



Policy Statement

Our approach to permissioning regimes

**HSC/E's mission is to ensure
that risks to people's health
and safety from work activities
are properly controlled.**

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HEALTH AND SAFETY COMMISSION

POLICY STATEMENT

OUR APPROACH TO PERMISSIONING REGIMES

Introduction – The purpose of this Statement

This Policy Statement explains the philosophy adopted by the Health and Safety Commission (HSC) and the Health and Safety Executive (HSE) in regulating health and safety in hazardous industries through the use of permissioning regimes.

This is the Commission's own Policy Statement. It describes our approach to those regimes for which we are directly responsible which may differ from the approach used by other agencies. It explains the circumstances under which the Commission will advise Ministers to introduce permissioning regimes, why permissioning regimes are needed, what they are intended to achieve and how they will achieve it. This Policy Statement is designed for those with some involvement in the permissioning regime process and for those wishing to gain an understanding of what is involved.

The Policy Statement builds on the Discussion Document *Regulating higher hazards: Exploring the issues* (DDE15) published in September 2000 and Lord Cullen's Part 2 report into the Ladbroke Grove Rail incident published in September 2001. Lord Cullen endorsed the use of safety cases, but raised important questions about what makes them effective in improving safety. Responses to DDE15 were favourable overall to our approach, but made a strong call for greater clarity, particularly to know *why* permissioning regimes are established and how consistent are their features.

This Statement responds to that call for greater public understanding of our approach to permissioning regimes. It sets out principles governing the introduction, development and maintenance of regimes, how the principles are implemented and explains the terminology used. However, it does not explain the origins of all regimes or justify why they were introduced. We are keen to create an environment of greater transparency, to secure confidence in the regimes whilst setting realistic expectations of what they might achieve.

The purpose of permissioning regimes

Permissioning regimes are an addition to the general framework of health and safety law. They are very resource intensive for both duty holders and regulators and normally attract charging of duty holders to cover the costs incurred by the health and safety regulator. The health and safety regulator here is the body that gives "permission", which for the purpose of the Statement will normally be HSE.

Because permissioning regimes are so resource intensive, introducing one will only be considered where the work activities involve significant hazard, risk or public concern eg where there are risks of multiple fatalities from a single or linked series of events and/or there are risks of widespread and significant adverse effects on human health. The Commission will propose a new permissioning regime to Ministers only after serious consideration and by applying the principles described in the Policy Statement. In doing so the Commission will endeavour to anticipate hazards arising from new work activities that may cause concern in future.

The term "permissioning regime" is used in this Policy Statement to describe those regimes under which the start or continuation of particular work activities are conditional upon a consent, license, letter of conclusion or acceptance of a safety case or safety report by the health and safety regulator. The term permissioning is not exact, in that not all regimes require explicit consent from the health and safety regulator. Nevertheless in all cases it is not possible for them to operate without documenting the hazards, risks and control measures to the satisfaction of the health and safety regulator.

Several regimes will have elements of permissioning within them, but for the purpose of this Statement we are concerned only with those regimes where permissioning is at their core. A list of the regimes can be found at the end of this document.

The regulatory context for permissioning

Our general approach to regulating health and safety, as set out in HSE's document *Reducing risks, protecting people* (R2P2)¹, is broadly risk-based. R2P2 describes a spectrum of possible controls (the hierarchy of options in appendix 2, which is summarised at Annex A to this Statement), from reliance on general duties to introducing "process" regulations, which set administrative requirements for the management of risks rather than specifying risk control goals for particular hazards.

We will propose process regulations generally as a last resort because they are resource intensive for both duty holders and the health and safety regulator, and it is a matter of principle to introduce a greater degree of regulatory intervention only where a lesser degree will not suffice. Process regulations may be of ascending stringency from notification, through safety cases to a licensing system – the last two equating to permissioning regimes. If the risks are so high that safety cannot be assured even under a permissioning regime, we will prohibit the activity. However this will be very rare.

Principles of permissioning regimes

When advising Ministers on introducing new permissioning regimes or when reviewing existing regimes we will be guided by the following principles.

Why will a permissioning regime be introduced?

Principle 1

We will propose a legislative regime involving some kind of “permission” by the health and safety regulator where there are or could be significant hazards which require a high degree of regulatory control. We will propose such a regime only as a last resort, where the normal forms of regulation are not sufficient and where the extra demands imposed by the regime are justified by the benefits it brings.

