of Railway Industry for Occupational Physicians to advise on the standards for appointing, training and assessing medical practitioners. The independent body could be responsible for setting standards and maintaining the standard to reflect changes in medical advances. HSE suggests such an independent body should have an appeal mechanism for medical practitioners who fail to get appointed and for workers who fail their medicals.

289 Some medical practitioners are employed in-house by dutyholders and not through an external body. These would not, therefore, fall within the accreditation system envisaged by Lord Cullen and would not ensure

consistency in the standards of appointment, competence and fair competition amongst occupational health contractors.

290 Another option is for individual certification of medical practitioners through the voluntary scheme discussed in Chapter 7. This would depend largely on the remit of Independent Body. This option would ensure that both in-house and employed medical practitioners were subject to the same accreditation system.

Option (b): Voluntary means-Independent Body to approve medical practitioners

291 An alternative approach is introducing a voluntary scheme through dialogue with an industry group to appoint an Independent Body to address setting medical fitness standards and competence standards for medical practitioners. This approach could be included in the scheme envisaged in paragraph 245, Chapter 5. This model would ensure compliance within dutyholders and if necessary appropriate enforcement action could be taken, if compliance is not achieved. This scheme may also provide a sound basis for the future given the current EC proposal on driver licensing with medical practitioners to be recognised by a competent authority. Experience in developing this would be beneficial in informing negotiation of future EC proposals.

Advantages

292 The benefits of option (a) and (b) are that it could produce a clear transparent and consistent national system for appointing or approving medical practitioners, which had an appeals mechanism, if required, and a means of investigating complaints.

Disadvantages

293 A downside of this scheme is the likely cost implications. Costs would be met through fees chargeable to medical practitioners by the body for approving them. Fees would be chargeable to medical practitioners by the body approving standards (which would be accredited by UKAS). Fees may also need to be levied on appellants including both medical practitioners and workers who fail their medicals. The initial costs in setting up such a scheme are outlined in an initial Regulatory Impact Assessment in Annex 10.

Option (c)- Specify competence requirements of medical practitioners in Regulations or ACoP

294 HSE could specify in greater detail the competence standards needed for medical practitioners e.g. membership of the Faculty of Occupational Medicine of the Royal College of Physicians and experience in rail transport systems. This could be incorporated into the Regulations and / or ACoP.

295 However this option does not address the issue of medical standards as mentioned in paragraph 283. It also does not address the appeals mechanisms (if required) for medical practitioners and workers.

296 There may also be some difficulties in specifying the level of competence required in an ACoP as this is dependent on how the medical standard is maintained.

297 The SCSWG felt option (a) best addressed the current problems of inconsistency in medical fitness and competence of medical practitioners.

Question 47: Which option will best ensure that medical practitioners are competent to undertake assessment of medical fitness on safety critical workers in the rail industry? What reasons do you have for choosing this option?

Question 48: Which option best ensures consistency in approving medical practitioners? (a), (b) or (c)? Please state your reasons.

Question 49: Who should approve the independent body- industry or HSE? Please state your reasons for your choice.

Question 50: If option (c) what level of training, qualification and experience would be required for medical practitioners in the rail industry?

Management of fatigue and hours of work

Requirements under the Working Time (Amendment) Regulations 2003

298 The Working Time (Amendment) Regulations 2003 (WTA) Regulations came into effect on 1 August 2003. The Regulations, which implemented the Horizontal Amending Directive, entitle railway workers to an average 48 hour working week, an average 8 hour night work limit, 4 weeks paid annual leave, statutory daily, weekly and in-work rest periods, and a health assessment for a night worker. Workers can choose to work for longer than the average 48 hours per week if they wish, although employers cannot require them to do so.

299 Certain categories of rail worker: those whose activities are intermittent, those who spend their working time onboard trains, and those whose activities are linked to the transport timetable and to ensuring the continuity and regularity of traffic, are exempt from the night work limits and rest entitlements, provided those workers receiving an equivalent period of compensatory rest. Many of these matters are left open to collective agreement between employers and employees.

300 The requirements of WTA Regulations are in addition to workers' contractual arrangements and do not affect existing statutory provisions under Health and Safety law. Most railway undertakings implement the requirements of the RSCW ACoP to set limits on hours of work by referring to the limits on working time set down by the rail industry following the Hidden Report into the Clapham train crash. These are in an annex to group standard GH/RT 4004 as advisory not mandatory requirements.

301 Where an employee has rights, which go further than those under the WTA Regulations, then those pre-existing rights continue to apply, so there is no reduction in the protection against fatigue offered to railway workers.

302 Where a Safety Critical worker is entitled to a limit on hours of work, rest periods, rest breaks or annual leave under either their contractual arrangement, the WTA Regulations or the RSCW Regulations, the worker may not exercise each right separately, but may take advantage of whichever right is, in any particular respect, the more favourable.

Fatigue

303 HSC asked HSE to explore how to provide a focus on fatigue as well as hours of work in the RSCW Regulations.

304 Currently, Regulation 4 focuses more on employers to ensure that so far as reasonably practicable, employees do not work excessive hours that would cause them fatigue and endanger safety. Industry currently uses the Hidden recommendations which are not based on any scientific approach but did reflect what was suggested to be achievable at the time. However, these limits only focus on hours worked and do not factor in any of the other causes of fatigue. The Evaluation Report concluded that the impact of the Regulations on hours of work have done little to address the problem areas of fatigue. This has been largely due to the industry's focus on the Hidden Limits alone.

305 Since the Regulations were introduced, a lot of research has been carried out into the understanding of fatigue and its causes. However, the application of this research within the rail industry has been very limited.

306 HSE's own research has led to the development of the Fatigue Index, a risk assessment tool that helps employers to calculate improved shift patterns for rotating shift work. The Fatigue Index is an HSE Microsoft Excel spreadsheet which analyses new and old roster patterns to profile daily fatigue levels on a shift pattern which may then indicate if there are any peak levels that need to be addressed. The Fatigue Index considers five factors which are known to have an impact on fatigue: start time, shift duration, length of time between duty spells, breaks within duty spells and the number of consecutive shifts.

307 [HSE research report²²](http://www.hse.gov.uk/research/crr_pdf/1999/crr99254.pdf) into the development of the Fatigue Index is available on HSE's website:
http://www.hse.gov.uk/research/crr_pdf/1999/crr99254.pdf.

The fatigue index has been validated. RSSB are currently undertaking research to review a number of such fatigue assessment tools. Employers can use the HSE Excel spreadsheet to input their current or suggested shift

²² HSE Report: Validation and development of a method for assessing the risks from mental fatigue.

roster patterns. The Fatigue Index then provides a profile of the potential fatigue levels on a shift pattern. The information can be displayed in graphical form, which will indicate if there are any peak levels that need to be addressed. Comparisons can be made with old and new rosters to consider potential higher risk areas that may need to be addressed.

308 Some dutyholders have found the Fatigue Index a very useful tool in raising awareness and encouraging discussion on fatigue matters. It has helped to identify and visualise where likely problems are and also provides employees a shared picture of all aspects of shift work. In some cases, it has encouraged a culture of going beyond the Hidden limits. One supplier of software for developing rosters for train operating companies has included the index in its latest version.

309 However, the Fatigue Index has limitations. These include the fact that it was not designed for permanent shift patterns or split shift systems. It was based on the research available up to 1999 and there were certain gaps in that research particularly in relation to the number of consecutive night shifts that should be scheduled. There are also still issues around the interpretation of the higher scores on the index. In addition, it is not able to take into account all aspects of the issues that affect fatigue. For instance, an employer can assess the planned hours/work patterns, but the actual work done can be very different eg there may be lots of additional overtime, workers swapping shift, emergency call outs. These factors are not taken into account in the Fatigue Index.

310 Alongside the number of hours worked, fatigue is influenced by, the work activity, duration of work activity, work patterns, human factors such as the working environment, travelling time to and from the place of work, social and domestic lifestyles and so on. Individuals also differ in terms of recovery time after work, their diet and health. There is also the added effect of an individual's determination to overcome the effects of fatigue, which could include the use of stimulants, e.g. caffeine.

311 HSE has explored with dutyholders their current assessment practices. These have included monitoring of fixed and rotating shift patterns, reaction time and ensuring rest periods are taken. However, most of these checks are performed visually at a local level and are not always reliable or indicate any potential longer-term problems. i.e. the problem may not be apparent at the time of assessment but may affect the employee during their time at work.

312 HSE intends to create proposals through this discussion to explore how to amend Regulation 4, ACoP and guidance to address this change in focus from hours of work specifically to include consideration of fatigue and causes of fatigue.

Question 51: Are consultees aware of any examples of any best practice on managing fatigue to incorporate in the amended guidance?

Means of Identification

313 Means of identification (ID) can be an important part in monitoring competence and medical fitness. This was confirmed in the Evaluation Report which found, that the majority of safety critical managers and workers interviewed were aware of the requirement to have a form of ID and have been asked to produce one at some point. The current requirements on a card or document are the individual's name, their photo and their employer's details. Any other particulars are left to the employer's discretion. This has led to industry developing and issuing a variety of different types and styles of ID documents and the information contained on them.

314 The proliferation of styles and types of ID requirements by industry has meant the number of ID cards or documents an individual could carry has increased or can potentially increase over time. It is possible that a safety critical worker will own many different forms of ID depending on the number of companies they are working for i.e. their direct employer will require ID, the company they are then contracted to may have different requirements for ID and so a further document is needed and so on. Many types of ID cards are required to be carried by safety critical workers eg CAB, Sentinel and safety critical ID. The Sentinel system is Network Rail's safety competence framework. Although initially this was developed to control competence of track safety workers nationally, this is now being expanded to include all safety, operating and technical engineering competencies for Network Rail employees and its supply chain. Many cards do not include the name of the employer, others eg Sentinel, include useful information on categories of safety critical work and medical restrictions.

315 Equally, an ID document that contains consistent information and is applicable across the entire railway network, would assist in streamlining the administrative burden, as all employers would be using the same criteria when identifying individuals.

316 Technology has advanced considerably since the Regulations came into force. The use of smart cards and microchips would enable information to be stored simply and effectively. This would align with the current EC proposals on driver licensing requiring licence or certificate to consist of a smart card where employee details are printed on the card and other information eg competence and fitness details are stored on a microchip, see paragraph 264

317 The Safety Critical ID could therefore be expanded to include the information that will be necessary for licensing for drivers and signallers (as required by Lord Cullen and the likely EC Directive on driver licensing). However, any development of a voluntary licensing scheme for drivers and signallers and the type of licence is still open to discussion and may be different to the safety critical ID card.

318 In trying to achieve a single safety critical ID card, the SCSWG felt there needed to be some form of standardisation of relevant information for safety critical workers.

Question 52: HSC would welcome your views on the type of information that needs to be contained on an ID document and how this information could be incorporated on the card. Your views on the potential implementation of smart card or similar technology across the rail infrastructure.

REGULATORY IMPACT ASSESSMENT

319 An initial regulatory impact assessment has been prepared for the review of the RSCW Regulations. This is found at Annex 10. Any comments on this RIA are welcome.

320 We are also keen to hear any other ideas that you may have to further improve the effectiveness of these Regulations.

CHAPTER 7

ASSURANCE OF COMPETENCE AND FITNESS THROUGH THE DEVELOPMENT OF AN ACCREDITED LICENSING SYSTEM FOR KEY SAFETY CRITICAL WORKERS

OBJECTIVES

321 To facilitate the development of an accredited licensing system to provide greater assurance of the competence and fitness of key safety critical workers in the rail industry.

BACKGROUND

Privatisation

322 Driver licensing was first considered in the early 1990s in preparation for the privatisation of British Rail. The Health and Safety Commission (HSC) conducted a study on the health and safety implications of privatising the railway and concluded that there were no specific statutory controls in place to ensure that the newly established duty holders would have robust systems to control the competence of their employees (See chapter 6, paragraph 2).

323 The report that HSC published '*Ensuring safety on Britain's Railways*' explored how a separate authority, similar in arrangement to the Driver Vehicle Licensing Agency (DVLA), could be set up to 'certify' railway staff. The authority would also develop standards for staff selection and training.

324 On further exploration the HSC concluded that the development of a licensing system was not required. Instead the competence and fitness of those with the greatest safety responsibilities would be better addressed through the introduction of the Railways (Safety Critical Work) Regulations 1994 (RSCW Regulations) (See chapter 6).

325 In 1995 the Department for Transport (DfT), chaired a working group to discuss issues associated with driver selection, training and competence. The group, including representatives from the former British Rail, Department of Transport, HSE, including Her Majesty's Railway Inspectorate (HMRI), reported that the introduction of a licensing system would have no additional benefits over the existing regulatory controls such as RSCW Regulations.

The Ladbroke Grove Rail Crash

326 Following the rail crash at Ladbroke Grove in October 1999, the Public Inquiry, headed by Lord Cullen, examined the issue of competence of train

drivers and signallers. The Inquiry found that there was no national standard in place by which the competence of drivers and signallers could be assessed.

327 Following these discussions, Lord Cullen made recommendations for the development of a licensing system for train drivers (Recommendation 25) and for signallers (Recommendation 26) (a full text of these recommendations is included in Annex 4). The main features of the licensing system proposed by Lord Cullen are:

- Licence issued to drivers and signallers once they are qualified in relevant rules and regulations and have passed an assessment of their competence;
- Central recording of those qualified as train drivers and signallers;
- Licenses to be revalidated every three years; and
- Training providers or operators to be accredited for training purposes.

The train derailment near Hatfield

328 The HSE investigation into the train derailment near Hatfield in October 2000 is still ongoing. However, early indications suggest that the likely cause was a broken rail and that this, in turn, was the result of a track defect. An interim recommendation was made for the development of a national accreditation scheme for rail examiners with similar features to the Personnel Certificate in non-destructive testing (PCN) system. Lead responsibility for developing such a system was placed upon Railtrack (now Network Rail), infrastructure maintenance contractors and track removal contractors. Full text of this recommendation is included in Annex 4.

329 The PCN system is for the certification of competence of personnel involved in non-destructive testing. It is accredited by the United Kingdom Accreditation Service²³ (UKAS) as meeting the requirements of the European Standard for Bodies Operating Certification of Personnel (EN45013) and is internationally recognised by many industries.

European proposals

330 The European Commission (EC) has recently started to draft a proposal for a Directive on train driver certification. The rationale behind the proposal is that train drivers should be mutually recognised as competent in all Member States with the aim to:

- Maintain and improve rail safety;
- Increase interoperability of trains between Member States;

²³ UKAS is the sole accreditation body recognised by Government to assess, against internationally recognised standards, organisations that provide certification, testing and inspection services.

- Increase public confidence in railways;
- Allow mobility of drivers across Member States; and
- Create a new European rail culture within a single rail system

331 The proposed European train driver's certificate would be part of a harmonised approach in the transport sector and would require similar provisions to that already established for power driven vehicles and boat masters.

332 On 16 July 2003, the EC's Directorate-General for Energy and Transport published a working document (EC-DG TREN-E2) [http://europa.eu.int/comm/transport/rail/index_en.html]. The proposed main requirements of the Directive are:

- a) Certification required for drivers of passenger and goods trains (including shunting engines and works trains);
- b) Certificates to include details of the driver and category type (e.g. local, high speed) on the licence itself; information on medical checks, rolling stock and infrastructure to be contained within an embedded electronic chip;
- c) Drivers trained and assessed on general competence, rolling stock and infrastructure;
- d) Assessment for physical and mental fitness, and basic language ability;
- e) Certificates issued to the drivers by the competent authority, in the UK this would be HSE (one aim of HSE's negotiations in Europe would be to remove this requirement from HSE);
- f) Periodic examinations required on a regular basis for competencies and fitness to be renewed;
- g) Certificate to be renewed every five years;
- h) Railway undertakings and Infrastructure Managers' safety management systems to include monitoring arrangements for drivers;
- i) Employers and drivers to inform the competent authority of any significant issues;
- j) The competent authority can delegate to an accredited body or individuals, the checking of general professional competence; the checking of professional competence relating to rolling stock and infrastructure; and the checking of physical and mental fitness;
- k) An appeal process; and
- l) The competent authority to keep an up to date register of certificates.

