

## THE REGULATORS APPROACH TO ASSESSING COMAH SAFETY REPORTS

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A recent European Directive requires member states to introduce legislation on the control of major accident hazards involving dangerous substances. Regulations will be introduced in February 1999 and central to these is a requirement for establishments above the threshold quantities of these dangerous substances to produce a written safety report. This paper outlines what a safety report is and when it is required. It explains the principles behind the regulator's assessment process and how they were drawn up. The paper also describes how the regulator, consisting of the HSE and environment agencies and dealing with health, safety and environmental major accident hazards, will assess these reports and outlines the procedures and criteria that will be used.

Key words: Safety Reports, Assessment, Major Hazards

### INTRODUCTION

On 9 December 1996, the Council of the European Union published European Directive 96/82/EC on the control of major accident hazards involving dangerous substances. This Directive is commonly referred to as the Seveso II Directive. UK proposals to implement this Directive were made in a Consultative Document published in early May 1998. The proposals are for a single set of regulations, to be called the Control of Major Accident Hazard Regulations (COMAH), to be made under the Health and Safety at Work Act 1974 and the European Communities Act 1972. COMAH will replace the existing Control of Industrial Major Accident Hazards Regulations 1984 (CIMAH).

COMAH will apply to establishments which have, or foreseeably have, threshold quantities of dangerous substances, including those which might be generated in the course of an accident due to loss of control of a process and without any differentiation between storage and processing. The regulations will be goal setting and will therefore place a duty on operators of establishments to take all measures necessary to prevent a major accident. There will also be more specific duties relating to notification, emergency planning, information to the public and accident reporting.

Central to COMAH is the requirement for establishments with higher thresholds of dangerous substances specified in the regulations (referred to as 'top-tier' establishments) to send a report to the competent authority. Sites with lower threshold quantities will be required to prepare a major accident prevention policy (MAPP), which sets out their policy for preventing and mitigating major accidents and demonstrating that they have a safety management system in place to achieve this.

COMAH will be enforced by the 'competent authority' (CA) which is the HSE and either the Environment Agency or the Scottish Environment Protection Agency (SEPA) working jointly or separately in the enforcement of the regulations. HSE and the Agencies will work together closely in their enforcement.

### WHAT IS A SAFETY REPORT?

The safety report is prepared by the operator of a top tier establishment and is a key element in identifying, preventing, controlling and mitigating major accident hazards.

Basically the report is prepared for the CA and should contain certain information and descriptions about:

- the management system and organisation of the establishment concerning major accident prevention
- the site and its locality and the areas where a major accident may occur
- the main activities and products, processes and operating methods
- the dangerous substances, including maximum quantities present
- the hazard and risk identification, analysis and prevention methods resulting in a description of possible major accident scenarios and the extent and severity of their consequences
- technical measures used for the safety of installations
- measures of protection and intervention to limit the consequences of a major accident, including technical measures taken and emergency response arrangements.

Operators are providing this information for the following purposes.

To demonstrate that

- a MAPP and a safety management system for implementing it have been put into effect
- major accident hazards have been identified and measures taken to prevent and limit their consequences for persons and the environment
- there is adequate safety and reliability in the design, construction, operation and maintenance of any installation re major accident hazards
- on-site emergency plans have been drawn up and information supplied to enable off-site plans to be drawn up

and that sufficient information has been supplied to

- enable the CA to make decisions about the siting of new activities or developments around existing sites.

In summary, operators will have to present the information in such a way that they demonstrate that they have taken all measures necessary to prevent a major accident. They are presenting a case that the measures they have in place, linked to their major accident hazard processes, do and will continue to control the risks and that the management arrangements will achieve this. The continued operation of an establishment does not depend on the acceptance of the safety report by the CA. However, the CA does have certain duties placed on it, which will be described later.

