ASSESSMENT OF THE PREDICTIVE ASPECTS OF COMAH SAFETY REPORTS

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This paper introduces the 'predictive assessment criteria' and complements other papers which describe the development of the Health and Safety Executive's (HSE) guiding principles procedures and criteria for safety reports submitted under the Control of Major Accident Hazard (COMAH) Regulations 1999. The 'predictive' assessment criteria are needed as part of the demonstration of safety required by Schedule 4 of the draft Consultative Document for the proposed COMAH Regulations (1).

Key Words - COMAH Safety Reports: predictive criteria

INTRODUCTION

The assessment of safety reports submitted under the Control of Industrial Major Accident (CIMAH) Regulations 1984 (2) is not based on any specific evaluation criteria for either the acceptance or rejection of the report. However, in addition to published guidance (3), internal guidelines are used by HSE as the basis for forming judgements about the validity of evidence presented in the report to determine whether or not there are gross omissions or serious deficiencies, when compared against the requirements of CIMAH Schedule 6. In turn, these deficiencies may also be indicative of failures to follow established good practice and safety standards and hence compliance with statutory duties under the Health & Safety at Work etc Act (HASWA) 1974 to control the risks from major chemical hazard installations. Such deficiencies can then be remedied both in terms of requirements for additional information to be submitted for the safety report and if necessary during the later inspections of the installation, for which the safety report is pivotal.

It is important to stress that assessment of the CIMAH safety report is not a measure of the level of compliance with HASWA and relevant statutory provisions. That assessment establishes whether the report contained sufficient information to satisfy the requirements of Schedule 6; a test of the evidence not the activity, A safety report could meet these requirements even though it may reveal areas of weakness in risk control measures. If a report which provided adequate information on Schedule 6 topics, indicated poor compliance on site and is used to determine inspection priorities then it would have fulfilled its purpose. Conversely weaknesses in a report which lead HSE to require extra information from the Manufacturer or even a re - submission of the report does not necessarily imply major defects in on site standards of health and safety. Under CIMAH only when an inspector used Regulation 4 would the Manufacturer be required to satisfy

HSE about the demonstration of safe operation of the activity. Under the COMAH regulations the type and scope of information provided to the Competent Authority (CA namely the Environmental Agency (EA) Scottish Environmental Protection Agency (SEPA) and HSE) is not expected to be significantly different from CIMAH. However, the purpose and use of the information will be significantly different in terms of the operator's 'demonstrations' to the CA.

The essential features of the predictive information required in a safety report are to show that appropriate and systematic analyses of the major accident hazards are carried out and the results presented in the report. These elements comprise:

- Hazard Identification and Analysis: the properties and hazards (fire, explosion and toxicological - including ecotoxicological) of the dangerous substances, nature of process and operating parameters

- Accident Scenario Analyses: the conditions events, both internal and external and mechanisms leading to loss of containment and release of dangerous substances which would have the potential for major impacts on people and the environment - together with broad but justifiable estimates of their likelihood

- Consequence Analyses: the quantification and assessment of likely impacts on people and the environment in terms of their extent and significance

During the assessments of the first submissions of CIMAH safety reports one of the major deficiencies found by HSE in the predictive information, was the failure to consider high consequence low probability accident scenarios. These were often dismissed on the basis of unqualified and unjustified assumptions that such events were considered to be 'non credible' and therefore 'discounted' from the accident scenario and consequence analyses. This was not only a major failure to meet the Schedule 6 requirement for identifying potential sources of major accident hazards, but also led to shortfalls in the information required to satisfy Regulations: 10 (On site Emergency plan) 11 (Off site emergency plan) and 12 (Information to the Public). Other areas included lack of or poor consideration of assessment of the impacts from major accidents on the environment; limited consequence analysis based on assumptions that safety control and intervention measures - such as automatic shut down systems and operator response - would always work effectively and not fail 'on demand'; absence of estimates for the likelihood's of events (even qualitative ranking) and limited evaluation of 'escalation' potential.

In many cases, it was evident through later discussions with HSE, that Companies had carried out a significant amount of work, which in some cases included quantified risk assessments, and had available large volumes of detailed information to cover the predictive aspects, but often missed the opportunity to adequately present this in their safety reports. Fortunately most safety reports, which are now at the stage of their CIMAH '9 Year' review, have addressed these issues to a satisfactory standard. However. it is often the case that these reviews do not take the opportunity to consider the implications of changes to and lessons learnt from operational and accident experience, and technological progress, including the use of up to date mathematical models for consequence analyses.

ASSESSMENT NEEDS UNDER COMAH

Britton (4) describes the essential features of a COMAH safety report, the principles behind the development of the Competent Authority's assessment processes and procedures for dealing with both health safety and environmental major accident hazards. Fundamental to compliance with COMAH will be requirements for the safety report to contain certain information which is presented in such a way that the dutyholder can demonstrate that they have "taken all necessary measures to prevent a major accident", ie 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.

It is worth repeating here that the continued operation of an establishment will not depend on the 'acceptance' of the safety report by the Competent Authority. However, the tests for adequacy of the report will need to take due cognisance of the CA's specific duties under COMAH. A key aspect of the Schedule 4 requirements for the minimum information in the safety report concerns 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' . This in turn underpins one of 5 elements of the dutyholder's demonstration to the CA, namely that" major accident hazards have been identified and measures taken to prevent and limit their consequences for persons and the environment". The bottom line in safety report assessment by the CA is to ensure that the safety report contains the information required to demonstrate the duties placed on the operator. Other important aspects of the CA's 'assessment' and duties which include communicating the conclusions of the examination of the report (Regulation 17) and prohibiting the operation of the establishment, installation or any part where the measures taken to prevent and mitigate major accidents are seriously deficient (Regulation 18).

PREDICTIVE ASPECTS OF COMAH SAFETY REPORTS

Appendix 1 gives the full text of the revised 'predictive assessment criteria', which first appeared in the COMAH Safety Report Assessment Manual (Pilot Version) issued by HSE on 1 April 1998 (5). The predictive aspects of safety reports covered by this set of criteria form part of the demonstration of safety required by Schedule 4 of the COMAH Regulations, which explains the purpose (Part 1) and contents (Part 2) of the Regulation 7 Safety Report. The duty created by Regulation 4 to take all necessary measures to prevent and mitigate major accidents and the duty to demonstrate it by Regulation 15(1) are based, in part, on information given in the safety report. Operators must provide evidence under Part 1 to *'demonstrate that major accident hazards have been identified and that the necessary measures have been taken to prevent such accidents and to limit their consequences for persons and the environment'*. The specific requirements for the minimum information to be included in the safety report are given in Part 2, paragraph 4 of Schedule 4 which concerns 'Identification and accidental risk analysis and prevention methods':

(a) detailed description of the possible major accident scenarios and their probability or the conditions under which they occur including a summary of the event which may play a role in triggering each of these scenarios, the causes being internal or external to the installation;

(b) assessment of the extent and severity of the consequences of identified major accidents.