333 Publication of the draft Directive is expected by December 2003. Negotiations on the proposal are expected to end by June 2004, with adoption in 2005. Transitional Provisions would need to be put in place during 2006; and implementation by Member States is expected to be by 2007.

334 In view of the impending European Directive, it is HSC's intention that development of any national licensing system envisaged by Lord Cullen is taken forward with a view to assisting European negotiations on the Directive and that the development of the UK licensing system takes into account EC proposals so as to minimise any further amendments to the licensing system in due course.

335 The '*Report on the Licensing of Train Drivers*' issued by Railway Safety (now RSSB) in November 2002 also recognises this point and stated that 'experience indicates that it would be folly to develop a UK driver licensing scheme that is significantly at variance with emerging European policy and practice'.

POLICY DEVELOPMENT

Links with other railway policy work

336 HSE has explored the development of a licensing system in the context of other policy work that relates to ensuring the competence and fitness of safety-critical staff:

- The review of the Railways (Safety Case) Regulations 2000 (RSC Regulations) (See chapter 3);
- Lord Cullen's recommendation on the development of an accredited certification system for suppliers of safety-critical products and services (See chapter 5); and
- The review of the RSCW Regulations (See chapter 6).

Consultation

337 HSE has consulted a number of key stakeholders from the rail industry whilst exploring a national licensing scheme. RSSB, infrastructure controllers (Network Rail, London Underground, Heritage Railway Association, Light Rail operators), freight operating companies, Association of Train Operating Companies (ATOC), infrastructure maintenance contractors, RMT, ASLEF, Rail Industry Training Council (now the Centre for Rail Skills), Rail Industry Advisory Committee (RIAC), Office of the Rail Regulator (ORR) and the Strategic Rail Authority (SRA) have been consulted. Key stakeholders were present at a Stakeholder Meeting on driver/signaller licensing hosted by HSE at ATOC's office in November 2002.

338 The lead government department for negotiation on the EC Directive for driver certification is the DfT. DfT is in close liaison with HSE who are the safety authority for the UK railway industry under EC proposals.

339 In developing models for a licensing scheme, HSE presented a paper to the HSC in April 2003 to seek possible initial views on how a licensing system for drivers and signallers should operate. HSC expressed the view that:

- Driver and signaller licensing should be pursued;
- RSSB could take an important role in the licensing system and could issue the licenses;
- Independent third party involvement was needed and HSE should explore the involvement of UKAS;
- Inclusion in the licensing system should be on the basis of risk; and
- Effective generic national standards for drivers and signallers would need to be developed.

UKAS Accreditation

340 HSE have been working with UKAS to take forward the points raised by HSC. UKAS advised us on how a certification body should operate for certification of personnel. They referred HSE to '*European Standard for Bodies Operating Certification of Personnel*' (EN 45013). This standard specifies general criteria that a certification body operating certification of personnel shall follow if it is to be recognised at a national or European level as competent and reliable in the operation of a system of certification personnel, irrespective of the sector involved. Proposals in the EC Directive (See paragraph 12) propose that accreditation should be based on the European standards of the EN 45000 series.

341 A key requirement of this standard is that the body undertaking certification should not engage in activities that could compromise its impartiality. A certification body should be an identified legal entity. Independence requires it to have full and clearly separate authority in respect of certification. Only in exceptional circumstances can a certification body certify its own employees.

342 During consultation, the majority of stakeholders shared HSC's view for the need for independent, third party involvement. Further, many stakeholders considered that any certifying body set up to issue and validate licenses should be commercially independent from the worker's employer. However, some stakeholders, for example ATOC, are strongly opposed to any form of independent assessment of their member's staff. Instead they considered that railway operators should be accredited to train, assess and certify their own staff.

343 RSSB's *Report on the Licensing of Train Drivers* stated that any organisation that trained, assessed and licensed and / or had a lack of organisational independence between trainers and assessors, could be a barrier to accreditation under EN 45013.

THE BENEFITS OF AN ACCREDITED NATIONAL LICENSING SYSTEM

Industry competence management and licensing systems

344 The railway industry already has a number of processes in place to manage the competence and fitness of drivers and signallers. For example, many dutyholders have developed a Competence Management System (CMS), some of which address the principles outlined in HSE's guidance; *'Developing and Maintaining Staff Competence'*²⁴. One of the proposals arising from the review of the RSCW Regulations (See chapter 6, paragraph ??) is a new requirement for all dutyholders to have a competence management system for all safety critical workers. This requirement should help to ensure improvement in the management of competence and fitness of drivers and signallers.

345 ATOC has an Approved Code of Practice requiring train operators to issue licenses to their drivers once the train operator is satisfied that the driver is competent to drive particular types of traction / train subject to them having the necessary route knowledge (ATOC/ACOP013). There is no restriction on who should assess the train driver, and the train operator is responsible for all decisions about who holds the licence.

346 In response to Lord Cullen's recommendation, Network Rail is starting to license all those involved in signalling operations. For example Signaller Safety Briefers, who coach, assess and brief Network Rail's signallers, have already been licensed and there is an objective to license signallers in the financial year 2003/04. Licensing is through the SENTINEL System, which is Network Rail's safety competence framework. Although initially this was developed to control competency of track safety workers nationally, this is now being expanded to include all safety, operating and technical engineering competencies for Network Rail employees and for its supply chain.

An accredited national licensing system

347 Notwithstanding the above, HSC considers that there are additional significant benefits in the existence of an accredited national licensing system for drivers and signallers:

a) *Consistency with other transport sectors*

²⁴ HSE's Railway Safety & Principles Guidance Part 3A "Developing and maintaining staff competence".

An accredited national licensing system would be consistent with other UK transport sectors as the licence would be issued by an independent body e.g. DVLA. Without this independence, any licensing system could be perceived as inferior to those in other transport sectors as companies who have a commercial interest would be issuing the licence.

b) *Licensing systems formally recognise competence*

An accredited national licensing system would formally and independently recognise that drivers and signallers have undertaken a common training and assessment process to ensure that they are competent and fit to adequately carry out their duties.

c) *Licenses are time limited*

Licenses, generally, have a time-limited validity. Licensed train drivers and signallers would need to be re-assessed at specified periods in order to retain their licence. This would ensure that licence holders remained competent and fit.

d) *Acts as a single identification card*

A licence issued under an accredited national licensing system will include key competencies and medical requirements to undertake a particular task. There should therefore be little need for other means of identification.

e) *Licenses can be portable*²⁵

Where licence holders have undertaken common training and independent assessment processes, licenses could be more easily recognised as valid by their new employer and / or any other licence awarding body in the same occupation. Information on the licence could be sufficient to indicate a workers competency to carry out specific tasks.

f) *Better tracking of workers*

An accredited national licensing system would have a central record of data on applicants and licence holders. This would prevent an applicant applying for a new licence without previous information on any suspension, endorsement or revocation being highlighted.

g) *Increase in public confidence*

The railway industry has attracted public concern because it does not require its key safety critical workers, in particular drivers, to be

²⁵ Licenses can only be portable if employers have the same standards and work with similar rules and regulations, with the same traction and similar medical standards.

licensed²⁶. It is expected that the public will have more confidence in the competence and fitness of drivers and signallers if they were subject to an accredited national licensing system that addressed the points raised in this paragraph.

h) Increase in regulator confidence

An accredited national licensing system for drivers and signallers would give greater confidence to HSE in dutyholder's arrangements for ensuring the competence and fitness of drivers and signallers. The common processes in such a system would assist the assessment of safety management systems, as described in safety cases, and the inspection of driving and signalling operations.

348 In addition, the existence of an accredited national licensing system would address many of the proposals contained in the EC's working document on driver certification (See paragraphs 11- 15).

Question 53: Do you agree that the licensing of drivers and signallers under an accredited national licensing system will provide the benefits described above? Are there any additional benefits? If so, what are they?

Question 54: What system, other than an accredited national licensing system, could better provide assurance that nationally, all drivers and signallers were working to a consistent level of competence and fitness? What would the benefits of such a system be over, and above those listed above and how would conflicts of interest be prevented?

SCOPE OF THE ACCREDITED LICENSING SYSTEM

Dutyholders within scope

349 General issues relating to a future scope for regulatory and industry schemes within the rail industry are described in Chapter 2. This Chapter questions whether there should be a common scope for future regulatory or industry schemes and whether there should be a threshold below which the requirements do not apply.

350 In relation to licensing, Lord Cullen placed the responsibility for developing licensing schemes with RSSB (See recommendation 47, contained in Annex 4). HSE understands that RSSB's responsibilities will, for the foreseeable future, be restricted to Network Rail controlled infrastructure.

351 HSC needs to consider the merits of licensing in terms of the whole rail infrastructure and has considered whether a licensing scheme should be

²⁶ Evidence for this was recently found in the HSE Research Report "Public Dialogue on Train Protection" by People Science and Policy Ltd

restricted only to those who operate on Network Rail controlled infrastructure; or whether, in addition, London Underground, the Light Rail industry, Metro and Tramways, and the Heritage Rail sectors should also be covered by the scheme.

352 To provide public confidence, HSC believe that all rail sectors should be part of the licensing scheme. However, certain operations could be excluded from a licensing system on the basis of risk. This would allow licensing requirements to be disapplied for some parts of the rail sector, for example low risk / low speed heritage operations.

Question 55: HSC would welcome your views on which dutyholders should fall within the scope of an accredited national licensing system and why?

Question 56: Should a threshold be used to establish who should be included in the accredited national licensing system? If so, how could the threshold be determined?

Personnel within scope

353 Lord Cullen identified drivers and signallers as those personnel who should be subject to the licensing system. An issue raised during consultation with stakeholders so far was the importance on ensuring the competence and fitness of those undergoing training.

Question 57: Should drivers and signallers undergoing training be included in the accredited national licensing system and how? If not included, how should the competence and fitness of trainees be ensured?

354 An interim recommendation from HSE's Hatfield investigation required the development of a national accreditation scheme for rail examiners similar to the PCN system (see paragraph 9). The PCN system is a UKAS accredited personnel certification system that meets the requirements of European Standard EN 45013.

355 One of the options raised in Chapter 6 is for medical practitioners to be certified by an independent certification body. This should ensure that safety critical workers are adequately assessed as medically fit against appropriate standards.

356 Network Rail's SENTINEL system covers a number of safety critical workers, e.g. track safety, and is gradually being expanded to include all safety, operating and technical engineering competencies for Network Rail employees and for its supply chain (See paragraph 26). Network Rail has also offered use of the system to other infrastructure controllers and train operators. An objective in Network Rail's '*Safety and Environment Plan 2003*' is to seek and gain external accreditation of the SENTINEL system (this was a key element of the licensing system as envisaged by Lord Cullen and HSC).

357 During consultations with stakeholders, the issue of licensing other safety critical workers was discussed. A range of views were expressed including that some felt that it important to include track maintenance staff in the licensing system.

Question 58: Should the accredited national licensing system for drivers and signallers also apply to other safety critical workers? If so, to whom should the licensing system apply and why?

Number of accredited licensing system required

358 Lord Cullen asked for two licensing systems, one for drivers and a similar system for signallers. Some stakeholders have suggested that it would not be possible to operate a single licensing system for drivers or signallers because of the variation in operational, infrastructure, signalling and rolling stock between railway sectors. They suggested that different licensing systems would be required, for example, one for heavy rail and one for metro systems.

359 An applicant that has suspensions, endorsement or revocations under one licensing system is unlikely to be prevented from applying for a new licence from another licensing system. This may be prevented if there is a single central recording system.

Question 59: Should there be only one accredited national licensing system that takes into account all those dutyholders and personnel that would be within scope (as discussed in Question 55 to 58) and why? If not, why and how many systems would be required?

Number of certification bodies

360 There may be no limitation in the number of certification bodies that could be appointed under an accredited national licensing system. This could cause difficulties in the tracking of information on workers (see paragraph 39).

Question 60: What are your views on the number of certification bodies that should be appointed under an accredited national licensing system?

MANAGEMENT OF THE ACCREDITED NATIONAL LICENSING SYSTEM

Role of RSSB

361 Lord Cullen placed the responsibility for the licensing of drivers and signallers with RSSB (See Annex 4). Early discussions with RSSB have indicated that they are not currently minded to have responsibility for the setting up and operation of the licensing system for drivers and signallers. They considered that operation of the licensing system would have significant

financial and resourcing implications for them. The RISB development group, under the chairmanship of the ORR did not consider such a role falling within the organisation's core functions, although its constitution agreement does not prevent it from doing such work if its members wish it to do so.

Role of HSE

362 Current EC proposals for driver certification would require HSE to issue licenses. However, this is not a role HSE would seek to hold and HSE / DfT will aim to persuade the EC that this is not appropriate. HSE see no reason why this duty could not be undertaken by an appropriate accredited organisation.

Role of a Steering Group

363 Someone will need to take responsibility for setting up the licensing system if Lord Cullen's recommendation is to be implemented. As RSSB are currently minded not to take on this role, HSE intend to facilitate setting up a Steering Group of key stakeholders to develop and oversee a framework for an accredited national licensing system. HSE would at least seek RSSB representation on this group. Other members could be ATOC, Network Rail, Trade Unions etc. The Steering Group may be guided by HSE and use the advisory function provided by UKAS to establish its role, remit, terms of reference and to develop a framework criteria. The work of the Steering Group could consider licensing as well as the proposal to establish an accredited certification system for suppliers of safety critical products and services (See chapter 5).

Question 61: Who should set up and manage the accredited national licensing system and why?

GENERIC NATIONAL STANDARDS FOR DRIVERS AND SIGNALLERS

364 Lord Cullen asked for common standards to be laid down for the training of drivers and signallers. This was supported by HSC.

365 The Centre for Rail Skills work with the rail industry to identify and develop National Occupational Standards (NOS) that form the basis of National Vocational Qualifications (NVQ) which cover rail operations, engineering maintenance and renewals, and installations. Currently, train drivers and signallers can undertake formal training to obtain NVQs.

366 Despite the industry being involved in the development of NOSs and NVQs, the number of train drivers and signallers gaining these qualifications has been, and remains, low. Instead, various types of standards have been developed throughout the rail industry. For example there are Railway Group Standards and ATOC Approved Codes of Practice that apply on Network Rail controlled infrastructure and company standards for London Underground and Heritage railways. Some of these relate to technical competence, others are

related to skills, safety and fitness. Parts of the rail industry report that their training processes are being amended to ensure that training is of a standard equivalent to the NOS.

367 Trainers and those undertaking certification in the accredited national licensing system will need to use appropriate common standards to train and assess drivers and signallers against. It is possible that the NOSs for drivers and signallers could be identified as a suitable generic national standard for this purpose.

368 Some stakeholders have stated that it could be difficult to develop generic standards because of the variation in operational, infrastructure, signalling and rolling stock between railway operators.

369 HSE intends to explore the development of the standards that need to be used in the accredited national licensing system as part of the remit of the Steering Group.

Question 62: What standards should be used to train and assess drivers and signallers as part of the accredited national licensing system and why?

Question 63: Is it possible that these standards could be generic national standards and if not, why?

ACCREDITATION OF TRAINING

370 In his report, Lord Cullen said that there did not seem to be a need for centralised training in his proposed licensing system. Instead he considered that those who carry out training (training providers or train operators) should be accredited (Recommendation 25, see Annex 4).

371 Lord Cullen also made a recommendation for the accreditation of suppliers of safety critical services (Recommendation 24 contained in Annex 4). Provision of training to drivers and signallers could be considered a safety critical service. Chapter 5 proposes the development of an industry owned accredited certification system for suppliers. Such a system is likely to only apply to contractors and not likely to apply to training undertaken within a company.

372 Although training is an important aspect in developing and maintaining staff competence, the provision of training itself cannot be used to confirm that a member of staff is competent. Determining competence and fitness is best achieved through appropriate assessment. Regardless of how a person had received training, assessment through an accredited national licensing system would confirm whether the person is competent and fit.