#### WHEN IS A SAFETY REPORT REQUIRED?

A safety report is required for each top tier establishment. This requirement is different from the CIMAH Regulations which required a safety report for each hazardous installation. We estimate that there are about 350 top tier establishments in England, Wales and Scotland. The need for a safety report and its timing will depend on the circumstances, which are outlined below.

#### Existing Major Hazard Sites (ex CIMAH)

There are transitional arrangements for operators of existing establishments who have submitted a safety report under CIMAH.

Establishments which came within scope of the CIMAH top-tier requirements and had submitted a safety report under these regulations, must submit their first COMAH safety report on the date that their CIMAH safety report update would have been due **OR** by 3 February 2001, if that is earlier. However, operators whose CIMAH update was due between 3 February and 3 August 1999 have until the 3 August 1999 to submit their COMAH report. The important feature here is that, in these circumstances alone, COMAH, as drafted in the Consultation Document (CD) will allow submission of a safety report in parts.

CIMAH linked an individual safety report to each hazardous installation, and therefore operators with a multi-installation establishment have the option of submitting, on the due date, either

- an installation report on the date that a CIMAH report would have been due, so long as the first installation report is submitted with with, what is often referred to as, the 'core' report. This should contain information about the establishment's management arrangements and site and locality descriptions.
- a complete report for the whole establishment.

The CIMAH and COMAH schedules for specifying the thresholds for dangerous substances at establishments are very similar, although there is an increase in the number of generic classification categories, which has led to a major reduction in the extensive list of specific substances named in CIMAH. These classification categories are linked to the Classification, Packaging and Labelling Directives for both substances and preparations and which have been brought into UK law as the CHIP Regulations. In practice, there will be some existing establishments which will be new to COMAH, which are described below, and a few establishments which will no longer require a safety report. This will mean, for example, that a large number of timber treatment sites handling copper chrome arsenate (CCA), will no longer require a safety report.

#### Existing sites new to major hazards legislation

The relatively minor changes to the thresholds for dangerous substances in the COMAH schedules compared to CIMAH will mean few establishments requiring a safety report for the first time. Warehouse sites look the most likely additions. However COMAH will apply (whereas CIMAH did not) to:

- chemical hazards on nuclear installations which are licensed under the Nuclear Installations Act 1965
- certain explosives sites subject to The Explosives Act 1875.

Operators of these establishments are required to submit a safety report by 3 February 2002.

#### New Establishments

The following describes the position concerning the submission of safety reports for brand new establishments as envisaged in the COMAH Consultation Document. Requirements concerning this may change after consultation.

Operators of brand new establishments, on which construction starts after COMAH comes into force, must submit a safety report to the CA within a reasonable period before construction. What a reasonable period is considered to be will depend on negotiations between the operator and the CA and whether in particular there has been early dialogue between the two before submission of the safety report. Without this, the CA is unlikely to require less than 3 months.

Operators will not be able to start the construction stage until they have received the conclusions from the CA. There is then a requirement for a second report to be submitted a reasonable period before the start of operations, which is taken to be the time when hazardous substances are used in the hazardous installation for the first time. Again there is a 'statutory hold point' because the operator must not start operations before the CA has given its conclusions on the safety report. In this case, a reasonable period is thought to be up to 6 months to allow the CA to assess the report, but again this may be reduced by early dialogue between the operator and the CA, in which information is provided..

The information provided in the 2 reports together should provide the complete information and provide the necessary demonstration described earlier. The split of information will vary depending on the specific project, but the pre-construction report should contain as a minimum the following information:

- description of the establishment installations and processes
- reasoning in selecting process options and chosen design concept
- description of the environment in and around the establishment which could be effected by a major accident
- identification of major accident scenarios
- information about the prevention, control and mitigation measures to be provided or the principles to be followed, where details are not finalised
- demonstration of an effective safety management system to ensure the quality of procedures for the control of design, procurement, construction and commissioning.

