Introduction

1 One of HSE's key purposes is to ensure that major hazard risks are properly managed. This document describes the core elements of HSE's Major Hazard Regulatory Model and approach to the regulation and control of risk in onshore and offshore high hazard sectors. It provides:

- the underpinning principles against which HSE will direct resources to activities that give rise to greatest risk, or are least well managed; and
- an overview (Annex 1) of a safety management system for major hazards.

Principles

2 The principles underpinning HSE intervention programmes and the actions of HSE inspectors are as follows:

- Responsibility for managing risk rests with the dutyholder and not with HSE.
- Dutyholders are responsible for identifying, profiling and managing the major hazard risks they create in a systematic way and for compliance with legal duties in respect of those risks.
- Major hazard dutyholders will be subject to a level of regulatory scrutiny that is proportionate to their risks and performance.
- In permissioning regimes, HSE will keep the arguments and commitments set out in safety cases/reports under constant review and critical assessment in light of actual dutyholder performance.
- The interplay between technical, organisational and management factors is critical to effective risk control.
- The effectiveness of senior management leadership is an important determinant of dutyholder success in managing major hazard risks.
- HSE inspectors will make regulatory decisions taking all these issues into account and, where a gap exists, use the Enforcement Management Model (EMM) to guide their actions.
- Regardless of their performance, dutyholders will be subject to a degree of periodic inspection to provide public reassurance that major accident risks continue to be managed appropriately.

Aims

3 The aim of HSE's regulatory intervention programmes in the major hazard sectors is to:

- Confirm, through sampling, that dutyholders have properly focused their risk management efforts on major accident hazards.
Confirm that, where dutyholders are subject to a permissioning regime, the basis of the demonstration remains valid and that the dutyholder can show they are effectively controlling risks.

Take proportionate action, including enforcement, to ensure that dutyholders make improvements where there is evidence of significant shortfalls or failures in the way they have implemented control measures.

Delivery

4 HSE will:

- plan intervention programmes on the basis of a common approach to risk ranking;
- assign greater emphasis to higher risk activities and poor performers;
- use operational intelligence from multiple sources – including safety cases/reports, previous performance and intrinsic hazard – to make best use of its resources;
- intervene with dutyholders at the right organisational level, particularly with senior managers and leaders;
- inspect – to common processes – by sampling key elements of a dutyholder’s major hazard management arrangements;
- confirm – and react to as appropriate – any evidence of failure by a dutyholder to demonstrate that commitments made in permissioning documents (safety cases, safety reports, licences) remain valid;
- be open with dutyholders about the purpose, content and timing of inspections;
- hold dutyholders to account for their risk management, take appropriate action in line with HSE’s Enforcement Policy Statement and make enforcement decisions based on the EMM;
- clearly communicate with dutyholders in terms which make clear where compliance has not been achieved, what measures are needed to achieve compliance and to what timescale;
- confirm any regulatory actions with employee representatives;
- follow up with dutyholders to confirm that any necessary improvements have in fact been achieved; and
- work with major hazard sectors to promote sustained improvement.

5 In specific areas this means the following.

Assessment

6 HSE will assess safety cases and safety reports to confirm that the dutyholder has demonstrated that they have established a suitable safety management system to prevent a major accident and to mitigate the consequences.

7 Under permissioning regimes, HSE will compare the findings from inspection or investigation against the control measures and safety management system described within the safety case or safety report or licence condition.

Inspection

8 HSE inspections in the major hazard sectors will focus on how well dutyholders manage risk by testing and sampling dutyholder arrangements in critical areas, including the key control measures relevant to major hazard scenarios. The core areas for attention will be set out clearly as part of sector and delivery plan.
arrangements. Within these parameters, inspectors will focus on, and test in detail, the most important layers of protection and accident prevention barriers and the systems which support them. They will use their professional judgement to decide how deeply to probe dutyholder performance and the underlying causes of failure before they make a regulatory decision.

9 Where inspection takes place in a permissioning environment, inspectors will further test their findings against the arguments set out by dutyholders.

10 Where an inspector identifies deficiencies which give rise to significant risk they will:

- identify the underlying causes as well as immediate ones;
- confirm the necessary remedial action; and
- take appropriate enforcement action in line with the EMM.

**Investigation**

11 When inspectors investigate accidents and incidents they will target the key aspects of risk control, and protective and mitigatory barriers, to identify any core failings in the dutyholder's safety management arrangements. Investigators will also identify whether technical or managerial failures identified are sufficiently serious to require enforcement.

12 At the end of any intervention, inspectors will confirm all matters requiring attention in writing. They will confirm which matters are subject to formal enforcement and why. If inspectors provide additional advice and guidance on good practice and areas for continuous improvement they will make the distinction clear.
Annex 1: How we expect dutyholders to manage major hazard risks

This annex gives an overview of a safety management system for major hazards. It should help inspectors assess dutyholder arrangements for managing major hazard risks and, specifically, to link technical, organisational and management aspects of risk control.