Question 64: Is accreditation of those providing training required in an accredited national licensing system and why?

ASSESSMENT OF COMPETENCE & FITNESS

373 Drivers and signallers would need to be assessed by a certification body as part of the accredited national licensing system. The competencies and fitness requirements that may need to be assessed include:

- a) **Medical and physical fitness** – RSCW Regulations require all safety-critical workers to be medically fit;
- b) **General competence** – Of the rules and regulations for railway operations;
- c) **Traction competence** – The type of rolling stock that the licensee is considered competent to drive;
- d) **Signalling Equipment** - Information on the types of signalling equipment the licensee is considered competent to operate;
- e) **Route knowledge** – Information on the particular aspects associated with the route that the driver is operating upon; and
- f) **Language competence** – It is important that people can understand safety critical communications, operating instructions and dealing with emergencies.

374 Some stakeholders have concerns about whether route knowledge could be adequately assessed under an accredited licensing system. This is because they consider that third party assessors would not have sufficient knowledge of operational, infrastructure, signalling and rolling stock specific to a particular railway operator to enable them to be competent.

375 An 'authority to work' from the employer may be necessary because a national licence may not be able to cover all specific knowledge and competence requirements required for a particular task.

376 The issuing of a licence should assist the dutyholder in determining whether or not a person can be allowed to undertake driving or signalling activities on its behalf. Even if the licence covered an assessment of all necessary competence and fitness requirements, the dutyholder may still want to issue an 'authority to work' to help maintain clarity about the dutyholder's accountability for controlling the risks associated with that activity.

Question 65: What competence and fitness requirements are required to be assessed before a driver or signaller can be allowed to work on the railway? Please explain why.

Question 66: Which of these competence and fitness requirements could be assessed as part of the accredited national licensing system, how and why?

Question 67: If all necessary competence and fitness requirements cannot be assessed as part of the accredited national licensing system, how should dutyholders provide assurance that there will be no conflict of interest in the assessment process?

Question 68: Is an employers' 'authority to work' required in addition to a licence issued under an accredited national licensing system and why?

APPEALS PROCESS

377 The accredited national licensing system is likely to need an appeals process for any driver or signaller who fails their assessments and would almost certainly be required for those whose licence has been revoked as a result of disciplinary action by their employer. Consideration will need to be given to any sanctions that should be placed on an employer or individual if a driver or signaller works without a valid licence. Provision of an appeals process may also be required to ensure compliance with the requirements of Human Rights legislation.

Question 69: What issues should be taken into account when establishing an appeals process and why?

Question 70: What would be the best way to operate an appeals process?

ISSUING THE LICENCE

378 A record should be made that the person has been assessed as competent and fit to carry out driving or signalling operations and a record made of the standards against which the person was assessed. This record should be kept and maintained by the organisation that carried out the assessment, and made available to others who may need to see it.

379 In addition, under the accredited national licensing system, the certification body will issue a licence to the person who has been successfully assessed. This document will need to include sufficient information to enable interested parties to confirm the identity of the person (name and photograph) and determine what level of competence and fitness that person has achieved. Other information²⁷ that may be needed on the licence includes:

- Name of the employer (RSCW Regulations require a means of identification that includes a photograph, the employee's name, the

²⁷ This would be subject to the Data Protection Act 1998 and the European Convention on Human Rights.

name of the employer and any other particulars that the employer wants to include²⁸); and

- Medical restrictions – such as if a worker needs to wear glasses.

380 There is a range of licence formats available, from paper document and booklets to plastic card with embedded electronic chips.

Question 71: What format of licence should be used for the accredited national licensing system and why?

Question 72: What information should be on the licence, why and where should it be contained (e.g. printed or on an electronic chip)?

Question 73: Is there any other information that would not be on the licence but would need to be easily made available to interested parties? If so, what, and why?

CENTRAL RECORDING

381 The certification body would hold records of assessment and licenses issued under HSC's proposed accredited national licensing system. Such information could be provided to interested parties²⁹. Paragraph 40 explained that there may need to be more than one certification body if the whole of the UK rail industry is to be covered. However, Lord Cullen called for the central recording of those who are qualified as drivers and signallers.

382 There is a risk that with more than one certification body, a particular certification body may not find out that the applicant had been suspended, have endorsements or be banned by another certification body. Similar problems led to Network Rail's predecessor, Railtrack, to develop the SENTINEL licensing system. This system uses a single card issue point, has card version control and a database holding a complete listing of individual's details and competencies, records of whether a card has been revoked or whether there are any restrictions placed upon the individual. It is possible to analyse and provide information to interested parties.

383 Current EC proposals for driver certification require a register of all certificates to enable information to be provided between Member States, safety regulators and employers of drivers who may want to check data during a recruitment procedure. This responsibility is placed upon the single body that issues the EC driver certificate, HSE under the current EC proposals. HSE see no reason why this duty could not be undertaken by an appropriately accredited organisation.

²⁸ ID cards, or similar documents are a requirement of the RSCW Regulations 1994 and remain part of the policy options arising from the review of the regulations (See chapter 6).

²⁹ This would be subject to the Data Protection Act 1998 and the European Convention on Human Rights.

Question 74: If there is to be more than one certification body (See Question 60), should there be a central recording system and why?

Question 75: If there is be a central recording system, how should it operate and by whom? If not, how do you prevent the risks identified in paragraph 382 from occurring?

MAINTAINING THE LICENCE

384 An accredited national licensing system should give greater assurance that the driver or signaller is competent and fit at the time that the assessment has been undertaken.

385 Chapter 6 outlines a proposal for a requirement for dutyholders to have a competence management system. This will require dutyholders to monitor the competence and fitness of drivers and signallers and to take appropriate action when competence and fitness is questioned. A monitoring system is also a requirement of the current EC proposals for driver certification (See paragraph 12).

386 Lord Cullen requested that drivers' and signallers' licenses should be revalidated every three years (Recommendation 25 & 26, See Annex 4). The EC's current proposals for driver certification state that the certificate is renewable every five years. In addition, to be able to keep the certificate the certificate holder will need to undertake more periodic checks. This includes knowledge of the line and of the rolling stock, to be checked every year or after every stoppage of work for more than three months.

387 Checking of knowledge and revalidation of the licence in an accredited national licensing system will give greater assurance that the dutyholder's competence management system is ensuring that its drivers and signallers are maintaining the necessary competence and fitness requirements.

Question 76: How often should a licence be revalidated, what requirements would need to be rechecked, when and why?

Question 77: If an 'authority to work' is required (as asked in Question 67), how often should this be revalidated and why?

TRANSITIONAL PROVISIONS

388 Clearly, when a new licensing scheme is introduced, a period of time will be needed while existing drivers and signallers are assessed and issued with licenses. Transitional arrangements would therefore need to be established for the accredited national licensing system to ensure that railways can operate safely, with minimum disruption to services, whilst drivers and signallers currently employed are assessed as competent and issued with licenses.

Question 78: What should be taken into account when establishing transitional provisions and why?

PROPOSED MODEL FOR AN ACCREDITED NATIONAL LICENSING SYSTEM

389 The sections above have outlined the key features of an accredited national licensing system that takes into account the steer provided by HSC at its meeting in April 2003, RSSB's current position on its role in the licensing system and takes note of the EC's current proposals for driver certification. This accredited national licensing system can be represented as a model, as outlined in Annex 11.

REGULATORY IMPACT ASSESSMENT

390 An initial regulatory impact assessment has been prepared for the development of a voluntary industry owned accredited national licensing system. This is found at Annex 12. Any comments would be welcome.

CHAPTER 8

INVITATION TO COMMENT

391 The railway industry continues to face significant challenges in building public confidence in its capability to manage risk competently, consistently and reliably. Success or failure is ultimately in the industry's own hands. Its future track record and perceived attitude to safety will be vital.

392 Nevertheless HSC's fundamental review of railway safety legislation provides an opportunity to take stock and establish a firm basis on which the industry can go forward. This Discussion Document is part of that review. It is intended to prompt discussion and debate before decisions are taken. Although there are some areas where the requirements of European Directives effectively prescribe the outcome, there are many others where there are no such constraints. We actively welcome constructive alternative ideas and proposals.

393 This Discussion Document is part of an ongoing process of dialogue and engagement with the railway industry, rail trade unions, passenger groups and other interested parties. The dialogue will continue through the remainder of this year and into the first half of 2004 as we work up a Consultative Document with specific proposals for change. As a first step some open seminars are planned and the HSE policy team will continue to listen to, and engage with, stakeholders. If you wish to attend the open meetings you will need to register in advance. Please contact David Gregson (see below for contact details).

394 In short this Discussion Document marks a key stage in establishing the future regulatory framework for safety in a vital part of the national infrastructure. HSC urges everyone in the railway industry, and other interested parties to contribute in shaping future railway safety requirements, and in building public trust and confidence in the railway industry.

395 Comments should be sent by 31 December 2003 to David Gregson at [email]. You are encouraged to use the proforma provided [insert link], adding supplementary pages if the proforma is insufficient. Comments may also be sent by post to David Gregson at Health & Safety Executive, Rose Court 3NW, 2 Southwark Bridge, London SE1 9HS.

396 Annex 13 sets out how HSE will handle the responses we receive. Please note that written responses received will be made publicly available unless the author specifies otherwise.

ANNEX 1**HISTORY OF THE RAILWAYS (SAFETY CASE) REGULATIONS**

1 Regulations on railway safety cases were originally (in 1993) conceived as a key element of a new railway safety regime, which would ensure that the privatisation of British Rail and consequent entry of new, possibly inexperienced, railway operators would not result in increased risks to the safety of passengers and staff. The 1994 Regulations, which were put in place in 1994, were intended to provide a framework within which health and safety standards would be maintained and where possible improved. The safety case regime was seen, in particular, as addressing safety at the interfaces between different railway operators.

2 The infrastructure controller, Railtrack, was given the role of accepting train and station operators' safety cases and then checking that they were complied with. This was seen as consistent with its responsibility under Health and Safety at Work Act 1974 to ensure that operators did not import undue risk onto its network; it also meant that HSE would not need to become too closely involved in the detail of individual train and station operators' safety cases, except as a way of checking that Railtrack was meeting its responsibilities for the safety of the railway system as a whole.

3 At the same time, the decision was made to apply the Regulations not only to the mainline railway but also to existing 'vertically integrated' operators such as the London Underground and light rail systems.

2000 changes

4 The devastating collision and fire at Ladbroke Grove in 1999 brought concerns about Railtrack's role in the railway safety system to the fore. Its role as formal acceptor of train and station operators' safety cases was questioned, and the dual responsibility of Railtrack's Safety and Standards Directorate (S&SD) – to Railtrack as part of the company's safety management system and to the Railway Group as a whole in setting Standards for train and station operators – was difficult in terms of public perception. In consequence, S&SD was transformed into Railway Safety, a separate company (albeit within Railtrack Group), and the 1994 Regulations were changed so as to:

- make HSE the formal acceptor of all safety cases;
- require the infrastructure controller to make a recommendation to HSE as to whether a train or station operator's safety case should be accepted;
- require a further, independent assessment of safety cases (including Railtrack's own), in practice by Railway Safety;

- require the infrastructure controller to procure independent annual audits, undertaken in practice by Railway Safety, of its own, and train and station operators' health and safety management systems; and
- add new duties on the infrastructure controller to take reasonable steps to ensure that train and station operators comply with their safety cases, and to report significant breaches and failures to comply with reasonable requests to HSE. This strengthened the previous position, where the infrastructure controller's monitoring activities had to be described in its safety case but were not the subject of specific duties.

5 The Railways (Safety Case) Regulations 2000 also made a number of changes to the required content of safety cases in Schedule 1 to the Regulations, including more detailed requirements on risk assessment and a requirement for train operators' safety cases to include arrangements for evacuation from trains in an emergency.

2001 changes

6 Amendments were introduced in 2001 to ensure that the Regulations covered not only the evacuation of trains but also escape (unsupervised exit such as was necessary in the case of Ladbrooke Grove). This responded to a recommendation from Lord Cullen's Part 1 Report.

2003 changes

7 Following publication of Part 2 of Lord Cullen's Report in September 2001, further changes were made which changed and partly reversed the 2000 changes:

- The Rail Safety and Standards Board (RSSB) was established on 1 April 2003 as an industry body charged with leading the industry's efforts to maintain and improve railway health and safety. This ended the 'half-way house' position adopted as an interim measure in 2000 where Railway Safety was established as part of Railtrack Group.
- The requirement introduced in 2000 for the infrastructure controller to procure an additional independent assessment of safety cases was removed. This simplified the overall procedure, and reflected Lord Cullen's view that there should be a clearer separation between the safety regulator and the industry. The safety case assessment function became entirely a matter for HSE.
- The requirement introduced in 2000 for independent annual audit was changed so as to require each railway operator to procure the audit from a 'competent body'. Placing the duty to procure audit on each operator, rather than on the infrastructure controller, was intended to increase operators' 'ownership' of audit findings. In addition, opening up the annual audit market to a range of 'competent bodies' was intended to encourage fresh approaches to audit. The changes also made for a clearer distinction between the systematic assessment of

the health and safety management system (audit) and the important but narrower duty of the infrastructure controller to check that operators comply with those aspects of their safety cases which could affect the infrastructure controller's ability to comply with its own duties.

ANNEX 2**KEY FINDINGS FROM AN EXTERNAL EVALUATION OF THE
IMPACT OF THE RAILWAY SAFETY CASE REGULATIONS
(CONDUCTED BY BOMEL LTD WITH NERA UNDER
CONTRACT TO HSE)**

- a) The safety case assessment regime and assessment process, particularly under the 2000 amendments, has stimulated the railway industry in the proactive use of risk assessment, encouraging duty holders to explore specific risks in greater detail and to identify and prioritise control measures.
- b) The introduction of the requirement for a development plan under the 2000 amendments potentially provides the outstanding link in the chain of continuous improvement. As presented by a number of duty holders, it provides a valuable mechanism to capture and structure actions for change and inform HMRI intervention plans. However, it must not be considered as an opportunity to defer taking actions which could be performed immediately (or in the short term). To maximise the effectiveness of development plans, closer scrutiny is necessary in some cases to ensure that timescales and resources are fully identified. Greater authority might be given to the plan if the responsibilities for completing the activities had to be specified in it.
- c) For most stakeholders, a major benefit of the Regulations arises from the process of developing a safety case, particularly if workforce involvement has been widespread. For a number of duty holders, this process has identified gaps in procedural documentation and has also led to the development of new Group Standards to fill the gaps.
- d) The apparent greater rigour of Safety Case assessment under the 2000 amendments (both in terms of deeper interrogation and the number of different organisations carrying out the reviews, with different skills, requirements and agendas) indicates a step change in the quality of Safety Case submissions, and potentially in the control of risks.
- e) Transfer of findings from the assessment, audit and inspection operations is important in the continuous improvement cycle. There are concerns that a diversity of organisations ('competent bodies') carrying out audit functions will reduce the exchange of good practice and lead to a lack of consistency across the industry.

- f) The safety management system documentation must be 'live', fully reflecting the current operational conditions. If operational or managerial changes (or material revisions) occur, these must be introduced or signposted from the safety management system immediately, without a time lag.