The risk analysis and assessment are inextricably linked with all parts of Schedule 4 in terms of the 'demonstrations' (Part 1) and information required from the safety report (Part 2). Because of this pivotal role of risk analysis and assessment there is a fundamental need to ensure that suitably robust assessment criteria are provided for the predictive elements of the safety report. These criteria were developed by external consultants under the close supervision and direction of a HSE Working Group, which included representatives from the Environment Agency, HSE's: - Nuclear Safety Division, Safety Policy Division, Explosives Inspectorate and other CHID Headquarters' Units. The criteria were prepared taking into account the following factors:

- consistency with Guiding Principles for Assessment and Administrative Principles set by the 'SHARPP' Project (Safety Report Handling Assessment Review Principles and Procedures) - see Britton (4)

- need to ensure universal applicability to cover environmental, health and safety risk assessments

The criteria will be applied by the Competent Authority (CA) to assess the fitness-for-purpose of the operator's major accident risk assessment. However, they do not cover other criteria which are being developed separately, such as

1) derogations under Regulation 7 (10) for which the European Commission has published criteria

2) the provision and exchange of information required under Regulation 16 which will be used by the CA to designate groups of establishments where the likelihood or consequences of a major accident may be increased because of the location and proximity of establishments in the group and the dangerous substances present - ie the consideration of the so called 'Domino Effects' referred to in Article 8 of the Seveso II Directive (6).

The criteria should also provide Operators with a clear and definitive steer on the issues which need to be addressed to satisfy their legal obligations. However, whilst these 'high level' criteria include explanatory notes and some examples of the type of information expected to produce a suitable risk analysis and assessment, they are not intended as guidance on the preparation of a safety report. Some Guidance can be found in (7). In due course, HSE will produce and make publicly available (in late 1999), internal guidance - which is outlined in later paragraphs of this paper - for use by MHAU's risk assessors to test the quality and adequacy of the operator's risk assessment. Again this is not intended as guidance on the preparation of safety reports. Similar detailed guidance will be issued by the Environment Agencies in due course.

Structure and Content of the Predictive Criteria

The overall structure of the criteria are shown in Figure 4.1 of Appendix 1 and are based on the 7 main components of the risk assessment process which in outline provide:

1) An understanding of the site operations, the materials involved and the process operating conditions

2) Identification of the hazards to people on-site and off-site and impacts on the natural and wider environment

3) Analyses of the different ways the hazards can be eliminated, reduced in scale, and controlled.

4) For the hazards that remain, predictions about the likelihood of the hazards being realised taking account of the chance of success and failure of possible preventive control and minimisation/ mitigation measures

5) Predictions about the corresponding consequences both when mitigation measures work and fail.

6) Evaluations/ Analyses about the associated risks and the options for reducing them to demonstrate that all measures necessarv to make them as low as reasonably practicable (ALARP) have been taken

7) A presentation of the results of the risk assessment to provide the evidence and arguments which demonstrate that all measures necessary have been taken to prevent and mitigate major accidents

For new plant step (3) is particularly important and the hazard analysis of the proposed design should consider the feasibility of:

- eliminating hazards and inherently safer approaches to reducing the scale of the hazards that cannot be eliminated

- reducing the likelihood of realising hazards and

- mitigating the consequences when these measures fail

The same considerations will generally apply to existing plant, but the scope for elimination and reduction in scale of hazards may be less practicable. Work is underway to produce assessment criteria for pre - construction and pre - operation safety reports under Regulations 7(1) to 7(5) based on the predictive criteria in Appendix 1 and other criteria (5).

COMAH does not specifically require the use of quantified risk assessment (QRA). However, the risk assessment whether it is quantitative, semi-quantitative, or qualitative is

considered to be the most logical and systematic process for the demonstrations required from the operator. Some of the questions that the risk assessment will need to address (5) for the demonstrations, are whether or not:

- the major accident hazards have been identified?
- the necessary measures have been taken to prevent major accidents?
- the necessary measures have been taken to limit the consequences of major accidents?

The depth of the analysis in the operator's risk assessment needs to be proportionate to the scale and nature of the hazard and the associated risks. To help assessors reach consistent professional judgements on this, the criteria are directly linked to the risk assessment process given above.

The criteria under Test

On 1 April 1998 HSE issued for wider consultation a draft ('Pilot') version of the COMAH Safety Report Assessment Manual (5) to complement the Consultative Draft Regulations and Guidance which were issued in May 1998 (1). Comments on the assessment criteria, inter alia, have been reviewed and modifications made where appropriate. In addition to external consultation a pilot exercise was carried out between April and June. This involved 4 Volunteer CIMAH Manufacturers, who submitted safety reports, for assessment against the newly developed HSE 'COMAH Criteria (5). Further details of this exercise are given in other papers presented at this symposium.

In most cases the responses to the format and content of the predictive criteria were positive and without exception there were no serious concerns about the range and clarity of the criteria. A number of relatively minor amendments have been made to the explanatory text, but the predictive criteria have not been changed. However, as expected, questions were raised about the level of detailed information expected by the Competent Authority. These issues are being addressed as part of the further guidance described in the next Section.

GUIDANCE FOR HSE RISK ASSESSORS

The main objectives for developing internal guidance will be to ensure consistency and proportionality, in the evaluation of information to meet the predictive assessment criteria. This guidance will not be published but it will be made publicly available. It should be stressed that this will not be a guide to the preparation of the risk assessments required in a safety report. However, together with other documents including European Commission's publication (7), and the Agencies' Environmental guidance, it is expected to provide a useful basis for Operators when developing their own internal guidance.

Structure of the Guidance

The original CIMAH guidance on predictive aspects was developed on the basis of HSE's experience in the assessment of the 'first submissions' of safety reports. Specific and important failings were identified which were generally common in the majority of these early reports. This was a valuable means of providing information to assessors, to enable them to make professional judgements about the standard to which a report had or had not satisfied the 'predictive' requirements of Schedule 6, but not as a means for either 'accepting' or 'rejecting' a report.

The main failings found in early CIMAH safety reports included:

(1) Factual Errors with respect to inventories and locations; procedures; process information and descriptions of safety systems

(2) Inadequate identification of or limitation of the sources and sizes of events and the range of initiating mechanisms in all sections of the installation (eg transfer operations) - including off site 'man made' events (eg aircraft impacts) and natural phenomena (eg seismic activity)

(3) Limited or no consequences assessment: large events often dismissed or ignored on the grounds of assumed low frequency - for which suitable estimates were not presented

(4) Consequences of major accidents to the environment

(5) The selection and use of unidentified and sometimes inappropriate mathematical models (source terms , dispersion and vulnerability - for which their limitations, and assumptions were not transparent

(6) Lack of justification and information about the effectiveness, availability and reliability of safety systems including the role of management and procedures - often assumptions that such systems would always be 100% reliable and never fail on demand thus limiting the duration and scale of consequences assessed

(7) Limited consideration of the multiple hazards of dangerous substances including dangerous substances produced during the course of an accident such as combustion products

(8) Limited description and consideration of the links between the consequences of events with specific initiating conditions and events nor consider 'escalation' (on site) and 'domino effects (off site)

(9) Little indication or justification or absence of 'harm criteria' based on suitable vulnerability models for the effects from fire, explosion, toxicological and ecotoxicological hazards

Based on these areas, internal guidance was produced to provide HSE risk assessors with background information about the type of information which should be expected to cover the predictive aspects of the report, namely hazard identification and phenomenology; accident scenario and frequency analyses and consequence analyses - together with information about the uncertainties in the various mathematical modelling parameters (for example see reference 8). In short the guidance was to provide details of the methods and criteria to ensure that inspectors could judge the adequacy and completeness of the information given in the safety report to satisfy the predictive requirements of Schedule 6, taking into account other relevant reference documents and not least, guidelines produced by Industry.