The following criteria, ie a combination of at least one criterion from A plus the criterion in B, will help us to determine the need for a permissioning regime: -

A

- there is a need to have regard to high, sustained and broadly based levels of societal concern², either existing or likely, over potential risks of harm (eg high levels of public dread or aversion associated with the hazard and the vulnerability of those exposed to the hazard); and/or
- there are significant risks of multiple fatalities from a single (or linked series of) event(s); and/or
- there are significant risks of widespread and significant adverse effects on human health;

And

B

- the proposed regime adds proportionate value in terms of risk control and/or allows specific activities (with clear benefits to society) to proceed.
- We will not recommend a regime *solely* to provide an added level of confidence to society, but achieving such a level of confidence will be a measure of the regime’s success.
- We recognise, however, that a decision on whether or not to impose a regulatory permissioning regime is ultimately for Ministers and Parliament. Circumstances may arise in which Ministers decide that non-health and safety factors must take precedence.

What are permissioning regimes intended to achieve?

Principle 2

We will develop permissioning regimes to secure systematic management of hazardous activities throughout the stages of design, construction, operation and decommissioning. The purpose is to ensure the risks are properly

controlled, so securing public confidence in high levels of health and safety without unduly compromising industry's ability to operate.

- The characteristics of individual regimes will reflect their specific objectives and the criteria which led to their introduction, including the nature of the hazards to be controlled and the degree of concern about them.
- The requirements of the permissioning regime will be proportionate to the hazards and risks at different stages of the life cycle of the regulated activity.

How will permissioning regimes achieve their ends?

Principle 3

Permissioning regimes build on the fact that the legal duty to manage risks lies with the organisations that create them. The key to receiving "permission" will normally be a description and demonstration of how duty holders manage their risks. The process of describing and demonstrating requires duty holders to think through their actual operations, from beginning to end, identify their hazards, and consider the risks and control measures or systems needed to comply with the requirements of the regime. Where complex management arrangements and several duty holders contribute to complying with the requirements we will usually expect a duty holder to describe the arrangements for interfacing with others. However, a description and demonstration are of no use without the active commitment of the duty holder in putting into practice what has been signed up to and the active involvement of the health and safety regulator to ensure (eg through post-permission inspection) that the arrangements are adequate.

- The duty holder's description and demonstration will be set out in a health and safety document or documents in which the duty holder satisfies itself as to the safety of proposed or actual operations. "Health and safety document" is a generic term used in this Policy Statement meaning safety cases, safety reports and similar documents required by or under legislation.
- The health and safety document normally will be assessed by the health and safety regulator as part of designing, constructing, starting, continuing, decommissioning or marking a new stage of operations and equally importantly used by the health and safety regulator as a basis for targeting post-permission inspections and verification.
- Duty holders must identify the hazards, assess the risks, review the extent to which health and safety is part of the process, develop effective control measures (for those hazards which cannot be eliminated) and record these in the health and safety document, which should be reviewed and kept up to date.
- The control measures recorded in the health and safety document must cover design and hardware, systems and procedures and human organisational factors as a collective whole; and should include the

- duty holder's safety criteria and performance standards as well as plans for improvement.
- Duty holders must properly resource their processes for producing and maintaining health and safety documentation.
 - Duty holders must implement the control measures, review them regularly and keep them up to date with a view to continuously improving them to reduce risks.
 - Duty holders must make and test arrangements for managing emergencies and mitigating their consequences.
 - The health and safety regulator will follow the HSC Enforcement Policy Statement³ to ensure that what has been signed up to is actually taking place.
 - Whilst such regimes inevitably involve detailed documentation and process, we will seek to avoid unnecessary bureaucracy.

Do permissioning regimes guarantee safety?

Principle 4

Permissioning regimes are **not** intended to provide a guarantee of health and safety in the operation of the duty holder's arrangements. Responsibility for health and safety can only lie with the duty holder.

- Health and safety regulator "permission" is an acceptance of the duty holder's approach to identifying and meeting health and safety needs, as demonstrated through the health and safety documentation. It is not an acceptance that the duty holder's arrangements are safe.
- Duty holders are responsible for demonstrating in writing and more importantly by their actions that they are controlling the risks.
- Regular acceptance of or granting of consent to health and safety documentation does not diminish the duty holder's ownership of it. The duty holder, not the health and safety regulator, is responsible for preparing, developing and amending the health and safety documentation to the acceptable standard.

What are the responsibilities of the regulator?

Principle 5

The health and safety regulator will discharge its responsibilities under the permissioning regime competently. Permissioning regimes demand a greater degree of resource, competence, training and involvement from the health and safety regulator as well as from the duty holder.

- The obligations imposed on the health and safety regulator require high levels of positive involvement and define the specific nature of that involvement.
- The health and safety regulator is responsible for the quality of the advice it gives to duty holders through its conclusions on the health and safety documentation and their management of the risks.