These reports are only required for new establishments. Operators introducing a new installation on an existing establishment will be required to prepare a single modification report, as discussed later. It is therefore unlikely that 'pre-construction' and 'pre-operation' reports will be required very often.

#### Review and updating of reports

Safety reports should be reviewed by the operator at least every 5 years, or whenever new facts or new technical knowledge mean that such a review is thought necessary, and the revised report submitted to the CA.

#### Modifications

Operators must review and revise their safety reports and inform the CA of the details of the revision before any modifications are made to

- the establishment or installation,
- the processes carried on
- or the nature and quantity of dangerous substances,

which could have significant repercussions on the prevention of major accidents. These considerations should be incorporated into the operator's plant/process change procedures. However, it should be remembered that changes to an establishment, under COMAH, include introducing a new installation, which would not normally be thought of as just a 'modification'.

For modification reports, there is no requirement to submit these within a reasonable period, but if the operator is to avoid retrospective action required by the CA, then early dialogue is again recommended. The period of early 'warning' that the CA would like will vary, depending on the type of modification, but for example, the CA is likely to take up to 6 months to examine a safety report for a new hazardous installation at an existing establishment.

#### WHAT IS ASSESSMENT?

Assessment is the structured process by which the CA examines the adequacy of safety reports. This examination will assess whether the safety report:

- contains sufficient information
- meets the purposes of a safety report which is primarily to provide the demonstrations required.

The CA's conclusions of its examination of the report, given to the operator of the establishment concerned, will be based on these 2 requirements. There is however a further statutory requirement on the CA. In examining the safety report and assessing whether the required demonstrations are made, the CA will carefully consider the measures and in doing so will

- prohibit the operator of this establishment, installation or any part, where a serious deficiency is identified.

Assessment is an 'enforcement' activity, using the term 'enforcement' in its wider sense to include the wide range of influencing techniques used by regulators, ranging from advice, letters, notices, licensing through to prohibition and prosecution. Each is successful in the right context, but each has to be used within a recognised framework. For assessment of COMAH safety reports, principles have been devised which fully take into account the Health and Safety Commission's policy for enforcement, that is that it should be transparent, targeted, proportionate and consistent.

However, assessment is also quite a complex process, which requires good management practice to deliver the enforcement policy. Not surprisingly, we decided that there was no more appropriate management model than that adopted by HSE in its own guidance (1) on effective safety management and therefore the principles of the assessment process should have a clear Policy and Organisation to deliver it, arrangements for Planning and Implementation, supported by suitable Monitoring, Audit and Review arrangements (known within HSE as the POPMAR model). With this framework in place, and learning from other assessment processes particularly safety case assessment in HSE's Offshore Safety Division and licensing arrangements in the Nuclear Safety Division, both of which have many similar aims, we were able to set out the principles and procedures for assessing COMAH safety reports.

## HOW HAVE THE ASSESSMENT PROCEDURES BEEN REVISED?

A project was set up in February 1997 called SHARPP (Safety Report Handling Assessment Review Principles and Procedures) to develop the guiding principles and procedures for assessment and to prepare criteria to be used by the CA as performance measures for assessing the information in the safety reports and helping to judge whether the necessary demonstrations have been made. The criteria have been divided into 5 parts:

- safety management systems
- descriptive criteria
- predictive criteria
- technical measures for prevention and mitigation
- emergency arrangements criteria

and were prepared by 5 separate teams. Details about these criteria will be given by colleagues in separate papers.

An important feature of the project is that it has been run by a Project Board which consisted of members from HSE and both environment agencies, who agreed their contributions to the various 'products' required by SHARPP. For example the agencies have been involved in the pilot exercise and the Environment Agency has been involved in the development of the assessment criteria.

As part of the project, procedures and criteria were prepared and incorporated into an 'Assessment Manual' for use in a pilot exercise, involving 4 teams of assessors from HSE and the agencies, assessing COMAH safety reports prepared by 4 volunteer companies. This assessment process was carried out over a period of 3 months and was complemented by consultation on the pilot Assessment Manual with trades associations, trades unions and individual companies, who had shown previous interest.