Preparation of COMAH guidance

Risk Assessors based in HSE's Major Hazards Assessment Unit (MHAU) will be required to assess the information given in the safety report about the techniques for identifying and analysing the hazards, consequences and risks and thereby confirm that the major accident scenarios have been properly identified to satisfy legal requirements.

COMAH guidance is being developed to take account of the experience gained in applying current CIMAH guidance and other factors such as:

- the majority of 'top - tier' installations involve relatively 'simple processes' handling flammable gases and liquids (including low pressure liquefiable gases such as LPG, methane and highly and extremely flammable liquids) and chlorine;
- clarity and suitability of information provided for all levels of experience (independent of assessor);
- the relevance of HSE's own risk assessment tools and models for providing land use planning advice to local authorities (8);
- whether or not it would be appropriate for HSE to express its views on the fitness for purpose of the variety of risk assessment methodologies used by industry;
- the availability and suitability of external published guidance on safety reports;
- the need to ensure a careful balance between prescription and professional judgement - and whether or not 'adequacy' statements linked to the criteria would be feasible
- take into account other HSE guidance documents eg assessment principles produced for the nuclear and off shore industries which include specific guidance on for example human factors; consequences models etc
- avoidance of overlap with other COMAH assessment guidance

Four possible structures were considered in terms of the degree to which each could match the factors identified above.

a) Option 1: 'Process Driven'

b) Option 2: 'Criteria Driven'

c) Option 3: Hybrid of Options 1 and 2

d) Option 4: Accident Scenario - Initiating Event Driven

After a detailed review and internal discussion, Option 1 is considered to be the easiest to use because each of the main sections are self contained and apply to a small group of substances with similar properties. The amount of redundant information used when assessing a safety report is minimal, but because each substance group chapter addresses each of the six 'headline' assessment criteria (see figure 4.1 in Appendix 1), a disadvantage will be the large volume of information required in each document.

The guidance will be produced in the form of separate Volumes to cover the most common substance/ process combinations and will include the following :

1. Methane
2. Liquefied Petroleum Gases (Propane and Butane)
3. Flammable Liquids (including Extremely and highly flammable liquids)
4. Chorine
5. Warehouses storing toxic substances
6. Explosives

However, it has been recognised that certain processes and dangerous substances cannot be easily dealt with under Option 1. A good example would be a COMAH petrochemical refinery utilising a Hydrogen Fluoride alkylation Unit and in such cases Guidance based on Option 2 - "Criteria Driven" - will also be prepared.

Conclusions

It is not expected that the information required to satisfy the predictive aspects of COMAH safety reports will be substantially different to that required under CIMAH. Those information needs have been the subject of many published technical papers over the last 12 years (note for example references 9 to 11). However, COMAH will introduce significant changes to the ways Industry and the CA present and use the information required in the safety report. Operators will need to demonstrate that they have 'taken all necessary measures to prevent a major accident', by presenting a case that these measures, linked to the major accident hazard processes do and will continue to control the risks from their activities. A crucial element in this requirement is the need for '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 to persons and the environment'.

This predictive information is clearly an essential feature of the COMAH safety report which must be properly and systematically, addressed by operators, and assessed by the

CA. Detailed and explicit assessment criteria have therefore been developed for use by the CA to ensure that, if met in their entirety, the risk analyses and assessment will be 'fit for purpose'. These 'high level' criteria will require further detailed explanation to ensure that the 'tests for adequacy' applied by the CA can and will be applied consistently and proportionately, to reflect the uncertainties and acceptable variations and uncertainties in risk assessment methodologies. For these reasons HSE will prepare more detailed guidance for its risk assessors, which in due course will be made publicly available and provide further assistance to Industry in the preparation of their COMAH safety reports.

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Appendix 1

[NB Criteria reference numbers align with the system used in the COMAH Safety Report Assessment Manual (Pilot Version) issued by HSE on 1 April 1998. In this document the Predictive Aspects are given in Part 2 Chapter 4]. Revisions to the text have been made as a result of the comments received during the 'COMAH Pilot' and external consultation which ended on 30 June 1998.

Predictive Aspects

INTRODUCTION

Scope

1 The criteria presented in this chapter of the Safety Report Assessment Manual are applied by staff in the Competent Authority (CA) to assess the fitness-for-purpose of the site operator's major accident risk assessment. The need for the operator to assess the risks stems from the requirement in Schedule 4, Part 1 paragraph 2 of the COMAH Regulations for the safety report to demonstrate that "major accident hazards have been identified and that the necessary measures have been taken to prevent such accidents and to limit their consequences for persons and the environment".

2 A risk assessment (RA) is fundamental to such a demonstration. The need for RA is also recognised in the EU guidance on the preparation of safety reports [1]. The risk assessment may be qualitative, semi- quantitative, quantitative, or a combination of these Operators will need to decide the scope and nature of their RA so that it is fit for-for-purpose in relation to their site specific circumstances and the demonstration required.

RELEVANT SECTIONS OF THE DIRECTIVE

3 The criteria in this chapter assess whether the operator's RA is both suitable and sufficient for the purposes of Schedule 4, Part 1 paragraph 2 (see paragraph 1 above), and Part 2, paragraph 4 'Identification and accidental risk analysis and prevention methods', particularly those under paragraphs 4(a) - accident scenarios, likelihoods etc; and 4(b) - assessment of consequences. It should be noted that Schedule 2 Part 2 defines the minimum information requirement. A suitable and sufficient demonstration of compliance with Part 1 para 2 may require more information and supporting arguments. These supporting arguments should be derived from the results of the risk assessment. Indeed the risk assessment is inextricably linked with all parts of Schedule 4 and the fundamental requirements under the H&S at Work etc Act (1974). The 1974 Act places duties on employers to:

(a) ensure the health and safety and welfare of their employees; and

(b) conduct their operations so that persons not in their employment are not exposed to risks to their health and safety.

The Environmental Protection Act (1992) extends these duties on employers to the protection of the environment.

Employers are required to ensure that these duties are met so far as is reasonably practicable. This legal duty is enshrined in the 'as low as is reasonably practicable principle' (ALARP[1]) used in current regulatory practice. RA is the means adopted for demonstrating that risks are ALARP and is a statutory requirement of some enabling regulations, for example the Management of Health and Safety at Work Regulations (1992) address (a) above.