In terms of costs and benefits attributable to the Railways (Safety Case) Regulations, the evaluation concludes:

- Overall, the Regulations represent 'value for money'.
- For a duty holder, the cost of developing and submitting a Safety Case is by far the largest single cost element associated with the Regulations (although the accumulated cost associated with ongoing safety management, material revisions, audits, etc. is equally significant for most duty holders). The upfront costs of implementing the requirements of the Regulations (whether at first introduction in 1994 or at subsequent major regulatory changes) should be seen as an investment for longer term realisation of benefits in terms of accident / incident reduction.
- Due to the time lag before benefits in risk levels are seen, the most realistic perspective of costs and benefits is that over the total permissioning regime since privatisation, rather than over discrete phases of that regime. The risk reduction contributions of the 2000 amendments are only just starting to be realised and will be potentially seen over the next 2-3 years.
- The cumulative cost of the Regulations to all stakeholders within the railway industry is estimated to be approximately £52 million since 1994. Benefits attributable to the Regulations over the same period are approximately £85 million, based on prevented equivalent fatalities for all types of rail risk (as provided by the Rail Safety and Standards Board). If only equivalent fatalities are considered which are judged to be under the direct control of railway operators (ie. Excluding risks arising from malicious acts), the benefit valuation reduces from £85 million to £53 million – still giving a nominal net benefit.
- The role of the Regulations in achieving improvements in rail safety has been isolated from other influences in order to attribute the financial benefit from the Regulations. Whilst this is difficult due to complex interactions of confounding influences (and was not attempted in previous railway Regulatory Impact Assessments), it is estimated that the Regulations are

'responsible' for approximately 15% of the overall safety improvement on the Network Rail controlled infrastructure.

ANNEX 3

THE RAILWAY SAFETY DIRECTIVE – KEY EXTRACTS

The extracts below are taken from the 'Common Position' text of the Directive, which can be found in full at <http://register.consilium.eu.int/pdf/en/03/st08/st08557en03.pdf>

The Directive is due to have its second reading in the European Parliament in the Autumn and should be adopted early in 2004.

Article 1 - Purpose

The purpose of this Directive is to ensure the development and improvement of safety on the Community's railways by:

- a) Harmonizing the regulatory structure in the Member States;
- b) Defining responsibilities between the actors;
- c) Developing common safety targets and common safety methods;
- d) Requiring the establishment in every Member State, of a safety authority and an accident and investigating body;
- e) Defining common principles for the management, regulation and supervision of railway safety.

Article 2 - Scope

1. This Directive applies to the railway system in the Member States, which may be broken down into subsystems for structural and operational areas. It covers safety requirements on the system as a whole, including the safe management of infrastructure and of traffic operation and the interaction between railway undertakings and infrastructure managers.

2. Member States may exclude from the measures they adopt in implementation of this Directive:

- g) metros, trams and other light rail systems;
- h) networks that are functionally separate from the rest of the railway system and intended only for the operation of local, urban or suburban passenger services, as well as railway undertakings operating solely on these networks;
- i) privately owned railway infrastructure that exists solely for use by the infrastructure owner for its own freight operations.

Article 4 – Development and improvement of railway safety

1. Member States shall ensure that railway safety is generally maintained and, where reasonably practicable, continuously improved, taking into consideration the development of Community legislation and technical and scientific progress and giving priority to the prevention of serious accidents.

....

2. Member States shall ensure that the responsibility for the safe operation of the railway system and the control of risks associated with it is laid upon the infrastructure managers and railway undertakings, obliging them to implement necessary risk control measures, where appropriate in cooperation with each other, to apply national safety rules and standards, and to establish safety management systems in accordance with this Directive.

Without prejudice to civil liability in accordance with the legal requirements of the Member States, each infrastructure manager and railway undertaking shall be made responsible for its part of the system and its safe operation, including supply of material and contracting of services, vis-à-vis users, customers and third parties.

Article 7 - Common safety targets

1. The CSTs shall be developed, adopted and revised following the procedures laid down in this Article.

3. The first set of draft CSTs shall be based on an examination of existing targets and safety performance in the Member States and shall ensure that the current safety performance of the rail system is not reduced in any Member State.

The second set of draft CSTs shall be based on the experiences gained from the first set of CSTs and their implementation. They shall reflect any priority areas where safety needs to be further improved.

All proposals for draft and revised CSTs shall reflect the obligations on Member States laid down in Article 4(1). Such proposals shall be accompanied by an assessment of the estimated costs and benefits, indicating their likely impact for all the operators and economic agents involved and their impact on the societal acceptance of risk. They shall contain a timetable for gradual implementation, where necessary, in particular to take account of the nature and extent of investment required to apply them. They shall analyse the possible impact on TSI for the subsystems and contain, where appropriate, consequential proposals for amendments to the TSI.

4. The CSTs shall define the safety levels that must at least be reached by different parts of the railway system and by the system as a whole in each Member State, expressed in risk acceptance criteria for:

- a) individual risks relating to passengers, staff including the staff of contractors, level crossing users and others, and, without prejudice to existing national and international liability rules, individual risks relating to unauthorised persons on railway premises;
- b) societal risks.

Article 9 – Safety management systems

1. Infrastructure managers and railway undertakings shall establish their safety management systems to ensure that the railway system can achieve at least the CSTs, is in conformity with the national safety rules described in Article 8 and Annex II and with safety requirements laid down in the TSIs, and that the relevant parts of CSMs are applied.

2. The safety management system shall meet the requirements and contain the elements laid down in Annex III, adapted to the character, extent and other conditions of the activity pursued. It shall ensure the control of all risks associated with the activity of the infrastructure manager or railway undertaking, including the supply of maintenance and material and the use of contractors. Without prejudice to existing national and international liability rules, the safety management system shall also take into account, where appropriate and reasonable, the risks arising as a result of activities by other parties

3. The safety management system of any infrastructure manager shall take into account the effects of operations by different railway undertakings on the network and make provisions to allow all railway undertakings to operate in accordance with TSIs and national safety rules and with conditions laid down in their safety certificate. It shall furthermore be developed with the aim of coordinating the emergency procedures of the infrastructure manager with all railway undertakings that operate on its infrastructure.

4. Each year all infrastructure managers and railway undertakings shall submit to the safety authority before 30 June an annual safety report concerning the preceding calendar year.

The safety report shall contain:

- a) information on how the organisation's corporate safety targets are met and the results of safety plans;
- b) the development of national safety indicators, and of the CSIs laid down in Annex I, as far as it is relevant to the reporting organisation;
- c) the results of internal safety auditing;

- d) observations on deficiencies and malfunctions of railway operations and infrastructure management that might be relevant for the safety authority.

Article 10 – Safety certificates

1. In order to be granted access to the railway infrastructure, a railway undertaking must hold a safety certificate as provided for in this Chapter. The safety certificate may cover the whole railway network of a Member State or only a defined part thereof.

The purpose of the safety certificate is to provide evidence that the railway undertaking has established its safety management system and can meet requirements laid down in TSIs and other relevant Community legislation and in national safety rules in order to control risks and operate safely on the network.

2. The safety certificate shall comprise:

- a) certification confirming acceptance of the railway undertaking's safety management system as described in Article 9 and Annex III, and
- b) certification confirming acceptance of the provisions adopted by the railway undertaking to meet specific requirements necessary for the safe operation of the relevant network. The requirements may include application of TSIs and national safety rules, acceptance of staff's certificates and authorisation to place in service the rolling stock used by the railway undertaking. The certification shall be based on documentation submitted by the railway undertaking as described in Annex IV.

3. The safety authority in the Member State where the railway undertaking first establishes its operation shall grant the certification in accordance with paragraph 2.

The certification granted in accordance with paragraph 2 must specify the type and extent of the railway operations covered. The certification granted in accordance with paragraph 2(a) shall be valid throughout the Community for equivalent rail transport operations.

4. The safety authority in the Member State in which the railway undertaking is planning to operate additional rail transport services shall grant the additional national certification necessary in accordance with paragraph 2(b).

5. The safety certificate shall be renewed upon application by the railway undertaking at intervals not exceeding five years. It shall be wholly or partly updated whenever the type or extent of the operation is substantially altered.

The holder of the safety certificate shall without delay inform the competent safety authority of all major changes in the conditions of the relevant part of the safety certificate. It shall furthermore notify the competent safety authority whenever new categories of staff or new types of rolling stock are introduced.

The safety authority may require that the relevant part of the safety certificate be revised following substantial changes in the safety regulatory framework.

If the safety authority finds that the holder of the safety certificate no longer satisfies the conditions for a certification which it has issued, it shall revoke part (a) and/or (b) of the certificate, giving reasons for its decision. The safety authority that has revoked an additional national certification granted in accordance with paragraph 4 shall promptly inform the safety authority that granted the certification under paragraph 2(a) of its decision.

Similarly, a safety authority must revoke a safety certificate if it is apparent that the holder of the safety certificate has not used it as intended in the year following its issue.

6. The safety authority shall inform the Agency within one month of the safety certificates referred to in paragraph 2(a) that have been issued, renewed, amended or revoked. It shall state the name and address of the railway undertaking, the issue date, scope and validity of the safety certificate and, in case of revocation, the reasons for its decision.

7. Before ...* the Agency shall evaluate the development of safety certification and submit a report to the Commission with recommendations on a strategy for migration towards a single Community safety certificate. The Commission shall take appropriate action following the recommendation.

* Five years after the entry into force of this Directive.

Article 11- Safety authorisation of infrastructure managers

1. In order to be allowed to manage and operate a rail infrastructure the infrastructure manager must obtain a safety authorisation from the safety authority in the Member State where he is established.

The safety authorisation shall comprise:

- a) authorisation confirming acceptance of the infrastructure manager's safety management system as described in Article 9 and Annex III, and
- b) authorisation confirming acceptance of the provisions of the infrastructure manager to meet specific requirements necessary for the safe design, maintenance and operation of the railway infrastructure including, where appropriate, the maintenance and operation of the traffic control and signalling system.

2. The safety authorisation shall be renewed upon application by the infrastructure manager at intervals not exceeding five years. It shall be wholly or partly updated whenever substantial changes are made to the infrastructure, signalling or energy supply or to the principles of its operation and maintenance. The holder of the safety authorisation shall without delay inform the safety authority of all such changes.

The safety authority may require that the safety authorisation be revised following substantial changes to the safety regulatory framework.

If the safety authority finds that an authorised infrastructure manager no longer satisfies the conditions for a safety authorisation it shall revoke the authorisation, giving reasons for its decisions.

3. The safety authority shall inform the Agency within one month of the safety authorisations that have been issued, renewed, amended or revoked. It shall state the name and address of the infrastructure manager, the issue date, the scope and validity of the safety authorisation and, in case of revocation, the reasons for its decision.

Article 12 – Application requirements

1. The safety authority shall take a decision on an application for safety certification or safety authorisation without delay and in any event not more than four months after all information required and any supplementary information requested by the safety authority has been submitted. If the applicant is requested to submit supplementary information, such information shall be submitted promptly.

2. In order to facilitate the establishment of new railway undertakings and the submission of applications from railway undertakings from other Member States, the safety authority shall give detailed guidance on how to obtain the safety certificate. It shall list all requirements that have been laid down for the purpose of Article 10(2) and make all relevant documents available to the applicant.

Special guidance shall be given to railway undertakings that apply for a safety certificate concerning services on a defined limited part of an infrastructure, specifically identifying the rules that are valid for the part in question.

3. An application guidance document describing and explaining the requirements for the safety certificates and listing the documents that must be submitted shall be made available to the applicants free of charge. All applications for safety certificates shall be submitted in the language required by the safety authority.

Article 17 – Decision-making principles

1. The safety authority shall carry out its tasks in an open, non-discriminatory and transparent way. In particular it shall allow all parties to be heard and give reasons for its decisions.

It shall promptly respond to requests and applications and communicate its requests for information without delay and adopt all its decisions within four months after all requested information has been provided. It may at any time request the technical assistance of infrastructure managers and railway undertakings or other qualified bodies when it is carrying out the tasks referred to in Article 16.

In the process of developing the national regulatory framework, the safety authority shall consult all persons involved and interested parties, including infrastructure managers, railway undertakings, manufacturers and maintenance providers, users and staff representatives.

2. The safety authority shall be free to carry out all inspections and investigations that are needed for accomplishment of its tasks and it shall be granted access to all relevant documents and to premises, installations and equipment of infrastructure managers and railway undertakings.

....

4. The safety authorities shall conduct an active exchange of views and experience for the purpose of harmonising their decision-making criteria across the Community.

The Agency shall support the safety authorities in these tasks.

Annex III – Safety management systems

1. Requirements on the safety management system.

The safety management system must be documented in all relevant parts and shall in particular describe the distribution of responsibilities within the organisation of the infrastructure manager or the railway undertaking. It shall show how control by the management on different levels is secured, how staff and their representatives on all levels are involved and how continuous improvement of the safety management system is ensured.

2. Basic elements of the safety management system.

The basic elements of the safety management system are:

- (a) a safety policy approved by the organisation's chief executive and communicated to all staff;
- (b) qualitative and quantitative targets of the organisation for the maintenance and enhancement of safety, and plans and procedures for reaching these targets;
- (c) procedures to meet existing, new and altered technical and operational standards or other prescriptive conditions as laid down
 - in TSIs, or
 - in national safety rules referred to in Article 8 and Annex II, or
 - in other relevant rules, or
 - in authority decisions,and procedures to assure compliance with the standards and other prescriptive conditions throughout the life-cycle of equipment and operations;
- (d) procedures and methods for carrying out risk evaluation and implementing risk control measures whenever a change of the operating conditions or new material imposes new risks on the infrastructure or on operations;
- (e) provision of programmes for training of staff and systems to ensure that the staff's competence is maintained and tasks carried out accordingly;
- (f) arrangements for the provision of sufficient information within the organisation and, where appropriate, between organisations operating on the same infrastructure;
- (g) procedures and formats for how safety information is to be documented and designation of procedure for configuration control of vital safety information;

- (h) procedures to ensure that accidents, incidents, near misses and other dangerous occurrences are reported, investigated and analysed and that necessary preventive measures are taken;
- (i) provision of plans for action and alerts and information in case of emergency, agreed upon with the appropriate public authorities;
- (j) provisions for recurrent internal auditing of the safety management system.

Annex IV - Declarations for network specific part of safety certificate

The following documents must be submitted to enable the safety authority to deliver the network-specific part of the safety certificate:

- documentation from the railway undertaking on the TSIs or parts of TSIs and, where relevant, national safety rules and other rules applicable to its operations, its staff and its rolling stock and how compliance is ensured by the safety management system;
- documentation from the railway undertaking on the different categories of staff employed or contracted for the operation, including evidence that they meet requirements of TSIs or national rules and have been duly certified;
- documentation from the railway undertaking on the different types of rolling stock used for the operation, including evidence that they meet requirements of TSIs or national rules and have been duly certified.

To avoid duplication of work and to reduce the amount of information only summary documentation should be submitted concerning elements that comply with TSIs and other requirements of Directives 96/48/EC and 2001/16/EC.

ANNEX 4**RELEVANT RECOMMENDATIONS FROM RAIL ACCIDENT
INVESTIGATION INQUIRIES AND REPORTS****SOUTHALL RAIL ACCIDENT INQUIRY REPORT**

General information on progress with the Southall recommendations can be found at

<http://www.hse.gov.uk/railways/railpublic.pdf> and
<http://www.hse.gov.uk/railways/railpublic2.pdf>

Recommendation 21

‘Controllers’ posts in Railtrack and TOCs should be designated as ‘safety-critical’ as defined in the Railways (Safety Critical Work) Regulation 1994’.

Action: Railtrack (now Network Rail) and
Association of Train Operating Companies

THE LADBROKE GROVE RAIL INQUIRY

The full text of Lord Cullen’s Part 2 Report can be found at

<http://www.hse.gov.uk/railways/paddrail/lqri2.pdf>.

More general information on progress with Lord Cullen’s recommendations can be found at

<http://www.hse.gov.uk/railways/railpublic2.pdf>

Part 2 Recommendation 19

‘The definition of responsibilities for the control of risk at specific sites which are shared by different railway operators and at the interfaces between them across the network should be refined and set out in the safety case. However, the details of the arrangements and agreements for these purposes should not be required to be set out in the safety case; it should be sufficient that the safety case provides information as to the means of access to them’.

Action: Railtrack (now Network Rail), Train
Operating Companies

Part 2 Recommendation 21

‘Duty holders should be under a statutory duty to comply with Railway Group Standards in so far as they relate to matters of health and safety’.

Action: HSC

Part 2 Recommendation 22

'The process of safety case acceptance should include the check that a system as described in the safety case is actually in place; whereas the audit would concentrate on how that system was working in practice and how it was ensuring and improving safety'.