## HOW WILL COMAH SAFETY REPORTS BE ASSESSED?

A new Division in HSE, the Chemical and Hazardous Installations Division (CHID), was set up in April 1996 focussed on the chemical and explosives industries and in particular to enforce the new COMAH Regulations. This Division will have the primary enforcement role in HSE for COMAH in conjunction with the Agencies. The principles for assessment have been developed within CHID.

The principles underpinning the assessment process are listed in Appendix 1. There are 10 Guiding Principles which set the policy and 8 Administrative Principles which set some fundamental principles on how the process is organised, implemented, monitored, audited and reviewed (POPMAR). The following paragraphs summarise the main points.

### Policy - Operator retains duty

Although the CA will examine each safety report and come to conclusions about it, as well as identifying any serious deficiencies in the measures it describes, the duty to ensure

that establishments, and installations within them, are designed, constructed and managed safely remains with operators.

#### Policy - All measures necessary

The term to take 'all measures necessary' to prevent or mitigate major accidents is not one that has any legal precedence in safety legislation in the UK. We have interpreted this to mean that hazards should be avoided if possible or reduced at source through the application of inherently safe principles. In this case, inherent safety means inherent safety, health and environmental protection (i.e. inherent SHE), in which, for example, the substances used are intrinsically less harmful or processes are used in which the consequences of loss of containment are reduced. Where risks remain, then the recognised principle of ALARP (as low as reasonably practicable) will be used by the risk assessor for health and safety issues and BATNEEC (best available technology not entailing excessive costs) for environmental matters. We recognise that the application of inherent SHE principles is economically more viable for new installations and these issues should be considered as early as possible during the design of the installation or any modification. Consideration of inherent SHE will be a particular feature of assessment for pre-construction reports. It is not intended to require major retrospective action on the basis of inherent SHE for currently existing installations.

#### Policy - Enforcement strategy

Assessment of safety reports will be part of an overall enforcement strategy for COMAH top tier establishments. It will not be an isolated or 'one-off' process. Information gained from assessing the safety report will be used to inform a subsequent inspection plan by the CA. Similarly, inspection will help the CA to continue to build its knowledge and experience of an operator and a particular establishment, which will help it to assess each subsequent report.

The assessment of a safety report is looking at a snapshot in time. It will be based on the documentary evidence in the safety report, or referenced by it. There will not be any site visits to check the accuracy of information, other than following up on suspected serious deficiencies, but conclusions will also be based on other intelligence such as from previous inspections, investigations, reference books and other sources of information. Assessors may seek further clarification from the operator on assessment issues, which exceptionally could include site visits.

The safety report will be used as a fundamental source of information for future inspection. After the assessment is completed, the assessors will make recommendations which will be developed into an inspection plan for the site. The inspection plan for each establishment will form part of the CA's wider inspection programme for the next 5 years. This period has been chosen because each safety report must be reviewed by the operator every period of 5 years. The contents of each safety report will be subject to verification as part of the inspection plan and the CA's conclusions may be subject to subsequent scrutiny as a result.



### Policy - Selection

It is neither possible nor sensible for the CA to examine every part of each safety report in detail. This is particularly the case for large reports dealing with complex or unusual processes. Instead, parts of a safety report will be selected for full examination. Selection will be guided initially by hazard and by previous assessments both at the particular and related establishments and installations. With this knowledge, account can be taken of plant or system vulnerabilities, or weaknesses in the safety management system and the risk of these contributing to major accidents.

Although a safety report may be selectively examined in detail, it will be read thoroughly at least once by the Assessment Manager (see below) and in practice we have found that all the assessors need to read the report in full to assess selected issues.