GENERAL GUIDANCE FOR ASSESSMENT OF THE PREDICTIVE ELEMENTS

4 The risk assessment needs to address risks to people both on and off-site and risks to the environment. Regardless of whether the approach to risk assessment (RA) is quantitative, semi-quantitative, or qualitative, a logical and systematic process needs to be adopted. Some of the questions that the RA needs to address are listed in Appendix 1 to Chapter 2 Part 1, 'Guiding principles'. The most relevant questions are those relating to risk analysis ie Q4, 5, 6, and Q11 (domino effects), and the corresponding questions relating to the pre-construction stage and pre-operational stages of the SRs for new establishments.

5 For new establishments the risk assessment needs to include consideration of the elimination of hazards and inherently-safe approaches to reducing the scale of hazards.

6 The risk assessment process for major hazard plant has a number of steps. In outline these are:

a) understand the site operations, the materials involved and the process conditions;

b) identify the hazards to people on-site and off-site and the environment;

c) analyse the different ways the hazards can be eliminated, reduced in scale, realised and controlled;

d) for the hazards that remain, predict the likelihood of the hazards being realised taking account of the chance of success and failure of possible preventive measures;

e) predict the corresponding consequences both when mitigation measures work and fail;

f) analyse the associated risks and the options implicit in (d) and (e) for reducing them.

g) Decide which measures need to be implemented to make the risks to people and the environment as low as reasonably practicable (ALARP[1]);

h) present the results of the risk assessment to provide the evidence and arguments which demonstrate that all measures necessary have been taken to prevent and mitigate major accidents.

7 For new plant step (c) is particularly important. The hazard analysis of the proposed design should pay particular attention to ways of eliminating hazards and inherently safer approaches to reducing the scale of the hazards that cannot be eliminated. Ways for reducing the likelihood of realising hazards and for mitigating the consequences when these measures fail are then analysed. The same applies to existing plant, but the scope for elimination and reduction in scale will be less.

8 The depth of the analysis in the operator's risk assessment should be proportionate to:

a) the scale and nature of the major accident hazards (MAHs) presented by the establishment and the installations and activities on it, and

b) the risks posed to neighbouring populations and the environment ie the assessment has to be site specific.

9 It is recommended that the assessor formulates a view on 'proportionality' at the start of the assessment process. The assessor will need to carefully consider (a) and (b) above when coming to a view. A simple site remote from population and sensitive environments with a single dangerous substance presenting a limited range of hazards may only require a simple qualitative risk assessment to demonstrate that the necessary prevention and mitigation measures are in place. For example a water treatment plant with a total inventory of 30te of chlorine and remote from population and sensitive environments may only need to demonstrate compliance with HSE guidance note HS(G) 28 for the safe handling of chlorine, with supporting statements to demonstrate that the risks to people off-site and the environment are ALARP. (A risk assessment is needed under the Management Regulations and this may form part of the COMAH report). If the qualitative route is adopted for control measures, the operator still has to demonstrate that all MAHs have been identified and that the severity of these has been assessed. In the case of chlorine the guidance published by the CIA and the chlorine producers on emergency planning is helpful here.

10 *On the other hand, the same chlorine site in a sensitive location and presenting risks* which may be tolerable to people and the environment will require a more detailed analysis to demonstrate that the associated risks are ALARP. Similarly complex site with

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[1] The ALARP (as low as is reasonably practicable) concept implies that ultimately there is a trade-off between the costs of risk reduction and the benefits obtained. This concept is sometimes referred to as BATNEEC (best available technology not entailing excessive cost) which is often applied in environmental contexts. The political and practical interpretation of 'reasonable' or 'excessive' is the key in the setting of safety standards to be achieved by operators. These and related issues are discussed elsewhere [2].

many processes and several hazardous materials in the vicinity of population and sensitive environments will require a much more detailed assessment and some quantification of the likelihood of hazardous releases and their consequences, and possibly of the associated risks. (NB All sites will require some quantification of the possible consequences to help develop the emergency plan).

11 For explosives facilities and operations which do not meet accepted quantity-safety distances (QDs) the justification that all measures necessary to control the risks will normally require a quantified risk assessment.

12 The fitness-for-purpose of the risk assessment will depend mainly on: the degree to which the expertise of the team conducting it matches the site-specific circumstances; the methods they use; the data and assumptions they adopt; and the time they invest. The safety report should therefore indicate the competence and expertise of the assessment team and describe the process and methods used to conduct the risk analysis and to assess the significance of the risks.

13 In evaluating the results of the operator's risk assessment, assessors will be guided by HSE's and the agencies' approach to risk regulation [3,4,5]. This is based on the concept of risk tolerability which requires duty holders to take measures to reduce the likelihood of hazards and to mitigate their consequences until the associated risks are ALARP. Essential considerations are the scope for hazard elimination and the adoption of inherently safer designs and whether good practice has been, or is to be adopted. Where relevant good practice is not yet established, duty holders will be expected to apply risk-reducing measures. In general, the higher the scale of the hazard and the associated risks the more the balance should tilt in favour of adopting further measures to control risks unless the costs (in money, time and trouble) are clearly disproportionate (excessive in the case of BATNEEC) compared to the benefits gained from the risk reduction. Operators will need to define the basis of their decisions on all measures necessary for controlling major accident hazards (MAHs).

14 In some situations an ethical approach to risk regulation is adopted. This approach may be defined in terms of predetermined levels of safety based on technically achievable standards (eg maximum emission levels (environmental quality standards, EQSs) for particular pollutants), or limits based on historical precedent eg the maximum tolerable level of the risk of fatality from major hazards for a hypothetical member of the public.

15 The TOR framework [3] brings the ethical and cost-benefit approaches together by imposing an absolute maximum level of risk set on the basis of equity. It also applies a lower limit defining broadly acceptable risks below which formal analysis of costs and benefits is not normally required. Residual risks between the two limits need to be made ALARP. Most decisions on whether risks are ALARP are made by exercising professional judgement on whether the risks are reasonable when set subjectively against the cost of further risk reduction. Some companies have adopted this approach and defined their own ALARP bands. In some cases more stringent criteria are set for new plant - typically an order of magnitude lower than the band for existing plant.