Safety management systems1 in a goal-setting legislative framework

None of the current major hazard regulatory frameworks prescribes in detail what measures the dutyholder has to take to prevent a major accident or mitigate the consequences. Dutyholders have to determine this for themselves. They then have to show how they have effectively implemented the appropriate barriers and protective measures. The process may need to be set out in a safety case or safety report, or through submission of relevant safety management information, before a consent is granted or a licence issued.

The elements of safety management systems

Major hazard risk control has to be systematic, and as well as preventive measures, should also confirm there are robust mitigation and emergency arrangements to limit the impact of a serious event. In this document, safety management system describes these arrangements. All safety management systems contain the steps: Plan, Do, Check, Act. The actions involved in delivering effective arrangements are described in Table 1, with a read across to process safety management.

Table 1 Summary of ‘Plan, Do, Check, Act’ and managing for health and safety

<table>
<thead>
<tr>
<th>Managing for health and safety</th>
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<tbody>
<tr>
<td><strong>Safety management system</strong></td>
<td><strong>Process safety management</strong></td>
</tr>
<tr>
<td><strong>PLAN</strong></td>
<td>Determine your policy; plan for implementation.</td>
</tr>
<tr>
<td></td>
<td>Identify and assess risks; identify controls; record and maintain process safety knowledge.</td>
</tr>
<tr>
<td><strong>DO</strong></td>
<td>Organise for health and safety; profile risks; implement your plans, including control measures.</td>
</tr>
<tr>
<td><strong>CHECK</strong></td>
<td>Measure performance (monitor before events; investigate after events).</td>
</tr>
<tr>
<td><strong>ACT</strong></td>
<td>Review performance; act on lessons learned.</td>
</tr>
</tbody>
</table>

1 Known as safety and environmental management systems in offshore regimes.
Control measures for major accident risks

HSE expects dutyholders to understand that major hazard risks have to be managed in a multi-layered way and that the layers of protection or control measures will address technical, managerial and procedural arrangements.

![Figure 1 Layers of protection](image)

Layers of protection can be depicted as a ‘bow-tie’ to emphasise the way barriers link in sequence in relation to each major hazard scenario.

![Figure 2 Bow-tie model of layers of protection](image)

The dutyholder should be able to show a logical and rational flow of analysis leading from hazard identification through to effective risk control, expressed as a set of appropriate ‘barriers’ (or risk control systems).

![Figure 3 Sequence of analysis to determine the appropriate control and mitigation measures for major hazards](image)

There is not a ‘one-size-fits-all’ solution to determining the appropriate control measures. Dutyholders should be able to show that they have properly profiled their major hazard risks. Inspectors should be able to assess the relative importance of the measures in place and their vulnerability to deterioration and failure when inspection sampling at major hazard establishments.
Major hazard leadership

Systems and arrangements and the supporting organisational safety culture cannot be sustained without effective leadership. The potentially complex systems and arrangements needed to manage major hazard risks need to be delivered and maintained by managers with vision and determination. This cannot be left as the sole preserve of safety specialists within an organisation.

Maintenance of control

Dutyholders have to routinely monitor and review their arrangements and act on the findings. As well as reactive monitoring through incident investigation, dutyholders should have programmes in place to audit their safety management system and use leading and lagging key performance indicators to provide routine information on performance.

Overview

These elements of a safety management system for major hazards are brought together in an overview in Figure 5 on page 7.

Further information

Information about managing for health and safety: www.hse.gov.uk/managing/

This document is available at www.hse.gov.uk/regulating-major-hazards/index.htm

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MAJOR HAZARD MANAGEMENT (the big picture)

Hazard Identification
- Processes or Activities Undertaken
- Hazardous Property: Condition
- Volume

Risk Assessment
- Probability
- Potential Impact/Consequences
- Challenges to Integrity or Containment

Risk Profile

Determine the Control Measures (Barriers)

Major Hazard Control Measures (Barriers)
- Preventive Barriers
- Mitigation Barriers

Outcome

CHECK, MEASURE & REVIEW
- Leading & lagging indicators to measure performance of control measures
- Audit Programme to check the design and suitability of control measures
- Investigate losses of containment events and major hazard incidents to identify failures in the control measures

Leadership
- To set an effective vision and culture for major hazard management

Intrinsic Hazard
- Toxic
- Flammable
- Reactive
- Corrosive
- Explosive
- Infectious

Physical Property
- Temperature
- Pressure
- Solid
- Liquid
- Gas

Plant Life Cycle - where relevant

Stage in Plant Life Cycle
- Operate
- Shut down
- Start up
- Modify