### Policy - Serious Deficiency

A site visit will be paid where a potential serious deficiency is identified in the measures described to prevent a major accident or limit their consequences during the assessment process. Action, jointly with the agencies where appropriate, will not be delayed to complete the assessment process. Assessors will have to obtain first hand evidence to support prohibition action and check the facts with the operator, before a prohibition notice is issued. Agreement will also be obtained from the inspector's line manager, before any notice is served.

### Organising

An Assessment Manager (AM) will be appointed for each safety report to be assessed, who will act as the primary point of contact for dealings on the report. The name of the AM will be agreed between HSE and the Agencies. Normally the AM will be the site inspector working in the HSE inspection group dealing with the site.

Assessment will be by a team composed of the necessary competences eg:

the local inspector - who will manage the assessment process, assess safety management issues and other matters on which he/she has knowledge and bring the conclusions together

the topic specialist - who will provide specialist input eg on process safety, mechanical, electrical or civil engineering. Teams will be located in 'local' offices and support will be provided by HSE specialists from outside CHID.

risk assessors - based in the Major Hazards Assessment Unit, who look at the techniques for identifying and analysing the hazards, consequences and risks and be able to confirm that the major accident scenarios have been properly identified

agency representatives - will look at the above issues, but considering the environmental consequences.

An assessment team will be assembled for each safety report and dismantled on its completion. Some of the team will have more than one task.

### Planning and Implementation

A diagram illustrating the flow of the assessment procedures is shown at Fig 1. Critical stages to the smooth working of the assessment team are the drawing up of the assessment plan, its implementation and the assessment outcome meeting.

The AM devises an assessment plan for each safety report to include:

- names of the assessment team
- the resources likely to be expected
- aspects of the report likely to be assessed, including the target agenda
- milestones and timing for particular stages of the assessment.

The Target Agenda sets the items in this safety report to be assessed in full and records the reasons for this. The descriptive parts i.e. that adequate information which is provided to meet Schedule 4, Part 2, the major accident scenarios and the MAPP are always selected for full assessment.

The assessment team members will be allocated their tasks and will be asked to conclude whether the operator has met the purposes required of a safety report and made the demonstrations specified in Schedule 4 Part 1, relevant to what they are examining. In examining the report, they may decide that there is insufficient information in the report itself to come to a conclusion. The assessors will obtain further information from the operator, liaising with the AM, until they are satisfied that they have sufficient to come to a conclusion. At this stage it should be become clear whether there are any serious deficiencies in the measures for preventing major accidents and limiting their consequences, including the management arrangements for delivering these measures. As individual members of the team undertake their examination, they will follow up on suspected serious deficiencies, again liaising with the AM.

During assessment, team members will also be accumulating information from the safety report and forming overall views about how the operator manages his establishment, not just as a result of the arrangements and systems described but also from the conditions described, in other words how they have been put into effect. All these matters will be discussed at an assessment outcome meeting. The prime purpose of the assessment outcome meeting is to produce agreed conclusions and initially send them in draft to the operator. The operator will then have an opportunity to discuss these with the assessment team, before conclusions are sent formally.

Where one or more of the demonstrations written in the safety report has not been made, the assessment team will decide the action they will seek from the operator. We envisage that this will require the issue of an Improvement Notice to remedy the problem/s. There may be deficiencies in the measures described, which are neither seriously deficient nor are they such to prevent the operator making the overall demonstrations. In these cases, the team will decide their relative importance and recommend how they should be addressed in the subsequent inspection plan.

#### Monitoring, Auditing and Review Arrangements

Key stages of the assessment process have been identified and arrangements for monitoring have been included. When finalised, the assessment procedures will be designed to conform to ISO 9000 quality procedures.

#### PILOT EXERCISE & CONSULTATION

Four operators of current CIMAH top-tier sites agreed to produce COMAH safety reports for their sites to allow assessment by the CA. The reports were produced for the beginning of April 1998 and were examined by separate teams of assessors who communicated their conclusions about the reports to the operators at the beginning of July 1998. A pilot version of the Assessment Manual was prepared for the assessors and copies sent to the operators. At the same time, copies of the pilot manual were sent to members of the Health & Safety Commission's Sub Committee on Major Hazards, selected organisations and other organisations that expressed an interest, during its development, in receiving a copy.