16 The concept of tolerability implies that existing control measures should be periodically reviewed to ensure they are properly applied and still appropriate. Whether they are still appropriate will depend on matters such as the availability of new options for reducing or eliminating risks due to technological progress, changes in society's perception of the particular risks, changes in our understanding of the risk analysis, the uncertainty attached to the risk estimates, and new lessons from accidents and incidents etc. Such reviews should figure prominently in safety report updates (see COMAH regulation 8)

17 Some of the risk analyses required to assess the impact on the natural environment and people may already have been documented for other purposes and it may be possible for the operator to re-use some of this information. It is not necessary to repeat the work but the original documentation must be clearly referenced and, normally, copies of the appropriate parts of it attached to the safety report." *(See CD on regulation 7(9).)*

18 The assessment criteria presented below for assessing the quality of the predictive aspects of safety reports are linked directly to the risk assessment (RA) process. The way the criteria are structured and applied is depicted in Fig 4.1. In essence the main steps of risk assessment translate into 6 top level criteria represented by the 6 large boxes - (steps (a) and (b) above are combined into box 1; step (c) may occur in each of boxes 2 to 5 or a combination of these). Criterion 4.1 deals with the operator's approach to RA since this will influence what is done at the various stages of the RA. Each of the six top level criteria (ie 4.1 - 4.6) must be met for the predictive aspects to be acceptable. To help assessors judge consistently whether the criteria are met or not, related lower level criteria are defined. The extent to which each of these applies and is met will determine whether the relevant top level criterion has been met.

19 The tests assessors should apply in making judgements about whether the criteria are met or not are not explicitly defined here. Given the complexity and diversity of the major chemical hazards industry it is not possible to define all the tests assessors will apply in a particular case. Professional judgement is required. These judgements will be strongly influenced by the site-specific circumstances described in the SR. To help assessors reach consistent professional judgements on this, the criteria presented below are linked directly to the risk assessment process. The explanatory text linked to the criteria gives insight into how judgement can be exercised. In addition, to help assessors achieve consistent decisions on the adequacy of the predictive aspects of SRs they will be issued with internal guidance, suitable training will be given and QA checks built into the assessment process.

20 The way assessors will work will depend very much on the nature of the safety report and their own discretion. For example if the site is a warehouse the first test an assessor may apply is "does the risk analysis consider the consequences of a fire in high wind speed conditions?" - as these produce the worst consequences. Alternatively the fire plume may be modelled as a ground level passive release in lower wind speeds. If neither if these apply the assessor should identify a significant omission in the report. The assessor should then give a quick review of the quality of the risk analysis so that any other omissions can be addressed by the operator when the report is revised.

21 In general assessors will familiarise themselves with the safety report to develop the level of understanding of the site and its processes that is sufficient for the assessment of the risk analysis and the conclusions drawn. For simple sites the criteria may be applied sequentially. Most other assessments are likely to require some iterative application of the criteria before the assessor reaches a conclusion. In carrying out this iteration the assessor will be testing whether the assumptions and judgements made at the various risk analysis stages are consistent with one another and accord with the factual information in the SR. The application of the criteria defined here may also expose weaknesses in the quality of the information supplied; such weaknesses, if any, are likely to become apparent under the stages linked to criteria 4.4 (ie event probabilities and sequences) and 4.5 (event consequences). The assessor will also be forming a view on whether the quality of the arguments supporting the company's view that 'all control measures necessary have been taken' are suitable and sufficient. The depth of the RA underpinning the demonstration should therefore be proportionate to the scale and nature of the hazards and the associated risks.

22 If the risk assessment demonstrates that particular dangerous substances present at an establishment are not capable of producing a MAH the operator may apply for a derogation under the EU harmonised criteria developed for this eventuality (regulation 7(10)).

ASSESSMENT CRITERIA

23 Risk assessment is fundamental to the demonstration that all measures necessary have been taken to control risks. Operators therefore needs to present their approach to risk assessment. The approach and the depth of the analysis will be influenced by site specific circumstances.

Criterion 4.1 ***The safety report should clearly state the operator's policy on the use of risk assessment to aid decision-making on the measures necessary to prevent major accidents and to mitigate their consequences.***

24 The policy should include a summary of the methods used to analyse risks and the criteria used to judge the significance of the residual risks when control measures have been implemented. The approach to demonstrating that these risks are ALARP is fundamental to the justification that all measures necessary have been taken. This includes the consideration of ways of eliminating hazards, reducing their scale, and other means for reducing the associated risks(ie reducing event likelihoods and mitigating the associated consequences). The approach should embrace current thinking on inherently safer design options, on relevant good practice and on engineering and procedural standards.

25 The basis on which the operator makes decisions on all necessary measures should be clearly stated.

26 The summary should make clear how the operator scopes (ie defines what is and what is not addressed) the risk assessment so that it is both suitable and sufficient. "Suitable" means that it is valid and appropriate for the operators situation and circumstances. "Sufficient" means that the supporting information and arguments are well developed and presented, and do not require further elaboration in order to provide a valid input to the demonstration that all measures necessary have been taken ie the risks to site personnel, people off-site and the environment are, in each case, ALARP. The depth of the analysis also needs to be proportionate to the scale and nature of the hazards, and the associated risks (see General Guidance above). The level of detail will depend on the site specific circumstances eg size and nature of installation and the proximity of population or sensitive environments. For example the off site risks at an LPG facility (provided the vessels are not mounded or fitted with passive fire protective coatings) are usually dominated by the fireball event scenario following whole tank failure; the contribution from the VCE scenario being much less significant. This means that the treatment of the drifting cloud scenario and possible VCE need not be comprehensive. However, the case of explosives facilities and operations, a qualitative approach based on the 'defence-in-depth' principle is appropriate, unless the facility does not comply with QDs - when a quantified risk assessment is needed to demonstrate that all measures necessary to control the risks have been taken.

27 The balance between qualitative, semi-quantitative and quantitative arguments will depend on the nature and complexity of the major accident hazard (MAH) events being analysed in relation to what is at risk. This is considered further under Criterion 4.6 (assessment of the risks).

28 The approach to making the RA a living document should be stated as this supports the periodic review of the safety reports required by the COMAH regulations (Regulation 8).

Criterion 4.1.1 ***It should be clear that human factors have been taken into account in the risk analysis.***

29 Plant personnel are an important part of safety systems. They may also unwittingly contribute to the initiation of a major accident as a result of human error (see Criterion 4.4.4). The role operatives play in controlling hazards and risks therefore need to be identified, and the consequences of failure to carry out such control should be understood so that the various roles can be prioritised. For example an operative may be required to take certain actions following an alarm, the risk analysis will need to make assumptions about the likelihood that the correct action is taken. This task may be critical if a high level of human reliability has to be assumed to make the risks ALARP. If so, automatic control and protection systems may be needed to reduce the reliance on the operator to intervene correctly. The necessary redundancy and diversity should be built into the control systems to achieve the required reliability. This will depend on the scale of the hazards and the associated risk.

30 Operatives need to be well trained, competent and motivated. Equipment and procedures need to be designed to minimise human error (routine unintentional failures,

decision making failures and violation of rules). These and other human factor issues are considered by assessors dealing with criteria in Chapters 2 and 5 of Part 2.

Criterion 4.1.2 ***Any criteria for eliminating possible hazardous events from further consideration should be clearly justified.***

31 The justification should be clearly presented and well argued. For example in the case of a plant processing toxic gases, consequence assessment may show that any failure resulting in a release smaller than that equivalent to a 10 mm diameter hole does not produce a hazard to current on - site or off-site populations. This provides a basis for defining major accident hazards. However, operators may need to take account of smaller releases which could trigger other events leading to event escalation. They should also consider any known or foreseeable changes to the sensitivity of the surrounding environment eg to water courses or future dwellings which may be built nearer to the site boundary. Such changes should be also considered whenever the RA is reviewed.