- Permissioning regimes provide the health and safety regulator with extended scope for intervention and sanction.
- The duty holder's documentation provides part of the basis for targeting health and safety regulator intervention.
- The health and safety regulator should have clear standards of service and timeliness, particularly when the start or continuation of the duty holder's operations depends on the regulator's decision. This assumes adequate submission of health and safety documentation in good time.
- Poor and inadequate performance by the duty holder will be identified by inspectors through assessment and inspection with compliance promoted by action in accordance with the principles of the Enforcement Policy Statement and judgement guided by application of the Enforcement Management Model⁴.

What type of permissioning regime will we recommend?

Principle 6

Permissioning regimes will be consistent with a goal setting framework, which is preferable to a prescriptive one not least because it makes duty holders think for themselves. Duty holders are responsible for and must have ownership of the hazards, control measures and management of risk and are responsible for keeping health and safety documentation up to date. This goal setting approach complements the main benefit of preparing health and safety documentation, and:

- Its flexibility is more likely to lead to arrangements for controlling risk tailored for the particular circumstances and which through health and safety document revision will remain so;
- Allows health and safety procedures to be adapted to the circumstances of the work activities;
- Encourages continuous improvement through keeping health and safety documentation up-to-date, reviewing, revising and resubmitting it as necessary, supported by regulatory inspections⁵;
- Enables the permissioning regimes to define the elements of the risk management systems;
- Elements of prescription⁶ may be appropriate in the supporting legislative framework or in industry standards of good practice.

How detailed will permissioning regimes be?

Principle 7

We will take a pragmatic approach to the detail of the regime to suit particular circumstances and considering each case on its merits. The key point is that permissioning regimes should provide for a high degree of regulatory control where there are significant hazards. Consistency between the different regimes is secondary to this.

- We will, for example, need to take account of any new EU requirements, but these principles will also inform UK negotiations on EU proposals.
- We will aim for consistency of terminology throughout; and commonality of provisions where this will bring benefits in benchmarking, transfer of expertise and sharing of good practice.
- We will work with other regulatory agencies to maximise consistency and avoid duplication.

How open and inclusive will permissioning regimes be?

Principle 8

We will design permissioning regimes to be operated and enforced openly and transparently within the limits set by the need to maintain commercial confidentiality⁷, national security and confidentiality of personal data.

- Permissioning regimes, including associated legislation such as requirements on workforce consultation, will require duty holders to consult those who take part in the operational arrangements described in the health and safety documentation, mainly employees, safety representatives, site contractors and others affected such as the emergency services and other regulatory bodies, on matters relating to their health and safety.
- Such consultation will allow those who implement the operational procedures to contribute their knowledge and experience of the operations to the development of the health and safety documentation, thereby securing additional confidence in the arrangements.
- We expect duty holders to allow enough time and resource to ensure those who implement the operational procedures are able to contribute to the process meaningfully. At the same time we recognise that consultation cannot be open-ended, there needs to be a reasonable cut off point.
- Duty holders will disclose relevant documents, decisions and information to those not taking part in the arrangements, but who may be affected by a particular aspect, primarily the public.
- Relevant information on emergency arrangements will be made available by the duty holder to the public and relevant bodies eg Local Authorities, emergency services. Emergency service providers will be consulted on their roles in an emergency.
- The health and safety regulator will keep workplace safety representatives informed of progress and provide notification of decisions.

How will we know if permissioning regimes are effective?

Principle 9

We will only propose introducing a new permissioning regime or strengthening an existing one if we are sure that proportionate measures are or will be in place to evaluate its effectiveness. We will also endeavour to establish such measures for existing permissioning regimes⁸.

- The benefits of the regime in maintaining and improving standards of health and safety should be proportionate to the costs of introducing and operating it.
- We will establish suitable baselines at an early stage to be able to measure achievement of the expected benefits.
- Regimes will complement and add value to the general legal framework. If this changes and a permissioning regime is no longer needed, we will propose it is removed.

What can you do if you are unhappy with the regulator's refusal to give permission?

Principle 10

We will propose adequate and consistent mechanisms for appeal against the health and safety regulator's refusal to give "permission" to undertake activities under permissioning regimes.

- The health and safety regulator will provide an explanation of the reasons for their refusal.
- The health and safety regulator will have easily accessible internal mechanisms for resolving issues relating to a refusal, which at the highest level will involve advice from someone independent of the regulator.
- Any appeal system will be open and transparent with clearly laid out procedures and arrangements.

A summary of the principles

Permissioning regimes are exceptional responses to conditions which could present significant health and safety risks. They bring greater regulatory scrutiny, more transparency and demand a more systematic approach by duty holders and regulators. Permissioning is not an end in itself, but a powerful tool to ensure that duty holders meet the conditions set for receiving and maintaining the permission, such as preparing health and safety documentation. This approach may not be appropriate for all hazardous activities, although those that pose a potential for significant public harm will normally be covered. It will also be more suitable for those involving complex risk management systems and/or significant technological change. Different regimes will also have different outputs, depending on their circumstances.