Action: HSE, Railtrack (now Network Rail)

Part 2 Recommendation 24

'Suppliers of products or services of a safety critical kind for use on, or in regard to, the railways on Great Britain should be required to hold an accreditation as a condition of being able to engage in that activity. But the features of such a system require further study.'

Action: HSC

Part 2 Recommendation 25

'There should be a system for the licensing and central recording of those who are qualified for the driving of trains in respect of their knowledge of the rules and regulations and the traction for which they have been assessed as competent. Training providers or train operators should be accredited and common standards laid down for the purpose. Drivers' licences should require to be revalidated every three years.'

Action: Railway Industry Safety Body³⁰

Part 2 Recommendation 26

'There should be a similar system for licensing the central recording of qualified signalmen, based on an assessment of their knowledge of the rules and regulations. Revalidation every three years should be required.'

Action: Railway Industry Safety Body

Part 2 Recommendation 28

'The safety regulator should cease to be dependent on Railtrack for a recommendation as to whether or not the safety case of a train operator or a station operator (or its material revisions) should be accepted. Instead the safety regulator should give Railtrack the opportunity to make any representation as to whether or not the safety case or revision should be accepted, and the grounds on which such a

³⁰ RISB was established in April 2003 under the name of Rail Safety and Standards Board.

representation is based. The safety regulator should likewise give the opportunity to any other train operator or station operator who may be affected by matters referred to in the safety case to make a similar representation, and for this purpose select whichever operators it considers to be appropriate in the circumstances’.

Action: HSC

Part 2 Recommendation 30

‘In regard to the safety case for Railtrack or any material revision, the safety regulator should give any train operator, selecting whichever it considers to be appropriate in the circumstances, the opportunity to make representations as to whether or not the safety case or revision should be accepted, and the ground on which the representation is based’.

Action: HSC

Part 2 Recommendation 47

‘The body (**RISB**) should also be responsible for the accrediting of the suppliers of products and services and the licensing of individuals, subject to the supervisory activity of the safety regulator’.

Action: Rail Regulator

HSE’S INTERIM RECOMMENDATIONS INTO THE HATFIELD DERAILMENT

The full text of the interim recommendations on Hatfield can be found at:

<http://www.hse.gov.uk/railways/hatfield/investigationb1.pdf>

The full text of HSE’s two interim reports on Hatfield can be found at:

<http://www.hse.gov.uk/railways/hatfield/interim1.htm> and

<http://www.hse.gov.uk/railways/hatfield/interim2.htm>

More general information on the Hatfield derailment can be found at:

<http://www.hse.gov.uk/railways/hatfield.htm>

Recommendation 1.1

‘Existing legal requirements for competence, within the Management of Health and Safety at Work Regulations 1999, and the Railways (Safety Critical Work) Regulations 1994 should be reviewed, to ensure they are sufficiently robust in so far as they relate to all employees whose decisions have a direct impact on public safety on the railways.’

Action: HSE

ANNEX 5**INITIAL REGULATORY IMPACT ASSESSMENT FOR THE REVIEW OF THE RAILWAY SAFETY CASE REGULATIONS****PURPOSE AND INTENDED EFFECT****Issue**

1. The Railways (Safety Case) Regulations 2000 (RSC2000) need to be revised to take account of the European Railway Safety Directive. Both RSC2000 and the Directive contain a permissioning regime based on HSE acceptance of railway operators' safety management systems. However instead of a 'safety case' as such, the Directive requires the submission of safety evidence and documentation. HSE will then issue a safety certificate or authorisation, valid for 5 years. The safety evidence required would be broadly similar to that required now.
2. Although the Directive extends only to the high speed and conventional 'interoperable' railway, it is likely that HSE will wish to maintain the wider scope of RSC2000, so that new Regulations will apply to self-contained railways such as the London Underground, metros and heritage railways. The discussion opens up the possibility of extending the new requirements to tramways, which are presently out of scope.

Objectives

3. To improve the current permissioning regime for railway safety management, the Railways (Safety Case) Regulations 2000, in line with the objectives of the review.
4. To implement relevant provisions of the European railway safety directive, taking maximum advantage of the opportunities it presents.

Risk assessment

5. Railway safety case regulations were first introduced in 1994 in response to privatisation and the fragmentation of the railway industry, as a way of ensuring that safety was maintained and wherever possible improved. Although trends in safety statistics are generally favourable, major accidents such as Southall, Ladbroke Grove, Hatfield and Potters Bar and weak public confidence in railway safety management have ensured that societal concern about railway safety is at a relatively high level.

OPTIONS

6. The Railway Safety Directive allows only limited flexibility in how new Regulations are cast and the limited options available will not materially affect costs and benefits. However, in relation to scope a number of

options are available. Two options have been considered and discounted:

- It would be possible to apply the new Regulations only to the 'interoperable' railway, whilst revoking RSC2000 in entirety, so that other railways such as London Underground would no longer be subject to an operational permissioning regime. However such an option is considered unacceptable.
- It would be possible to apply new Regulations to the interoperable railway and to maintain RSC2000 in relation to other railways. However this would be confusing and does not appear to offer real advantages, since the evidence required in both RSC2000 and the Directive is broadly similar.

7. The options presented in the Discussion Document are as follows:

- Option 1: Bring tramways into scope;
- Option 2: Bring other transport systems currently out of scope (eg monorail systems) into scope;
- Option 3: Take out of scope train operators carrying out maintenance or renewal activities on the railway.

INFORMATION SOURCES AND BACKGROUND ASSUMPTIONS

8. The information in this RIA on the cost of preparing and gaining acceptance of a safety case is derived from industry sources. Other information is from HMRI and other HSE sources.

BENEFITS

Health and safety benefits

9. The new regime implies somewhat less detail in new safety cases, with more emphasis on post-acceptance audit and inspection. New general duties will be introduced, arising from the Safety Directive, which will give added emphasis to key principles of safety management such as the maintenance and improvement of safety and the assessment and control of risk. These developments are expected to bring about an improvement in safety systems, which in turn will lead to safety benefits.

Other benefits

10. A major benefit of the new regime is that it will be less bureaucratic and simpler to administer.

COSTS

Business sectors affected

11. The business sectors affected will depend on the chosen scope of the Regulations as set out in the options above. There are currently 110 safety cases for heavy rail, metro, possessions and freight. About 35 of these are major railway operators, the rest are smaller operators with smaller safety cases.
12. Under option 1 about 13 tramways which are either operating, under construction or planned and would be brought into scope. Under option 2, about four existing or planned new monorail systems would be brought into scope. Under option 3, there are about 25 train operators carrying out maintenance activities on the railway that would be taken out of scope.

Compliance costs to industry

Certificate

13. Under the proposals, the safety case will be replaced by a safety certificate or authorisation, which lasts 5 years and is revocable. There may be additional costs from the resubmission of evidence for the safety certificate or authorisation every 5 years. However, in practice it is believed that this cost will be approximately offset by the current cost of reviewing the safety case every 3 years.

Change in scope

14. All the following options relate to a change in the number of safety cases produced. The costs of producing a safety case was reported by dutyholders (excluding heritage railways and Network Rail) to range between £12,000 and £350,000 (including both preparation and submission, and the assessment process). The highest and lowest estimates both came from individual dutyholders, suggesting a more reliable estimate might be a range of costs centring on the average cost. The average cost of a submission was £83,400 and the average cost of acceptance was £39,500, making a total cost of £122,900. For the purposes of this RIA we shall assume a range of £100,000 to £150,000 for the total cost of producing a safety case. However, it should be noted that individual cases vary greatly.

Option 1: Bring tramways into scope

15. There are approximately 13 tramways that would be brought into scope. The total cost of compliance for all of these tramways is estimated at between £1.3m and £1.95m

Option 2: Bring other transport systems into scope

16. There are or will be approximately four monorail systems that would be brought into scope. The total cost of compliance for all four systems is estimated at between £0.4m and £0.6m.

Option 3: Take out of scope train operators carrying out maintenance activities

17. There are currently around 25 train operators carrying out maintenance activities on the railway. The cost savings of these vehicle operators no longer preparing a safety case is between £2.5m and £3.75m.

Transition

18. [Need a paragraph from policy about why there are no transition costs]

Costs to HSE

19. There will be no additional costs to HSE from a change in scope of the Regulations as HSE recovers the full economic cost of the safety case work they do via a fee levied on the dutyholder. However, there is expected to be a redistribution of resources within HSE involved in the proposed change in emphasis, i.e. an increase in post acceptance inspection and audit, and a decrease in paper work.

Total costs to society

<i>Cost area</i>	<i>Cost estimation</i>
Certificate	Neutral
Option 1: Bring tramways into scope	£1.3-£1.95m
Option 2: Bring other transport systems into scope	£0.4-£0.6m
Option 3: Take out of scope train operators carrying out maintenance activities	Cost saving: £2.5 - £3.75
Transition	Neutral

SMALL FIRMS' IMPACT TEST

20. Heritage railways are unlikely to be affected in most cases, as the great majority are not required to have a safety case and are not likely to be required to have a safety authorisation under the new Regulations. The Heritage Rail Association has been involved in the policy development process.

COMPETITION ASSESSMENT

21.No competition issues have been identified.

Uncertainties

22.The cost element of the RIA centres around the estimated cost of producing evidence for a safety certificate or authorisation, which is subject to some uncertainty. As mentioned earlier in the RIA, individual safety cases vary a great deal, resulting in a large range of cost estimates for producing a safety case. For the purposes of the RIA, we selected a smaller range, centered around the average cost of producing a safety case. Whilst we believe this is more accurate than using the full cost range from the responses, it still may not reflect a given position.

ENFORCEMENT AND SANCTIONS

23.Operating without a valid safety certificate or authorisation will be an offence. New operators will therefore need to apply to HSE for a certificate or authorisation well before they wish to start operating. (However, existing safety case will be used as a basis for an application for a certificate or authorisation, facilitating and minimising the cost of the transition to the new regime.) Operators will need to reapply for a new certificate or authorisation every 5 years.

ANNEX 6

**DEFINITIONS OF TRANSPORT SYSTEMS IN SCOPE OF THE
REMAINDER OF ROTS**

The Regulations apply to 'any relevant transport system' defined as 'a railway, a tramway, a trolley vehicle system or a *prescribed system of guided transport* (Schedule 1)

1. Railway (includes metros) – 'railway means a system of transport employing parallel rails which:

- a) provide support and guidance for vehicles carried on flanged wheels; and
- b) form a track which is either of gauge at least 350mm or crosses a carriageway (whether or not on the same level)

2. Tramway - 'tramway' means a system of transport used wholly or mainly for the carriage of passengers and employing parallel rails which

- a) provide support and guidance for vehicles carried on flanged wheels and
- b) are laid wholly or mainly along a street or in any other place to which the public has access (including a place to which the public has access only on making a payment).

3. Trolley vehicle systems. 'Trolley vehicle system' means a system of transport by vehicles constructed or adapted for use on roads without rails under electric power transmitted to them by overhead wires.

4. Prescribed modes of guided transport

a) Magnetic Levitation – *a mode in which the vehicles are supported and guided by means of magnetic force.*

A 'Maglev' is a transport system which runs using high powered magnets to raise vehicles above the track and also to propel and brake them. With friction almost eliminated, Maglevs can be propelled forwards at speeds of up to 400 km/hour for very high speed train services.

b) Monorails – *a mode in which the vehicles are supported and guided wholly or mainly by means of a single rail or beam.*

A monorail is a single rail serving as a track for passenger or freight vehicles. In most cases the rail is elevated, but monorails can run at ground level or below ground. Vehicles are either suspended from, or straddle, a narrow guideway.

Guided Bus systems (c-e)

Guided buses are normal buses that are capable of operating on a road, but are guided for all, or part of their route.

c) **Road based with cable guidance** – *mode in which vehicles are capable of operating on a road and guided wholly or mainly by means of a cable, wire or other device which is not in direct physical contact with the vehicles.*

In these systems the cable is usually buried beneath the road. There are none in operation in the UK, although some operate in Europe, mainly in airports.

d) **Road based with rail guidance** – *capable of operating on a road and guided wholly or mainly by means of a single rail or slot.*

In these systems the buses either clamp onto a single rail or fit into a slot in the road. There are none at present in Great Britain, though there are operating systems in France, but there is always the possibility that proposals will be submitted in future.

e) **Road based with side guidance** – *vehicles are supported by means of a track or other structure not being a road and are guided wholly or mainly by means of wheels bearing outwards against fixed apparatus.*

This describes the guided bus systems currently operating in Great Britain. The buses are fitted with normal wheels, but also have a set of side wheels behind the main wheels that extend outwards to provide guidance against a raised kerb. These buses operate normally on the public highway, but where the traffic is particularly congested, they move into concrete bus 'corridors' constructed alongside the highway. At this point the guide wheels come into contact with the walls of the guideway to guide the bus. (The wheels do not slot into a rail or groove in the walls).

Other guided systems (essentially people-movers)

f) **Track based with side guidance** – *vehicles are supported by means of a track or other structure not being a road and guided wholly or mainly by means of wheels bearing outwards against fixed apparatus.*

There is some doubt as to what this category was intended to cover, but in practice this rather broad definition includes systems such as the 'people-movers' operating at various airports in Great Britain and other miscellaneous modes of transport.

ANNEX 7

**INITIAL REGULATORY IMPACT ASSESSMENT FOR THE
REVIEW OF THE RAILWAYS AND OTHER TRANSPORT
SYSTEMS (APPROVAL OF WORKS, PLANT AND EQUIPMENT)
REGULATIONS 1994****PURPOSE AND INTENDED EFFECT****Issue**

1 There has been an approvals regime for bringing new works into use on the railways since 1840. The current Railways and Other Transport Systems (Approval of Works, plant and equipment) Regulations 1994 (ROTS) require operators of railways and other 'relevant transport systems' to obtain approval from HSE before bringing into use any new or altered works, plant and equipment that are capable of 'materially affecting' the safe operation of the system³¹.

2 A number of factors have contributed towards the HSC's decision to review the approvals regime:

(a) New requirements for an 'interoperable', trans-European railway system are gradually reducing the scope of ROTs which is seen as incompatible with single market requirements. However, ROTs will continue to apply to the other relevant transport systems. The 'remainder' of ROTs comprises:

- *metros;*
- *heritage railways;*
- *tramways;*
- *trolleybuses;*
- *prescribed modes of guided transport systems.*

This is a significant and expanding group of transport systems and includes LUL (which carries more passengers than the entire national railway), other large, metropolitan metro systems and an increasing number of trams and guided buses.