The pilot and consultation exercise has proved invaluable. A number of important points have been learned as well as detailed points concerning the criteria. Further guidance was required by assessors on how to use the criteria. The criteria are provided as a guiding framework within which professional judgements are made: they are not intended to be a tick list representing a pass or a failure for each criterion. They are 'high level' and will eventually be supported by more detailed guidance to assessors on performance standards that will meet these criteria e.g. what might be expected in safety reports dealing with LPG filling installations or ammonium nitrate fertiliser stores.

#### Demonstration

It was clear from the pilot reports received that further guidance was required on what should be contained in a safety report and how operators should present this information to help them make the required demonstrations under Schedule 4 Part 1. The CA now plan to prepare an on-sale booklet for report writers providing guidance on how a report might be structured and the type of information to be included. This will be guidance and not an approved code of practice to support the regulations.

In relation to the purposes of a safety report required by COMAH 'demonstration' is thought to mean 'show' or 'make the case/argument' rather than at the stronger end of the meaning of demonstration such as 'prove beyond doubt'. The implication is that prima-facie information should be used and professional judgement should be exercised by the assessor, rather than extensive in-depth scrutiny or exhaustive examination.

### Proportionality

Concerns were expressed by assessors and consultees alike that the criteria, although thorough, could overwhelm operators and that there needed to be a sense of proportion. COMAH applies to a wide range of establishments differing in size, numbers of employees, complexity, resources and expertise available, technology, culture and environment surrounding the site. They have one thing in common; they all have major accident potential, although even with this there is a wide variety of hazards. Clearly it would be unreasonable for the safety report for a small ammonium nitrate store to look the same as a report for a multi million pound oil refinery but both must make the same demonstrations.

The demonstration should be proportionate. The depth of the demonstration relates to the hazard but more particularly to whether the process is unusual, innovative, complex or whether there are existing standards/guidance. The size of the establishment or the resources of the operator do not determine of the depth of demonstration required, only the amount of information required to describe what is going on.