This means there is no standard model for permissioning regimes, though their underlying principles should be the same.

How will we use this Policy Statement?

We keep the whole of the legislative framework for health and safety, including permissioning regimes, under review to ensure they remain fit for purpose. In reviewing permissioning regimes we will compare the regimes against these principles to identify any deviations. Our aim will be to develop regimes over time to converge so far as possible with the principles – and therefore to that extent with each other, while recognising that there may be good reasons in practice which limit the scope for convergence. In particular, where the details of regimes reflect particular circumstances, our principle of pragmatism recognises they will remain distinct so long as they remain fit for purpose. We will also keep this Statement under review, to ensure it remains true to our evolving experience of operating permissioning regimes.

We welcome the views of those involved with the operation of permissioning regimes in any way, whether as duty holders or as other stakeholders, on the implementation of these principles in existing permissioning regimes.

The following are examples of permissioning regimes for which HSC/E is responsible:

- Nuclear installations
- Railways
- Offshore installations
- Onshore major hazard sites
- Work with genetically modified organisms
- Gas distribution
- Work with asbestos
- Explosive manufacture and storage
- Keeping of petrol

When the Policy Statement does not apply

This Statement is aimed at regimes governing particular work activities. It is not aimed at regimes which require approval to bring into use products or substances, which have different characteristics, though many of the principles will also apply in practice. Nor does it cover regimes that involve licensing individuals to carry out particular tasks eg to dive commercially. The Policy Statement does not cover permissioning regimes designed by other regulatory agencies to have different objectives from those applied by us. We already have Memoranda of Understanding and other arrangements to facilitate co-operation and co-ordination with other regulators. We will build on these arrangements with other regulatory agencies on legislative and permissioning regime matters to avoid duplication and to learn from others' experiences.

¹ HSE's Reducing risks, protecting people (R2P2) is available from HSE Books, PO Box 1999, Sudbury, Suffolk CO10 2WA Telephone 01787 881165.

<http://www.hse.gov.uk/risk/theory/r2p2.pdf>

² Paragraph 25 of R2P2 provides a definition of societal concern which is reproduced at Annex A to this Statement.

³ HSC's Enforcement Policy Statement is available from HSE Books and on HSE's website.

<http://www.hse.gov.uk/pubns/hsc15.pdf>

⁴ The Enforcement Management Model can be found on HSE's website.

<http://www.hse.gov.uk/enforce/emm.pdf>

⁵ This reflects Lord Cullen's recommendations (Piper Alpha and Ladbroke Grove) that safety cases should be "living documents".

⁶ R2P2, under the "Hierarchy of options", lists those areas where prescription is justified.

⁷ HSE guidance to its staff on commercial confidentiality is to respect the veracity of the claim unless it seems unreasonable, whereby staff should seek further information to confirm it.

⁸ Evaluation of the impact of current regimes has been and will be commissioned, though it will be some years before we can build up a full picture of the effects.

Annex A – Definitions

Extract from “Reducing risks, protecting people” – paragraph 25

Definition of individual concerns and societal concerns

These and other studies have established that hazards give rise to concerns that can be put into two broad categories:

Individual concerns or how individuals see the risk from a particular hazard affecting them and things they value personally. This is not surprising since one of the most important questions for individuals incurring a risk is how it affects them, their family and things they value. Though they may be prepared to engage voluntarily in activities that often involve high risks, as a rule they are far less tolerant of risks imposed upon them and over which they have little control, unless they consider the risks as negligible. Moreover, though they may be willing to live with a risk that they do not regard as negligible, if it secures them or society certain benefits, they would want such risks to be kept low and clearly controlled.

Societal concerns or the risks or threats from hazards which impact on society and which, if realised, could have adverse repercussions for the institutions responsible for putting in place the provisions and arrangements for protecting people, eg Parliament or the Government of the day. This type of concern is often associated with hazards that give rise to risks which, were they to materialise, could provoke a socio-political response eg risks of events causing widespread or large scale detriment or the occurrence of multiple fatalities in a single event. Typical examples relate to nuclear power generation, railway travel, or the genetic modification of organisms. Societal concerns due to the occurrence of multiple fatalities in a single event are known as societal risk. Societal risk is therefore a subset of societal concerns.

Extract from “Reducing risks, protecting people” (page 59)

Summary of hierarchy of options

Based on our wealth of experience in applying the framework and while taking account of the constraints, the following procedure has evolved for identifying options most likely to work for new regulatory measures and the order in which they should be considered:

- Reliance on the general duties and the Management of Health and Safety at Work etc. Regulations.
- Use of guidance.
- ACOPs. These may help whilst still allowing scope for alternative, equally good, ways of controlling hazards and reducing risks.
- Goal-setting regulations. These may help to amplify general duties.
- Specific or prescriptive regulations.