(b) *The Health and Safety Commission (HSC) has publicly stated that HSE will not directly approve goods and services where there is an adequate system of conformity assessment in place. ROTs is one of the few direct approvals schemes still operated by HSE and must therefore be reviewed in the light of the HSC's stated policy and the move away from approval initiated by the interoperability requirements.*

³¹ ROTs, Regulation 4 (1)

Objectives

3 *A regime that will ensure that risks arising from the introduction of new/altered works, plant and equipment on relevant transport systems continue to be properly controlled.*

Risk assessment

4 *The approvals regulations provide an additional layer of regulatory control for the introduction of new works, plant and equipment on relevant transport systems, which sits above the general requirements under the Health and Safety at Work Act (HSW) and the Transport and Works Act (TWA). If ROTS is revoked HSE needs to ensure that the risks arising from the introduction of new works, etc. continue to be properly controlled.*

OPTIONS**Option 1: No Change**

5 *Under this option ROTS in its current form would be retained with no further amendment.*

Option 2: Amendment

6 *Under this option the regulations would be retained, but amended to move to a risk based philosophy, addressing some of the key issues identified earlier in the paper. Possible revisions include:*

- a) narrowing the scope to remove some of the 'other transport' systems, e.g. trolley/guided buses, which could be controlled solely under road transport and not a mixture of legislative regimes as now;*
- b) narrowing the scope to focus on complex, high risk schemes and/or giving HMRI a formal 'screening' power, similar to that used for the high speed interoperable railway, which would allow them to screen out lower risk schemes (this is already done to a certain extent);*
- c) providing for 'fast tracking' of proposals which have been third party independently assessed.*

Option 3: Revocation/'interoperable' model

7 *This would involve revoking ROTS completely and replacing it with new regulations to introduce a system of third party assessment for high-risk transport systems and schemes, with final 'authorisation' by HSE.*

Option 4: Revocation/'life cycle' model

8 *This model would involve revoking ROTS and developing a 'lifecycle' approach to safety on the railways and other relevant transport systems within the revised safety management permissioning regime. In practice this would mean:*

- *building a design notification requirement for major new works and alterations into the new safety management regulations; and*
- *extending the requirements for operational safety cases/certificates to transport systems in the remainder of ROTS that meet the criteria for permissioning regimes.*

9 *This option could also include a requirement for operators to seek independent assessment/verification of schemes for new/altered works prior to notifying HSE.*

Option 5: Revoke ROTS/no replacement

10 *The final option is to revoke ROTS and not replace it at all, relying instead on general health and safety requirements, other legislation and standards to control the risks arising from the introduction of new/altered works, plant and equipment.*

INFORMATION SOURCES AND BACKGROUND ASSUMPTIONS

11 Information contained in this note has been taken from HSE sources.

BENEFITS

Health and safety benefits

Option 1: No Change

12 There will be no additional health and safety benefits.

Option 2: Amendment; Option 3: Revocation/'interoperable' model and Option 4: Revocation/lifecycle model

13 Increased health and safety benefits as these options involve a refocusing of resources away from the lower-risk areas, where there is only a marginal increase in safety through intervention, towards higher-risk areas where interventions give correspondingly higher increases in safety.

Option 5: Revoke ROTS/no replacement

14 There are likely to be health and safety disbenefits due to the removal of the system without replacing it.

Other benefits

Option 1: No Change

15 There will be no additional other benefits

Option 2: Amendment

16 An additional benefit of option 2 is that it will require minimal adjustment from duty holders and benefits from fast tracking where proposals have been third party assessed.

Option 3: Revocation/'interoperable' model

17 The major additional benefit of option 3 is that it allows HSE to withdraw from the direct approval of new/altered works in accordance with HSC's policy. Other benefits include:

- a quicker 'turn around' time between submission of a scheme and bringing the new works into use. This is likely to result in cost savings to industry both in terms of resource input and financial penalties from financial backers for late completion of works;
- releasing HMRI resource for other high priority work;
- consistency with the European 'interoperable' system for the mainline railway.

Option 4: Revocation/'lifecycle' model

18 The main benefit of this option is that it encourages an holistic approach to safety by addressing design issues within the context of the overall operational safety. It also:

- allows HSE to withdraw from direct approval in line with HSC's policy on conformity assessment;
- places the responsibility for the safe introduction of new/altered works firmly on the operator;
- is consistent with the approach taken in other HSE permissioning regimes;
- fully integrates the approvals and the current safety case regime resulting in greater transparency;
- allows for a quicker 'turn around' of new schemes with the cost savings described in paragraph 16;
- releases HMRI resource for other high priority work;
- introduces some convergence with the European 'interoperable' system for the mainline railway.

Option 5: Revoke ROTS/no replacement

19 Remove HSE from the approvals process, align with HSE's policy.

Total benefits

20 *The greatest benefits would accrue from Option 4 which has all the advantages of Options 2 and 3, but also introduces an holistic approach to safety by addressing the entire lifecycle of new processes under a single permissioning regime.*

COSTS

Business sectors affected

21 This will depend on how the scope of the revised regulations is drawn. Currently, the Regulations impact on the 'other relevant transport systems', i.e., metros, heritage railways, tramways, trolleybuses and prescribed modes of guided transport systems such as monorails and guided buses. There are approximately 4 metro systems, approximately 100 heritage railways, 13 tramways, 14 guided busway systems, 8 monorails and 6 airport 'peplemovers' either operating, under construction or planned for the UK. However, the Discussion Document suggests that guided buses should be taken out of scope of a future permissioning regime.

Compliance costs to industry

Option 1: No Change

22 There will be no additional costs under this option.

Option 2: Amendment

23 The cost of an approval to dutyholders will consist of the cost of preparing the approval, as well as HSE charges for assessing the approval. At this stage it is not possible to quantify the cost to industry of preparing an approval. HSE's charge out rate is £150 per hour, and past charges to industry cover a huge range of £30 to £10,000. We shall take HSE's charge to industry as the minimum cost of an application for approval, with the assumption that the cost of preparing the approval will be some amount in addition to this.

24 The 14 operators of guided buses would make cost savings if they were excluded from future permissioning arrangements. There are approximately 2 guided bus schemes per year, each taking a maximum of 10 hours to assess. The saving from no longer being charged for these 20 hours of assessment will be £3,000. As mentioned above, this is the minimum cost saving, with additional savings from industry no longer having to prepare the applications.

25 If lower risk schemes were removed from scope, focussing the approvals regime solely on higher risk schemes, there would be cost savings to duty

holders in all transport systems. It is estimated that minor schemes will cost a maximum of £400 to assess. In 2001/02 there were 402 approvals. If we assume that a quarter of these are low risk, then costs will be around a minimum of £40,000.

26 Under this option, dutyholders would have the option to fast track approvals by having them third party assessed. The cost of third party assessment is estimated to be higher than HSE assessment, but it is not possible to quantify by how much. The numbers choosing the fast-track option is uncertain, but as it is voluntary, and not required by the Regulations, it will not be included as a cost within the RIA.

Option 3: Revocation/'interoperable' model

27 As this option is a significant departure from the existing Regulations, there would be familiarisation and transition costs. At this stage, the scale of these costs is uncertain.

28 Under this option, there would be cost savings to dutyholders from re-focusing the Regulations. The cost savings from removing guided bus schemes is estimated at £3,000 (see paragraph 24), and the cost savings from removing minor works £40,000 (see paragraph 25), making a total cost saving of a minimum of £43,000.

29 The fees charged by third party assessment bodies are likely to be higher than HSE charges for approvals work. At this stage it is not possible to quantify how much higher these fees would be, but there would be additional costs for the remaining approvals each year.

30 There will be additional costs to 'Heritage Railways' and some people movers that operate at speeds of less than 25mph and are therefore currently exempt from HSE charges. This applies to most heritage systems and people movers, but it is uncertain how many of the remaining approvals would be attributable to them. However, the additional cost would be the whole of the third party assessment fee, rather than just the additional amount over and above HSE charges.

Option 4: Revocation/'lifecycle' model

31 As this option is a significant departure from the existing Regulations, there will be familiarisation and transition costs. At this stage, the scale of these costs is uncertain.

32 Under this option, there will also be the cost savings to dutyholders from refocusing the Regulations. This was estimated to be a minimum of £43,000 (see paragraph 28).

The major cost implications of this option are as follows.

a) *Cost of design notification.* This is expected to be approximately the same as preparing a submission under the approvals regime as similar information will be required. Therefore there will be no additional costs in this area.

b) *Cost of Third Party assessment.* These will be incurred in addition to HSE charges and are expected to be higher than the existing HSE charges. It is difficult to judge how much higher they will be, and this will depend to a certain extent on the type of third party assessment required. A structured scheme of third party assessment with accredited assessment bodies will result in costs similar to those for Option 3 (depending on the competitiveness of the market), although trade associations may be in a position to provide a cheaper service. A scheme that allows the use of in-house expertise is also likely to result in lower costs.

c) *Cost of HMRI assessment.* A system of third party assessment of new schemes should lead to a reduction in existing HMRI assessment and therefore in charges to dutyholders. However, this will be a gradual reduction as the new regime beds down and HMRI develops confidence in the quality of third party assessment.

d) *Cost of preparing a safety certificate.* Extending the safety management system to encompass all the transport systems in the remainder of ROTS except guided buses will mean that new dutyholders will incur additional costs for the production of a safety case/certificate. The estimated cost of producing a safety case and having it assessed/accepted under the current safety case regime covers a huge range of between £12,000 and £350,00 for mainline train operators and infrastructure maintenance companies and around £9,000 for Heritage rail. The safety certificate for new dutyholders, such as tramways, is expected to cost something between the heritage estimate and the lower end of the range for the mainline operators, i.e £9,000 - £12,000. The majority of heritage railways and people movers operating at speeds of 40kmph or less will not be charged for this work, but will incur some costs in the preparation of the safety case [to be estimated]. The cost to the 27 other operators in the remainder of ROTS (excluding guided buses) is estimated at between £243,000 and £324,000.

Option 5: Revoke ROTS/no replacement

33 If the Regulations were revoked and dutyholders were no longer required to submit applications for approvals, there would be a cost saving to duty holders from no longer submitting applications for approvals. Past charges to industry range from £30 to £10,000, but taking into account the average charges in each time band, a suitable range would be £100 to £7,000. In 2001/02 there were 402 approvals issued, so the cost savings from no longer applying for these approvals would be between £40,200 and £281,400.

Summary

Option	Cost estimate to industry
Option 1: No Change	No cost changes
Option 2: Amendment	- Refocusing cost savings: Guided buses: £3,000 Low risk: £40,000
Option 3: Revocation/'interoperable' model	- Refocusing cost savings: £43,000 - Third part assessment: Incremental additional cost for existing fee payers New additional cost for fee payers previously exempt
Option 4: Revocation/'lifecycle' model	- Refocusing cost savings: £43,000 - Notification - broadly neutral - Additional cost of third party assessment (both types) - some cost saving on HMRI assessment (to be estimated) - Cost of safety cases to new dutyholders: £243,000 - £324,000.
Option 5: Revoke ROTS/no replacement	Cost savings £40,200 - £281,400

Costs to HSE

34 There will be no additional cost to HSE from these proposals as HSE recovers the full economic cost of all approvals and safety case work via the fee charged to the dutyholder.

SMALL FIRMS' IMPACT TEST

35 The small firms affected by these Regulations include the majority of heritage railways. Heritage railways interests are represented by the Heritage Rail Association which has already been consulted and will be consulted again during the review process.

36 There is expected to be a significant impact on small firms under options 3: Revocation/'interoperable' model and 4: Revocation/lifecycle model as they would incur additional costs for third party assessment. However, option 4 offers a potentially cheaper form of third party assessment that allows the use of internal expertise. It is difficult to estimate how often Heritage railways apply for approval, but it is thought that, in total, they apply for approx 20-30 approvals per year. The additional costs on these small businesses may also be mitigated by the exclusion of some minor railways from the scope of the regulations.

COMPETITION ASSESSMENT

37 In theory, option 3 could have competition implications in its introduction of third party assessors. However, in practice, it is unlikely that

there are a sufficient number of suitable assessors, making the option unworkable in practice.

Uncertainties

38 Many of the costs and benefits in the RIA are extremely speculative due to the uncertainty surrounding the policy which is due to be decided upon with the results of this discussion document. Because of this, many of the costs are illustrative or unquantifiable at this stage.

39 The cost of an application for approval is uncertain. The charge to industry of assessing an application for approval is uncertain, but attempts to estimate it have been made from HSE data. Another uncertainty is the cost to industry of preparing an application for approval, as it is not been possible to estimate it at this time. Because of this, we have stated that the minimum cost to industry will be the charge by HSE for assessing the approval, but the costs of preparation would be in addition to this.

40 It has also not been possible to quantify the costs of third party assessments at this stage, or the costs of familiarisation and transition associated with options 3 and 4.

ENFORCEMENT AND SANCTIONS

41 The options set out in the ROTS paper have been considered individually below:

Option 1: No Change

42 Compliance – currently high. No change.

43 Enforcement/sanctions – Regulations are enforceable, although penalties under ROTS are rarely used. However, duty holders cannot operate if they do not obtain an approval.

Option 2: Amendment

44 Compliance - Narrowing the scope of the Regulations to exclude minor works is likely to increase compliance as duty holders are more likely to submit applications for high risk, complex schemes.

45. Enforcement/sanctions – sanctions may be used more frequently if the revised regulations can be brought under HSW (still to be considered).

Option 3: Revocation/ 'interoperable' model

46 Compliance – this model is likely to result in increased costs for duty holders and new costs for small heritage railways that are not currently

charged by HSE for approvals work. This may result in lower levels of compliance if duty holders try to reduce costs.

47 Enforcement/sanctions – as for (2). New requirements are likely to be brought within HSW.

Option 4: Revocation/safety case model

48 Compliance – compliance with the current safety case regulations is high as acceptance of a safety case is required before operations may commence. It is likely that this level of compliance will also apply to new design notification requirements.

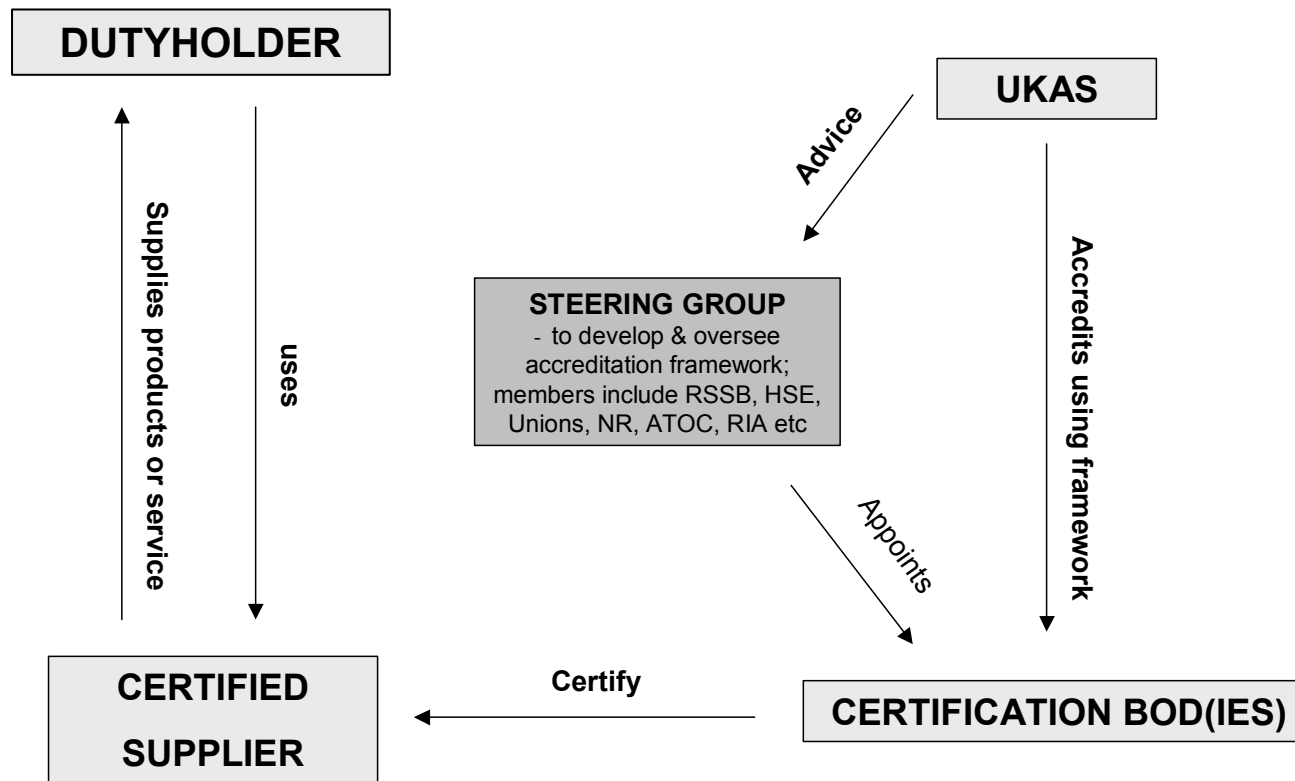
49 Enforcement/sanctions – HSW and the Safety Case Regulations.