32 In situations where this 'protection' based approach is not sufficiently limiting ie the hazard ranges from very small releases extend into population or sensitive environmental areas, a risk based approach may be needed. This requires the contribution to the residual risk of releases of different sizes to be considered so that a justifiable 'cut-off' can be decided. All contributions to release likelihood need to be taken into account otherwise, the 'cut-off' will be overly optimistic.

33 The criteria should be applied at an early stage to limit the scope of the predictive aspects of the risk assessment. Assessors will assess the validity of the operator's criteria.

Criterion 4.2 ***The safety report should demonstrate that the operator has used information and data that are suitable and sufficient for risk analysis.***

34 Schedule 4, Part 2, paragraph 4 of the Directive requires identification of possible major accident scenarios for risk analysis, and the identification and analysis of the adequacy and feasibility of possible prevention and mitigation methods. A suitable and sufficient risk analysis can only be achieved if all relevant information required at Schedule 4, Part 2, paragraph 3 is supplied and the quality of that information is consistent with the needs of risk analysis.

35 A prerequisite is that the safety report has satisfied the criteria developed in Chapter 3 Part 2 which relates to Schedule 4, Part 2, para 1 to 3.

36 However, the information required for risk assessment can be diverse and extensive. For example, weather data is needed to assess the risks of all hazardous materials, but the detail required is process and location specific. Consider lightning: the likelihood of lightning strikes is not a significant issue for LPG facilities but could be the cause of a warehouse fire. On the other hand cold weather is unlikely to pose a threat to a pesticide warehouse, but could cause problems for butane tanks. For many situations involving toxic gas releases an assessment of the consequences in two weather stability/wind speed

combinations may suffice, but for warehouse fires it is the likelihood of high wind speeds and the corresponding consequences that dominates the off-site risk.

37 Similarly, to assess the consequences of hazardous events, a range of harm levels to people and the environment need to be considered, particularly for emergency planning purposes. This requires the use of appropriate harm criteria. Harm criteria for the effects of toxic, thermal, and overpressure effects are generally available but lack accuracy. By comparison, the corresponding criteria for the effects of toxic materials on the environment are relatively scarce and less accurate. Environmental and human impact assessment is therefore an area of considerable uncertainty, and the operator should therefore justify the suitability of the adopted harm criteria. The justification needs to be tested by the assessor. For these types of reasons, assessors considering the predictive aspects will have to be satisfied that the quality of the information supplied and used by the operator is sufficient to support the level of risk assessment required.

Criterion 4.3 ***The safety report should identify all potential major accidents and define a representative and sufficient set for the purposes of risk analysis.***

38 Schedule 4, Part 2, paragraph 4 of the Regulations requires identification of all possible major accident scenarios for risk analysis purposes, and the identification and analysis of measures for preventing and mitigating major accidents. To make the risk analysis feasible a representative and sufficient set of major accident scenarios needs to be considered.

Criterion 4.3.1 ***The safety report should demonstrate that a systematic process has been used to identify all foreseeable major accidents***

39 The chemical industry is diverse and complex, and presents MAHs ranging from damage to water courses to toxic effects for people downwind of a warehouse fire. A structured approach to hazard identification is therefore required. The process will usually overlap with other stages in the risk analysis.

40 In assessing whether this criterion is met assessors will consider the adequacy of the coverage of different types of MAHs. All MAHs may be broadly classified as loss-of-containment accidents which may be categorised as follows:

a) Loss of containment accidents due to vessel or pipe work failures;

b) Explosions (batch reactors, tank explosion due to operator error eg wrong contents, BLEVES);

c) Condensed Phase Explosions relating to explosives;

d) Large fires (Warehouses, pool fires etc);

e) Events influenced by emergency action or adverse operating conditions etc (eg allow fire to burn rather than apply water (ie mitigation); dump reactor contents

to drain to avoid explosion (ie prevention), abnormal discharge to the environment, etc.;

f) other types of MAH or abnormal discharge.
(Such matters are addressed by criteria in Chapter 6 of Part 2 which deals with emergency response)

41 The coverage of the different types of MAHs needs to be suitable and sufficient for risk assessment purposes. The way the MAHs have been identified should be made transparent. The importance (ie the safety criticality) of each scenario is addressed by subsequent criteria. The potential major accident scenarios need to include the worst case on-site and off-site scenarios both for people and the environment, and be sufficiently comprehensive for assessing the adequacy of methods for preventing major accidents and for limiting their consequences with respect to people and the environment. One way of approaching this would be to:

a) identify the 'worst case events' in relation to people and the environment;

b) assess the consequences. If they are trivial there is no need for further predictions. If they are significant, a range of major accidents needs defining and analysing (see below);

c) the balance between qualitative and quantitative analysis will vary, but in general the level of quantification should be proportionate to the scale and nature of the hazards.

Criterion 4.3.2 ***The hazard identification methods used should be appropriate for the scale and nature of the hazards.***

42 The hazard identification methods will vary depending on the type of plant and circumstances. The approach adopted and the expertise of the team involved should be described. This will help the assessor to take a view on the 'completeness' of the list of major accident scenarios.

43 Methods that might be used include:

a) HAZOP (Hazard and Operability Studies)

b) Safety reviews and studies of the causes of past major accidents and incidents

c) Industry standard or bespoke checklists for hazard identification

d) FMEA (Failure Mode and Effect Analysis)

e) Job safety analysis (eg Task Analysis)

f) Human error identification methods.

44 At this stage of the assessment process the focus is on the completeness (but see Criterion 4.1.2) of the event list rather the associated detailed consideration of event initiators and event sequences which is developed under the risk analysis stages linked to Criteria 4.4 (event probabilities and sequences) and 4.5 (consequence analysis). For example whole tank failure into a bund, limited vessel failure, guillotine fracture of a pipe, etc. Foreseeable failure modes leading to each major accident is considered at Criterion 4.4. Scenarios need to cover events when protection and mitigation (actual or proposed for further risk reduction) measures fail to operate. In the case of fires, for example, the events need to take account of any seasonal or operational variations in the range and quantities of stored substances.

Criterion 4.4 ***The safety report should contain estimates of the probability (qualitative or quantitative) of each major accident scenario or the conditions under which they occur, including a summary of the initiating events and event sequences (internal or external) which may play a role in triggering each scenario.***

45 Schedule 4, Part 2, paragraph 4(a) requires a detailed description of all possible major accident scenarios and their probability, or the conditions under which they occur, including a summary of the events which may play a role in triggering each of these scenarios, the causes being internal or external to the installation. These are minimal requirements and should not be seen as a choice, though in some straightforward situations one of the alternatives may suffice. In more complex situations a satisfactory demonstration under Schedule 4 may require the consideration of the conditions under which events occur, their likelihood, and how the events interact so the likelihood of certain major accidents can be estimated..