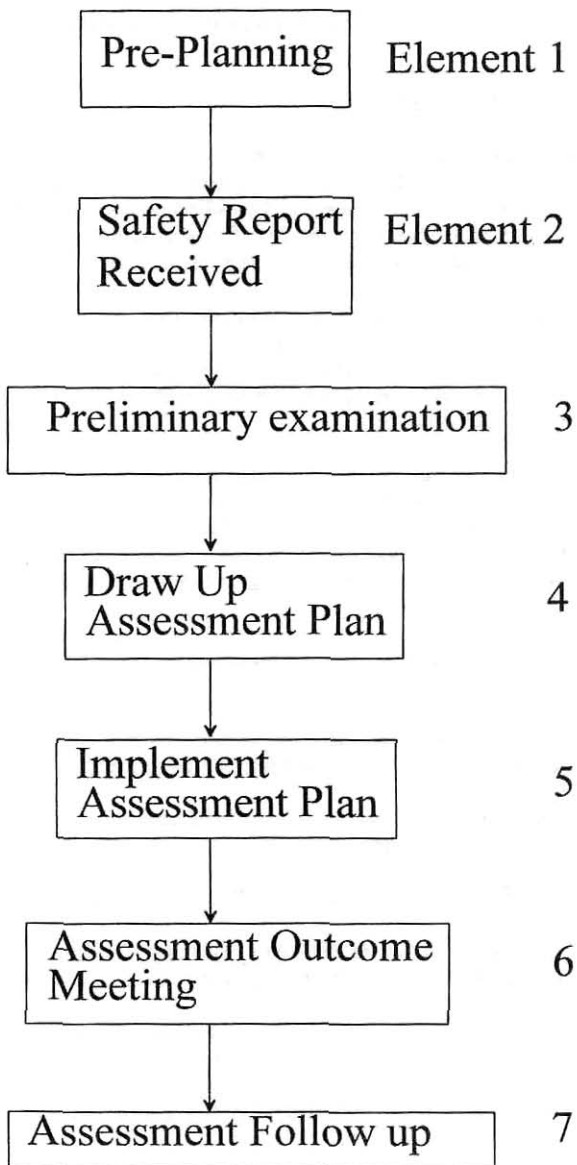
### CONCLUSIONS

The introduction of the new COMAH Regulations in February 1999 has meant that the regulator has completely revised its procedures for assessing safety reports because of new requirements on the operator, duties on the regulator for the first time and because the regulator is a competent authority consisting of 3 bodies i.e. HSE, the Environment Agency and SEPA. As a result, the procedures have been prepared following a recognised management model for ensuring 'quality'. These procedures and the actions taken will meet the enforcement policy followed by HSE and ensure that the regulator is consistent in its approach, proportionate in its action and targets the right parts of the report for detailed consideration, as well as being transparent. The procedures have been tested in a major pilot exercise and key stakeholders have been consulted, resulting in a number of significant changes. The revised procedures will be made available in a manual to anyone requesting it and we plan to make this document available on the HSE Internet web site.

### REFERENCES

1. HSE Booklet (HS/G65) Successful health and safety management, HSE Books

**Figure 1 Flow Diagram of Safety Report Assessment Procedures**



**PRINCIPLES FOR ASSESSMENT**

**GUIDING PRINCIPLES**

- GP1** The duty to ensure that necessary measures have been taken to prevent major accidents and to limit their consequences at an establishment remains with the operator and no conclusions reached following assessment of a safety report by the CA diminishes that duty, nor do such conclusions imply that the CA consider the establishment, or parts of the establishment, to be 'safe'.
- GP2** Assessment is a structured process by which the Competent Authority (CA) examines the adequacy of safety reports against the purposes set out in Schedule 4 Part 1 of the COMAH Regulations and which contributes to the CA's decision about whether the measures taken by the operator for the prevention and mitigation of major accidents are seriously deficient.
- GP3** Hazards should be avoided if possible or reduced at source through the application of inherently safe principles. Where risks remain, then recognised principles such as ALARP (as low as reasonably practicable) for health and safety matters or BATNEEC (best available technology not entailing excessive costs) for environmental matters should be used to determine the extent of the preventive and mitigation measures required.
- GP4** The assessment of the safety report is part of an overall enforcement strategy for top tier COMAH sites.
- GP5** Conclusions about the safety report will be based on an assessment made against criteria by means of a structured process. The process and criteria will be published.
- GP6** The conclusions of an assessment can be based on a full consideration of selected parts of the safety report.
- GP7** The CA's assessment conclusions will be based on the evidence in the safety report.
- GP8** The contents of the safety report and those conclusions will also be subject to verification and further scrutiny as part of a continuing inspection programme.
- GP9** Where a potential serious deficiency is identified, the site before action is taken. Normally the CA's line management action before such action is taken.
- GP10** The CA's actions will be confirmed in writing to the operator.

**ADMINISTRATIVE PRINCIPLES**

- AP1 An Assessment Manager will be appointed for each safety report to be assessed and the name made known to the operator to provide the primary point of contact for communications about the report.
- AP2 Assessment will be by a team composed of members with the necessary competences.
- AP3 The CA's performance standards will be published and met.
- AP4 The assessment procedures will be set out in a manual and will follow ISO 9000 quality assurance principles.
- AP5 The effort put into assessing a safety report will depend on a number of factors including the hazard, but enforcement will be proportionate to the risk, as identified by the CA.
- AP6 Monitoring against published performance standards will be an integral part of the assessment process.
- AP7 Procedures will include an in-built mechanism for review.
- AP8 The assessment process will be auditable.