Option 5: Revoke ROTS/ No replacement

50 Compliance – not applicable

51 Enforcement/sanctions – not applicable.

ANNEX 8 - MODEL FOR THE ACCREDITATION / CERTIFICATION OF RAILWAY SUPPLIERS



ANNEX 9**INITIAL REGULATORY IMPACT ASSESSMENT FOR IMPROVING THE MANAGEMENT OF THE SUPPLY CHAIN THROUGH CERTIFICATION OF SUPPLIERS OF SAFETY-CRITICAL PRODUCTS AND SERVICES****PURPOSE AND INTENDED EFFECT****Issue**

- 1 Following the Ladbroke Grove rail crash in October 1999, the Public Inquiry headed by Lord Cullen looked at the supply of safety-critical products and services.
- 2 These discussions led to two recommendations. In Recommendation 24, suppliers of safety critical products and services would be required to hold an 'accreditation' as a condition of being involved in that activity.
- 3 Lord Cullen recommended that some system for quality control of companies who supply to the industry should be explored. A company would be 'accredited' if an external body, i.e. an independent third party assessment, had determined it had suitable processes for controlling the safety of products and services it provides.
- 4 Recommendation 47 said that a new body (Rail Industry Safety Body – now called the Rail Safety and Standards Board) should be responsible for this accreditation, subject to the supervisory activity of the safety regulator.

Objectives

- 5 A framework for a certified supplier management scheme would:
 - Ensure a consistent standard for supplier management across the rail industry;
 - Encourage suppliers to maintain, and if necessary, improve standards of capability and competency to supply to the railway industry, which demonstrates an understanding of the safety-critical products supplied;
 - Encourage purchasers to manage their suppliers by using a transparent, systematic and consistent process.

Risk assessment

- 6 A proposed supplier management scheme which features the element of an independent third party assessment may lead to a lowering of risks on the railway system, and possibly a reduction in the number of rail-related accidents. Using the accredited / certifying route has the advantage of a single,

transparent and repeatable approach, which should improve consistency, avoid variable standards and result in better risk management.

OPTIONS

7 The following options were considered:

- Reliance on existing industry schemes (no further action required by HSC/E).
- Approval / accreditation / certification of suppliers by an independent bod(ies), which would have overall accreditation by the United Kingdom Accreditation Service (UKAS)
- Facilitating the development of an industry owned, industry wide accreditation / certification scheme
- Introducing the requirement for duty holders to use certified suppliers via regulation.

8 All options were put forward to HSC in April 2003 for its early view on a preferred route for further exploration and policy development. HSC agreed to the following:

- It did not consider existing industry schemes, at present, to achieve implementation of Recommendation 24 and, therefore, provide an adequate assurance in the rail industry's ability to manage suppliers of safety critical products and services.
- HSC was not minded, at present, to propose regulation in this area.
- HSC would like HSE to facilitate the development of an industry owned, industry wide accreditation / certification scheme, with the recently established Rail Safety & Standards Board (RSSB) taking an important role in such a scheme.
- Independent third party involvement was needed in the accreditation / certification scheme to be developed and HSE should explore the involvement of the United Kingdom Accreditation Service (UKAS).
- The accreditation / certification scheme should apply to the whole of the rail industry, with the initial focus being the establishment of the system on Network Rail Controlled Infrastructure.

The Proposed Option

9 HSE would facilitate the setting up of a key stakeholder Steering Group to develop and oversee the accreditation / certification framework, enabling it to be voluntary and industry owned.

10 The Group may be guided by HSE, and use the advisory function provided by UKAS to establish its terms of reference, role, remit and development of a framework criteria.

11 This collaborative approach would ensure a potential scheme is appropriately industry-owned and industry-wide.

12 The Steering Group would be responsible for appointing a Certification Body(s) to certify suppliers according to the specified criteria. Advice on the remit and function of a Certification Body would be provided by UKAS, followed by an assessment. If the proposed Certification Body satisfies UKAS assessment, accreditation would be granted for it to carry out the certification role.

INFORMATION SOURCES AND BACKGROUND ASSUMPTIONS

13 Information contained in the RIA has come from HSE and industry sources. This scheme is voluntary, but we have assumed a high take up rate due to the large cost saving involved.

BENEFITS

Health and safety benefits

14 The purpose of a supplier accreditation / certification scheme should achieve the following benefits:

- A degree of safety assurance of products and services, based on an independent and impartial assessment;
- Increased confidence that suppliers have adequate processes in place which demonstrates they understand the safety-criticality of products and services, and can produce documentary evidence to validate product approval, conformity to standards etc, and workers are competent to carry out the tasks for which they are supplied;
- Confidence that suppliers have effective systems in place to manage sub-contractors to ensure traceability, and that safety performance monitoring has been/is taking place across the supply chain.

15 Overall, an effective accreditation / certification scheme could lead to a lowering of risks on the railway system and a reduction in the number of related accidents.

Other benefits

16 There will be large cost savings from replacing the current fragmented system which can require a supplier to carry out a number of audits, with a streamlined system.

COSTS

Business sectors affected

17 These proposals will impact on all suppliers of safety critical products and services for Network Rail Controlled Infrastructure, London Underground controlled infrastructure, the light rail industry, metro and heritage rail sectors.

Compliance costs

Accrediting the independent body

18 There could be a cost from accrediting the independent body. However UKAS has suggested that there may already be an existing, suitable, accredited independent body which may be appointed, implying no additional costs in this area, although this is subject to further exploration.

Certifying the suppliers

19 There are approximately 1,200 suppliers of products. Suppliers of services are expected to total only a fraction of this number of product suppliers. For the purposes of this RIA we shall assume that there are around 1,300 suppliers of safety critical products and services. It is not possible to estimate the cost of certification at present, but it is expected to cost significantly less than the existing system of multiple auditing.

Redistribution of costs

20 There may be some redistribution of the costs of certification between the dutyholder and the supplier. It may be the case that the supplier issues a charge to the dutyholder to access their safety information. As this is just a redistribution of the costs, it will not be included within the RIA.

Cost savings from replacing current audits

21 By introducing a universal system of accreditation and certification, the suppliers will no longer have to undergo the numerous audits required of them by dutyholders at present. This will result in a huge cost saving.

22 It is extremely difficult to estimate the cost of an individual audit for a supplier. However, Achilles, a company which runs the existing Proof system of auditing suppliers for most of the main duty holders in the rail industry, charge approximately £2000 for an audit of a product supplier of 6 product groups.

23 We can assume that this fee is the maximum cost of auditing to a supplier. The total cost to the 1,300 suppliers of these audits is £2.6m.

Summary of costs

Cost area	Cost estimate
Accrediting the independent body	Possibly minimal, but subject to UKAS chargeable fees
Certifying the suppliers	Cheaper than current system
Replacing current audits	Cost saving up to £2.6m

24 The overall size of the cost saving will depend on the cost of certifying the suppliers which has to offset against the cost saving of up to £2.6 million.

Costs to HSE

25 As the scheme is industry-owned, there should be no additional costs to HSE, over and above policy development costs.

SMALL FIRMS' IMPACT TEST

26 It is expected that a number of the suppliers of safety critical products and services will be small firms. However, these proposals are not expected to have a disproportionate impact on these firms. In fact, small firms have the most to gain from a streamlining of the process, as they are the least likely to have sufficient resources for the constant auditing that happens under the current system.

COMPETITION ASSESSMENT

27 These proposals are not expected to have an adverse affect on competition. They will impact equally on all suppliers, and so are unlikely to alter the market structure.

Uncertainties

28 The number of suppliers of safety critical products and services is uncertain, as is the cost of certifying these suppliers. The cost of certifying the suppliers will effect the size of the cost saving – the higher the cost of certification, the smaller the overall cost saving. However, it is generally accepted that the proposed system will be cost less than the current multiple audit system, so there will be a cost saving of some size.

ENFORCEMENT AND SANCTIONS

29 HSE would have no responsibility for enforcement and/or sanctions in cases where a duty holder has not complied. It would look to industry to develop its own penalty scheme.

ANNEX 10**INITIAL REGULATORY IMPACT ASSESSMENT FOR
IMPROVING THE MANAGEMENT OF COMPETENCE, FITNESS
AND FATIGUE OF SAFETY CRITICAL WORKERS IN THE RAIL
INDUSTRY****REGULATORY IMPACT ASSESSMENT (INITIAL)****PURPOSE AND INTENDED EFFECT****Issue**

1. The HSC Report 'Ensuring safety on Britain's railways' (ESORB) recommended that the setting of standards and assessing competence for train drivers (and possibly other key staff undertaking key safety critical tasks) should be subject to regulatory control beyond the existing general requirements of the Health and Safety at Work etc Act 1974 and relevant statutory provisions. In addition, consideration needed to be given to imposing some control on the hours of permitted work and rest of train drivers.
2. The recommendations from the HSC Report were implemented through four sets of railway health and safety regulations in 1994. The RSCW Regulations dealt with issues of competence, fitness and hours of work of safety critical workers
3. Over the recent years, rail accident/incidents like Southall, Ladbroke-Grove, Potters bar, Hatfield and Chancery Lane have highlighted competence of safety critical workers and designation of safety critical workers as a major underlying problem. In particular Lord Cullen made a number of recommendations concerning competence issues in his Part 2 Report into the Ladbroke Grove Accident. Recommendation 24 requires accreditation of suppliers of safety critical products and services. Recommendations 25 and 26 require the licensing of drivers and signallers

Objectives

4. To ensure that duty holders have a clear regulatory framework to ensure that they manage the competence fitness and safety critical workers in order to prevent workplace accidents and ill-health errors that can lead to catastrophic accidents.

Risk assessment

5. Clarification of the definition is needed so as to capture those workers who are not in scope. The risk in not clarifying the definition could lead

to accidents or ill-health in having workers who are not competent and fit to carry out safety critical tasks. The requirement for competence management system is introduced to reduce the risk of incompetent and unfit workers carrying out safety critical activities.

OPTIONS

6. The following options are to ensure that medical practitioners are competent to undertake assessment of medical fitness on safety critical workers.

Option 1

7. HSE could approve a body under a specific Regulation to take responsibility for setting medical fitness standards and to run a scheme to certify medical practitioners. The United Kingdom Accreditation Services could accredit this scheme. This suggested body should also have an appeals mechanism for medical practitioners who fail to get appointed and for workers who fail their medicals.

Option 2

8. HSE could specify in greater detail the competence standards needed for medical practitioners e.g. membership of the Faculty of Occupational Medicine of the Royal College of Physicians and experience in rail transport systems.

INFORMATION SOURCES AND BACKGROUND ASSUMPTIONS

9. The information contained in the RIA has come from HSE and UKAS (United Kingdom Accreditation Service).

BENEFITS

Health and safety benefits

10. The options for addressing competence of medical practitioners reduce the risks in employing a medical practitioners who may give an incorrect assessment of fitness of a worker which could lead to ill-health or an accident.
11. Placing emphasis on fatigue rather than hours of work would enable employers to have systems in place for managing fatigue and hence reduce the risks caused by fatigue.

COSTS

Business sectors affected

12. The Regulations have inherited the definition and application to transport systems from the Transport and Works Act 1992. The Regulations cover railways, tramways, metros Heritage rail and specific systems of guided transport as specified in order made by Secretary of State eg monorails at Gatwick Airport. There are currently 150,000 safety critical workers on Network Rail's Sentinel system, which will account for the majority of safety critical workers. Taking into account the safety critical workers working under other dutyholders, and the widening of the definition, it is estimated that there will be 200,000 safety critical workers under the scope of the new Regulations.

Total compliance costs

Change in the definition of a Safety Critical worker

13. The change in the definition of a safety critical worker should capture workers preparing trains in the depot, those responsible for installation, commissioning and inspections. It is extremely difficult to estimate the exact numbers of workers brought into scope as a result of the wider definition of a safety critical worker, or to estimate the marginal cost of the current Regulations, but it should be noted that there would be some additional costs for these workers.

COMPETENCE MANAGEMENT SYSTEM

14. The proposals require a competence management system (CMS) to ensure the competence of workers. However, as the current regulations already require workers to be able to demonstrate their competence, the costs of a CMS are likely to consist solely of the staff time and software used in setting up and running the system itself. It should also be noted that many dutyholders operate their own form of CMS, further reducing potential costs.

15. The costs are difficult to quantify, but expected to be minimal.

Medical fitness: Option 1

16. The costs to industry will occur in gaining accreditation of independent bodies, running the certification scheme for medical practitioners as well as the cost from the appeals mechanism.

17. The costs of accrediting an independent body depends on a number of factors, but UKAS was able to give a rough estimation of the cost of accrediting a new independent body to be between around £9,000 and £10,000 per body. The total cost of accrediting will depend on the number of independent bodies.
18. Network rail use around 50 occupational health providers who have approximately 1-4 doctors each, giving an approximation of 50-100 medical practitioners needing certification. There will also be some additional medical practitioners employed by other dutyholders but the 50 to 100 estimation, should be a good approximation for the total number of medical practitioners requiring certification. There will be a cost of certifying these medical practitioners, but it is not possible to estimate this cost at this time.
19. A certain proportion of these medical practitioners are likely to need training to the specified standard required by the independent body for certification. It is difficult to estimate the number of practitioners that will require training, or the form this training may take. Therefore, it is not possible to estimate the level of costs involved.
20. This option will also contain an appeals mechanism for medical practitioners who fail to get appointed and for workers who fail their medicals. For other systems with appeals mechanisms in place for worker who fail their medicals, (offshore and diving) there were appeals in roughly 0.2% of medicals occurring. If there were 100,000 medicals taking place under the proposed Regulations, it can be assumed that there might be approximately 200 appeals.
21. The cost of the appeals system will depend on how the system is set up. The diving appeals system works as a second opinion, from a doctor from outside the industry, on the evidence available at the time. This system costs between £150-£400 per option, so if adopted would cost between £30,000 and £80,000 for the 200 appeals. If the system was to go further than this, it would be very costly. It would also have to be decided who would pay for the appeal – HSE pays for appeals in diving, employers pay for appeals in offshore.
22. There will also be a cost of the appeals mechanism for medical practitioners who fail to get appointed. However, due to the numbers involved, this is expected to be a much smaller cost.

Medical fitness: Option 2

23. HSE could specify in greater detail the competence standards needed for medical practitioners. This would mean the only costs would be the costs of training the medical practitioners to the required standard.

MEANS OF IDENTIFICATION

24. There are expected to be approximately 200,000 safety critical workers who will need to carry a Safety Critical Worker Identification card. Currently as there is no standard Safety Critical Worker ID card, each company operates its own system, resulting in a proliferation of cards safety critical workers need to carry. Introducing a standard ID card would replace this proliferation of cards with a single card listing all competencies.
25. Currently, Sentinel (Network Rail's ID provider) operates a system that costs £20 per competence renewal. As each safety critical worker has a number of competencies that have to be renewed on a regular basis, this system works out to be costly. Replacing this system with a standard smart card system should make this system of renewals cheaper and easier.
26. It has been suggested that a reasonable cost for a smart card would be around £25, making the initial cost of issuing all safety critical workers with this card around £5m. In addition to this there will be the added cost of readers and employing the technology to update the cards on the respective competence, fitness or assessment. However, once the card is issued and the technology in place, the recurring cost of updating the card is expected to be very low.
27. It has been estimated that the Sentinel system costs industry £33m, so when compared to this figure, it is clear that the Safety Critical Worker identification card will have a large cost saving to industry.

Costs to HSE

28. The costs of work undertaken by HSC/E in facilitating setting up an independent body voluntarily.
29. Additional work resulting from capturing more safety critical workers, for HMRI in ensuring that dutyholders are satisfying their statutory requirements under the new legislation.
30. If it is decided that HSE should pay for appeals under the medical fitness options 1, there will be a cost of between £30,000 and £80,000 per year.