46 The purpose of this criterion is to assess the extent to which the requirement in Schedule 4, Part 2, paragraph 4(a) has been complied with; in particular that the depth of the analysis of the likelihood of realising each major accident scenario under Criterion 4.3 is sufficient relative to the scale and nature of the hazard it presents. The use of operational experience is an important input to the analysis. The operator should bear in mind that the different scenarios may have different levels of significance for employees, people and the environment.

47 An essential feature of the safety report (Schedule 4, part 1, paragraph 2) is the demonstration that the measures necessary for preventing and mitigating major accidents are suitable for their intended purpose and have been applied. (*The off-shore industry refer to these measures as safety critical elements, SCEs. The assessment of the technical suitability of the control measures implemented by the operator and the performance achieved by them is dealt with in Chapter 5 of Part 2, but the quality of the predictive arguments underpinning that justification is considered here*).

Criterion 4.4.1 ***The safety report should demonstrate that a systematic process has been used to identify events and event combinations which could cause MAHs to be realised.***

48 All foreseeable causes (initiating events) of the MAH identified under Criterion 4.3 should be considered. Insights gained from the study of previous accidents and incidents can be a useful starting point. The scope of such studies should consider the causes of accidents in other industries which present societal risks. The operator should present evidence to demonstrate that the event sequences triggering the scenarios are correctly identified and clearly justified.

49 Where a sequence or combination of events may lead to a major accident, for example an automatic isolation system fails and the operator fails to respond correctly to an alarm, an assessment should be made of the effects of failure on plant and equipment designed to prevent, detect, or mitigate the hazardous conditions. The purpose of the assessment is to decide whether the event is so hazardous that the reliability of the automatic system is sufficiently high to render the risks ALARP even if the probability of the operative failing to respond is relatively high. Human error should also be addressed as an accident initiating event in addition to intervention activities eg loading wrong reactants into a batch reactor, or wrong operating procedure leading to an abnormal discharge to a water course.

Criterion 4.4.2 ***All safety critical events and the associated initiators should be clearly identified***

50 Safety critical events or event sequences are those that dominate the contribution to risk at different distances from the plant. They are relevant to the identification and implementation of suitable control and protection measures for preventing hazardous events or mitigating their consequences.

51 The risk analysis should make clear which events are critical from a safety view point. This requires consideration of the likelihood of the various MAHs and the associated consequences. Operators need to use appropriate methods for assessing the probabilities of each of the listed major accidents.

52 Implementation of control and protection measures should reduce the risk arising from these events. The failure of the control measures to prevent the hazard from being realised or to mitigate the associated consequences then become critical events. The risk analysis should then determine whether the residual risks (determined by the reliability of the control measures etc) are ALARP or whether more needs to be done. This is considered by criteria Criterion 4.6 which consider, among other matters, whether the contribution of each risk reduction measure is then linked to the hazard identification and risk analysis process in a transparent way.

53 If potential control measures are rejected the reasons need to be clearly justified.

Criterion 4.4.3 ***Estimates of, or assumptions made about, the reliability of protective systems and the times for operators to respond and isolate loss-of -containment accidents etc need to be realistic and adequately justified.***

54 The quantitative or qualitative arguments presented in the safety report need to be realistic. Significant departure from arguments currently acceptable to risk assessors will need careful presentation and justification, particularly if the scale of the hazards and the associated risks is significant. Well reasoned and plausible arguments backed-up by evidence in the form of credible performance data etc will usually be required.

55 Qualitative arguments will need to be based on currently accepted good standards for engineering and safe systems of work. The assessor will be looking for evidence to support the operator's view on the likely demand on the various control measures and systems and what the consequences might be if these fail.

56 If an operative has to intervene to close an isolation valve manually when automatic isolation fails, the release duration will be determined by the time taken to intervene successfully. In such cases release duration's less than 20 minutes will require realistic justification.

Criterion 4.4.4 ***The methods used to generate event sequences and estimates of the probabilities of potential major accidents should be appropriate and have been used correctly***

57 Appropriate methods include the use of relevant operational and historical data, fault tree analysis (FTA) and event tree analysis (ETA), or a combination of these. The methods and assumptions used will therefore need to be described. In particular any failure rate data used for the base events in the FTA will need clear justification in terms of the site-specific circumstances. It will not be sufficient to adopt data from published sources without justification of their suitability, unless it is shown (eg through a sensitivity analysis) that the conclusions of the risk analysis are not sensitive to such data. When the estimates of the likelihoods of the safety critical events are sensitive to the data and assumptions used suitable and sufficient justification is needed.

58 The methods used need to be fit for purpose and used correctly. To enable assessors to judge whether methods have been used correctly, the operator should describe the process and methods (including human error identification and analysis) adopted to generate any probabilities or event sequences, together with assumptions and data sources used. Checks against company benchmarks should be included when appropriate.

59 The sensitivity of the conclusions to the assumptions and other uncertainties may need to be assessed - see also Criterion 4.6. For example, in the case of explosives facilities there is a lack of data on event probabilities leading to considerable uncertainty in the estimation process. Sufficient detail is required to enable an experienced risk assessor assessing the safety report to make a judgement on the quality of this part of the risk analysis.

Criterion 4.4.5 ***The safety report should provide adequate justification for event probabilities that are not consistent with historical or relevant generic industry data.***

60 When making judgements about the quality of the estimates of event probabilities HSE will compare the estimates with values commonly used and accepted by experienced risk analysts. In some cases an assessor may perform independent checks to verify that an estimate (qualitative or quantitative) is reasonable.

61 The operator's justification may include quality procedures, plant experience, or other acceptable evidence. The risk assessment assessor will identify the most important parts of the predictive aspects where the justification needs to be further evaluated eg when considering the preventative and mitigation measures in detail later in the assessment process, or for verification during subsequent inspection.

Criterion 4.5 ***The safety report should provide details to demonstrate that suitable and sufficient consequence assessment for each major accident scenario has been carried out with respect to people and the environment.***

62 Schedule 4, Part 2, paragraph 4(b) requires an assessment of the extent and severity of the consequences of identified major accidents. (A range of severity's will need to be considered so that corresponding 'hazard zones' defining the extent of affected areas can be mapped out by suitable and sufficient consequence analysis. For people the harms considered should include fatality, serious injury and hospitalisation. A range of potential harms to the environment may also need to be considered.)

63 The purpose of this criterion is to assess the extent to which the requirement in Schedule 4, Part 2, paragraph 4(b) has been complied with; in particular that the severity and extent of each major accident has been properly assessed. The safety report should therefore demonstrate that a systematic process has been adopted for assessing the possible consequences of each major accident hazard.

64 For 'upper - tier' sites, Schedule 4 requires the hazards from all dangerous substances present to be assessed, regardless of quantity. If a substance is present in quantities sufficient to cause a major accident hazard then a detailed consequence assessment is required.