Other costs

31. No other costs have been identified.

SMALL FIRMS' IMPACT TEST

32. It is expected that these proposals will not have a disproportionate impact on small firms.

COMPETITION ASSESSMENT

33. It is expected that there will be no negative competition effects as a result of these proposals.

Uncertainties

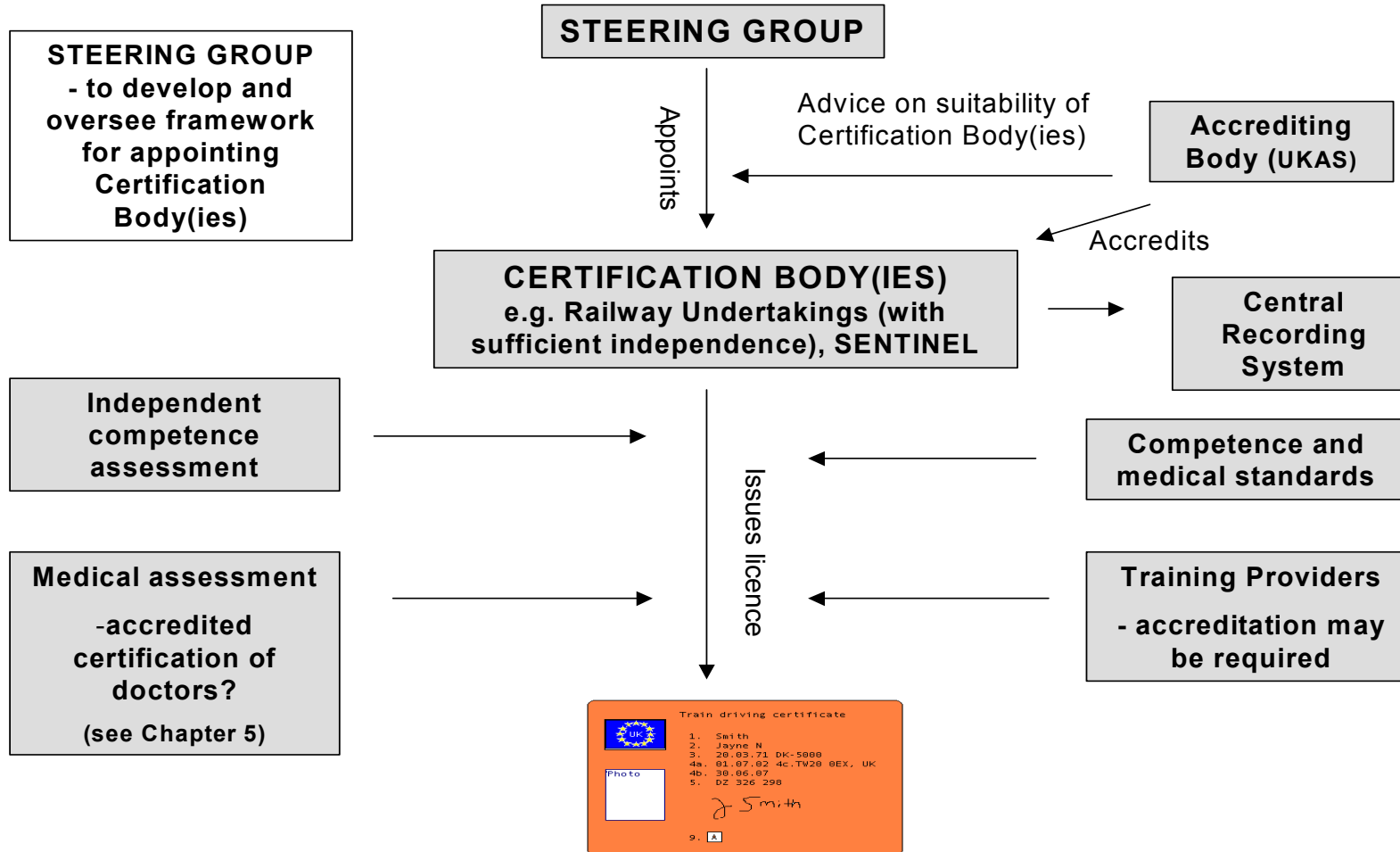
34. There are a number of uncertainties in this RIA

- Number of safety critical workers
- Number of medical practitioners
- Number of medical practitioners needing training and the cost of this training.
- Number of appeals and the cost of appeals.
- Cost saving of identification card.

ENFORCEMENT AND SANCTIONS

35. HSE would have responsibility for enforcement and/or sanctions in cases where a duty holder has not complied.

ANNEX 11 - MODEL FOR AN ACCREDITED NATIONAL LICENSING SYSTEM



ANNEX 12**INITIAL REGULATORY IMPACT ASSESSMENT FOR AN ACCREDITED LICENSING SYSTEM FOR DRIVERS AND SIGNALLERS****PURPOSE AND INTENDED EFFECT****Issue**

1 A national accredited licensing scheme is proposed to take into account recommendations 25 and 26 of Part 2 of Lord Cullen's Public Inquiry Report into the Ladbroke Grove Rail Crash. The Inquiry discussed the competence of train drivers and signallers and following these discussions Lord Cullen recommended that licences be introduced for train drivers and signallers as one way of better managing the competence of these key safety critical workers.

2 The European Commission (EC) has stated that it wishes to introduce a Directive on driver licensing, which is due to be published in December 2003. The Directive is primarily being introduced to help harmonise driver requirements throughout the European Union.

3 At this stage, HSC's proposed scheme will be voluntary, but it is assumed that there will be a high take-up due to the proposed EC Directive that may make the scheme compulsory through regulation within a few years.

4 The RIA will focus on assessing the costs associated with introducing a voluntary national accredited licensing scheme, as opposed to a regulated EC scheme. However, it is intended that development of the national accredited licensing scheme should dovetail as much as possible with developments in Europe.

Objectives

5 There are a number of key objectives of the national licensing scheme:

- Improving Health and Safety on the railways;
- Improving the competence and fitness of train drivers and signallers;
- Increase regulator and public confidence that train drivers and signallers are competent and fit;
- Development of appropriate generic standards for competence and fitness for drivers and signallers;
- Better tracking of key safety critical workers; and
- Consistency with other transport sectors.

6 In addition to these, the National Licensing Scheme should address the key objectives of the proposed EC Directive, in particular:

- Increase interoperability; and
- Increase mobility (portability) of drivers across Member States.

PROPOSED MODEL FOR LICENSING SCHEME

7 The proposed model considered is:

- Industry appoints an accredited certification body(ies) to issue licences for drivers and signallers. The licence would be granted after the applicant has undergone a successful assessment of competence and fitness. The appointment would be on the basis of the advice of United Kingdom Accreditation Service (UKAS).

INFORMATION SOURCES AND BACKGROUND ASSUMPTIONS

8 Information contained in the RIA has come from internal HSE sources and UKAS and all prices are in the current price year (2003). Although the proposed scheme is voluntary, we have assumed a high level of take-up due to requirements in the proposed EC Directive.

BENEFITS

Health and safety benefits

9 The health and safety benefits are difficult to quantify. There will be a general improvement in health and safety over and above that which is already required by existing health and safety legislation. The following benefits have been identified:

- Setting generic standards on competence that have to be adhered should help to ensure consistency of, and help raise the level of competence in, the industry. This would also apply to fitness;
- Greater assurance to the regulator, railway operators and the public that drivers and signallers are competent and fit;
- A time limited licence is more likely to ensure that drivers and signallers remain competent;
- A way of helping dutyholders to fulfill responsibilities under health and safety legislation by providing a better means of demonstrating that a required degree of competence and fitness of its drivers and signallers has been reached; and
- Improved assurance of a competent and fit workforce should lead to fewer incidents and a safer railway for both employees and the public.

Other benefits

10 Other non health and safety benefits:

- Easier movement of drivers and signallers between companies and within Europe as there should be mutual recognition of competence and fitness standards assessed as part of the licence;
- Information on drivers and signallers will be centrally held and more easy to pass on when a driver leaves one job for another;
- A central recording system could help with human resource issues as better profiling is possible;
- Rapid verification of driver and signaller details will assist regulators and others who need to check the competence of railway workers; and
- Compliance with proposals for driver licensing in Europe.

COSTS

Business sectors affected

11 Subject to the outcome of discussions of the scope of the licensing system, the proposals could impact on all parts of the rail industry.

12 Possible numbers of drivers who could be subject to the licensing system is approximately 25,500. 14,000 drivers operate over Network Rail controlled infrastructure, London Underground employ 3,500, light rail and tramways employ about 2,300 drivers in total, RSSB records show 2763 drivers employed by the freight operating companies and it is estimated that there are 3,000 drivers on heritage railways.

13 Possible numbers of signallers who could be subject to the licensing system are approximately 6,900. Approximately 5,000 operate over Network Rail controlled infrastructure, around 400 on London Underground controlled infrastructure and it is estimated that heritage railways employ a further 1,500.

Compliance costs

Accreditation of the certifying body(ies)

14 There is uncertainty how many certification bodies there will be.

15 The costs of accrediting a certification body depends on a number of factors, but UKAS was able to give a rough estimation of the cost of accrediting a new certifying body to be between around £9,000 and £10,000 per body.

Issue of License

16 The license will be a focal point for information on drivers and signallers. An example of a national system that has an identification card is the SENTINEL system that operates on Network Rail controlled infrastructure. Network Rail proposes that its signaller will be licensed through this scheme in the financial year 2003/2004. Signallers employed by other companies and drivers do not currently use the SENTINEL system.

17 To be registered on SENTINEL costs £20 plus £20 per competency. It is expected that drivers will need three competencies, and signallers will need a minimum of one competency, making the cost per individual £80 and £40 respectively. To issue cards to other signallers would cost £76,000 (£40 x 1900) and to drivers £2,040,000 (£80 x 25,500); making a total of £2,116,000.

Central recording system

18 This will depend on the number of certification bodies that will be approved for the national accredited licensing system.

19 If there is only one certification body, then the costs should be minimal. This is on the basis that the databases used by the SENTINEL system for issuing licences could also be used for the central recording system. There will need to be administrative costs factored in.

20 If there are more than one certification bodies, then there are a number of options: there could be common databases between the certification bodies; one of the certification bodies could operate a national central recording system on behalf of the other certification bodies; or a different body may have to be accredited to run the central recording system. The costs of setting up additional recording systems is uncertain, but it is reasonable to assume that it will be a greater cost than simply expanding a current system.

Setting of competence and medical standards

21 Setting generic standards on competence that have to be adhered to by the whole industry. Development of standards will involve industry e.g. the recently established Centre for Rail Skills. It is extremely difficult to estimate the cost of developing such standards.

Accrediting training providers

22 Training providers may have to be assessed and certified by an independent third party to meet a particular standard. This may only apply to the suppliers of training services. There would be costs involved in both the assessments and the certification of the training providers. For Network Rail's Personal Track Safety Courses (PTS) on Network Rail controlled infrastructure there are 1200 trainers employed by 90 training providers. These deal with approx 145,000 PTS SENTINEL card holders. The number of training providers under a national licensing system should be considerably less than for track safety.

Assessment of competence

23 It is unsure how this will work in practice and unquantifiable at this particular time.

Appointment of Medical Practitioners

24 It is proposed that medical assessment would be undertaken by industry appointed doctors. To become appointed, the doctors would have to be independently assessed and meet a particular standard that was accredited by a third party. Network Rail use around 50 occupational health providers who have approximately 1-4 doctors each, giving an approximation of 50-100 medical practitioners needing appointment. There will also be some additional medical practitioners employed by other dutyholders but the 50 to 100 estimation, should be a good approximation for the total number of medical practitioners requiring appointment. The process for appointment is unsure at this present time and costs there unquantifiable at this time.

Medical assessment

25 Medical assessments of drivers and signallers would need to be undertaken before the licence could be issued. Dutyholders already carry out medical assessment of drivers and signallers. This is not included in the RIA as there should be no additional costs.

Summary of costs

<i>Cost area</i>	<i>Estimation of cost</i>
Accreditation of the certification body(ies):	£9,000 - £10,000 / body
Issue of Licence	£2,116,000
Central recording system: - one certification body - more than one certification body	Minimal Greater than A
Setting of competence and medical standards	Unquantifiable
Accrediting training providers	Unquantifiable
Assessment of competence	Unquantifiable
Appointment of medical practitioners	Unquantifiable

Costs to HSE

26 HSE may incur costs from the following:

- Setting up a steering group;
- Input into development of framework for national accredited licensing system;
- Liaison with UKAS and agreeing what certification body(ies) will have to do to be accredited;

- Contributing to the development of competence and medical standards; and
- Supervising the licensing system once it has been set up.

27 These costs are difficult to quantify, and should be considered as policy development costs which typically are not included in an RIA. Funding for this work is already covered until the end of the financial year 2004/2005.

SMALL FIRMS' IMPACT TEST

28 This may be a significant issue for the 108 Heritage Railways if they come under scope. The Heritage Rail Association, which represents the Heritage sector, and other stakeholders will be consulted on these proposals.

COMPETITION ASSESSMENT

29 It is difficult to assess the possible competition effects during this stage of the policy development process. One area where there could be competition concerns is in the issuing of licenses by a single body.

UNCERTAINTIES

30 Many of the costs and benefits in the RIA are highly speculative at this stage of the policy development process. Once the policy has been further developed following the Discussion Document, it should be possible to better quantify the costs.

31 As discussed earlier in the RIA, the proposal is for a voluntary licensing scheme, so the rate of take-up is uncertain. However, because it is likely that an EC Directive will make some type of licencing scheme compulsory in the near future. We have therefore assumed a relatively high take-up rate.

ENFORCEMENT AND SANCTIONS

32 The licensing scheme will be voluntary. It is likely that dutyholders will comply with the national accredited licensing scheme if they know that it is a prelude to a scheme they will have once the Directive is implemented.

33 The EC Directive may need to be implemented through Regulations, which will be enforceable.

ANNEX 13

1. We will acknowledge your response and consider it carefully. We may contact you if we have a question arising out of your response or if we would like you to expand on your response.
2. To make our consultation process as open as possible, we [will post a summary of the responses we receive on HSE's website. We] will [also] make available to the public [all] the comments we receive at our information centres in Sheffield and London. Copies [of the comments] will be available at a small charge to cover our costs. However if you state clearly in your written response that you do not want your views to be made public, we will respect your wishes.
3. If you respond in a personal capacity rather than as the postholder of an organisation, you should be aware that the information you provide may constitute 'personal data' within the terms of the Data Protection Act 1988. For the purposes of that Act, HSE is the 'data controller' and will process the data for health, safety and environmental purposes. HSE may disclose that data to any person or organisation for the purpose for which it was collected, or where the Act allows disclosure. You have a right to ask for a copy of the data and to ask for inaccurate data to be corrected.

ANNEX 14**LIST OF ABBREVIATIONS**

ACoP	Approved Code of Practice
ATOC	Association of Train Operating Companies
ASLEF	Associated Society of Locomotive Engineers and Firemen
CMS	Competence Management System
CSI	Common Safety Indicators
CSM	Common Safety Methods
CST	Common Safety Targets
DfT	Department for Transport
DNV	Det Norske Veritas
DVLA	Driver and Vehicle Licensing Agency
EC	European Commission
HMRI	Her Majesty's Railway Inspectorate
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HSWA	Health and Safety at Work Etc Act 1974
ICP	Independent Competent Person
LUL	London Underground Limited
NCCA	National Competency Control Agency
NOS	National Occupational Standard
NVQ	National Vocational Qualification
ORR	Office of the Rail Regulator
PCN	Personnel Certificate in Non-Destructive Industry
RIA	Railway Industry Association
RIAC	Rail Industry Advisory Committee
RISB	Railway Industry Safety Body
RITC	Rail Industry Training Council
RMT	Rail Maritime and Transport Union
ROTS	Railways and Other Transport Systems (Approval of Works, Plant and Equipment) Regulations 1994
RSC	Railways (Safety Case) Regulations 2000
RSCWR	Railways (Safety Critical Work) Regulations 1994
RSPG	Railway Safety Principles and Guidance
RSSB	Rail Safety and Standards Body
SCSWG	Safety Critical Stakeholder Working Group
SRA	Strategic Rail Authority
TOC	Train Operating Company
TSI	Technical Specification for Interoperability
UKAS	United Kingdom Accreditation Service
WTA	Working Time (Amendment) Regulations 2003