65 The methods used for assessing the consequences of potential major accident impacts on people are now quite mature compared to those for predicting environmental impacts. In applying the methods assumptions need to be made and these should be stated and justified. The criteria below follow the general framework for consequence assessment. Whether these apply, and the extent to which they apply to particular events will depend on the situation. For example, in the case of an LPG facility the risk dominating event will usually (mounded and insulated vessels excepted) be whole tank failure followed by immediate ignition of the BLEVE, resulting in a fireball. If the cloud resulting from the BLEVE event does not ignite immediately it will drift on the wind. Subsequent ignition may result in a flash fire or vapour cloud explosion. If no ignition sources are encountered before the cloud is diluted below the lower limit of flammability, no serious consequences arise. The possible outcomes following an LPG release are usually developed by Event Tree Analysis (ETA). The consequences of each outcome are then assessed using appropriate models. In the case of a loss-of-containment accident resulting in a drifting cloud all the criteria below apply.

66 The worst case scenarios need to be addressed.

67 Operators will need to state which models have been used and justify their suitability. When the scale of the hazards is significant, well validated models should be used throughout the assessment.

Criterion 4.5.1 ***Source term models used should be appropriate and need to have been used correctly for each relevant major accident hazard***

[Note: Appropriate means 'fit for purpose' - the rationale above defining suitable etc applies. 'Correctly' is described under Criterion 4.4.4 and Criterion 4.5.6.]

68 The source term defines the nature, size, and duration of the release. In the case of releases into the atmosphere, matters such as the influence of obstacles on jets and air entrainment into the release are also addressed. This enables the source term to be defined in terms of the parameters needed by the dispersion model used to predict how the release will disperse. A good introduction to source term models is provided elsewhere [6].

Criterion 4.5.2 ***The material transport models used should be appropriate and need to have been used correctly for each relevant MAH***

69 Releases of hazardous materials can harm people, and pollute the air, water courses, or land. The spatial and temporal variation in contaminant concentration from the release point will depend on the mode of transport. For example there are many competing models capable of predicting the spatial and temporal variation in concentration downwind of a release dispersed in the atmosphere.

70 The choice of model depends on whether a loss-of-containment accident gives rise to:

a) a passive (neutrally buoyant) or a heavier-than-air cloud.

b) a cloud which contains aerosol which reacts with ambient moisture entrained into the cloud (eg releases of anhydrous ammonia and anhydrous hydrogen fluoride.) It also depends on other factors such as whether the release gives rise to large hazard distances - in which case the validity of the model is an important issue; and

c) whether the dispersing clouds will interact with obstacles or terrain features.

71 A range of weather conditions usually need to be considered. For the more significant events it may be necessary to test the sensitivity of the predictions to any assumptions made about the source term.

72 A passive dispersion model may, depending on circumstances, be adequate for a simple plant which releases a heavy gas. This may overestimate the downwind extent of the hazard, but will underestimate the lateral extent. This needs to be borne in mind when justifying the choice of model.

Criterion 4.5.3 ***Other consequence assessment models (eg BLEVE, Warehouse fire etc) used should be appropriate and need to have been used correctly for each relevant major accident***

73 The models should be named and described, and their suitability justified.

Criterion 4.5.4 ***The harm criteria or vulnerability models used to assess the impact of each MAH on people and the environment should be appropriate and have been used correctly for each relevant major accident.***

74 Sensitivity of the results to the choice of harm criteria or model, or the way it is used may be needed, particularly when the scale and nature of the hazard and risks is significant. It is recognised that harm criteria for the environment are scarce and uncertain. Nevertheless, justification for the approach to environmental impact assessment and data used is needed. An essential requirement is that the operator's controls meet the relevant EQSs.

Criterion 4.5.5 ***Assumptions used are justified, realistic, and not unduly optimistic***

75 The sensitivity of the results to assumptions that are pivotal to the analysis should be tested, particularly when the scale and nature of the hazard and risks are significant

Criterion 4.5.6 ***Estimates of the severity and extent of each major accident consequence are realistic.***

76 The operator should check that the predictions are realistic by comparison with published assessments and with company benchmarks. If not errors in any of the above steps may have arisen and should be corrected.

77 HSE and the agencies' assessors will exercise judgement in a similar way, but using CA benchmarks and views about the models used by the operator.

Criterion 4.6 ***The findings and conclusions from the predictive risk analysis should summarise the relationship between the hazards and risks and demonstrate that the measures adopted to prevent and mitigate major accidents make the risks ALARP.***

78 Schedule 4, Part 2, paragraph 4 of the Regulations requires identification of possible major accident scenarios for risk analysis purposes, and the identification and analysis of prevention methods. Paragraph 4(b) requires an assessment of the severity and extent of each major accident. This needs to be assessed in relation to the functioning and failure of existing control measures and assessment of whether there is a need for further controls to reduce the likelihood of major accidents and the extent and severity of the associated consequences.

79 The purpose of this criterion is to enable a view to be taken on the suitability and sufficiency of the risk assessment for drawing soundly based conclusions. It should be clear that the operator's approach to demonstrating compliance with the 'all necessary measures' requirement, is fit for purpose.

80 The scope and depth of the analysis, and the comprehensiveness of the presentation of the risk assessment therefore will generally be proportionate to the scale and nature of the hazards and the residual risks, and sufficient for demonstrating that all necessary control measures have been taken. There should be clear links between the conclusions and:

a) the analysis of the risks, including hazardous event likelihoods and the associated consequences; and

b) the measures (technical or procedural) taken to make the risks ALARP.

81 The ALARP arguments may be qualitative and focus on relevant good practice and sound engineering principles. Several sources of authoritative indications of good practice exist:

i) Prescriptive legislation

ii) Regulatory Guidance

iii) Standards produced by Standards-making organisations

iv) Guidance agreed by an organisation representing a particular sector of industry

v) Standard good practice adopted by a particular sector of industry.

82 There is clearly an order of precedence from i) downwards and any conflicts between these sources of good practice should be resolved in favour of the one higher in the list.

83 HSE expects good practices to be followed; but if good practice is used as the sole justification of ALARP, several stringent requirements need to be met. These include:

i) the practice must be relevant to the operator's situation;

ii) any adopted standard must be up-to-date and relevant; and

iii) where a standard allows for more than one option for conformity, the chosen option make the risks ALARP;

84 More complex situations may require the presentation of quantitative arguments coupled with cost benefit analysis in order to provide the justification that all measures necessary have been taken. If quantitative arguments are used the methods, assumptions and the criteria adopted for decision making should be explained. For example in the case of fatality risks to people off-site it is common practice [3] for the maximum tolerable level of individual fatality risk to be set at 10-4 per year and for the broadly acceptable level to be set at 10-6 per year. For new plant a lower maximum tolerable risk level may be adopted. The use of cost benefit analysis (CBA) enables society's aversion to particular group or societal risks to be considered in a transparent way. Corresponding criteria for judging the significance of environmental impacts have yet to be developed and agreed. Nevertheless operators need to state and justify the benchmark criteria adopted for their environmental impact assessments.

Criterion 4.6.1 ***The safety report should demonstrate that a systematic and sufficiently comprehensive approach to the identification of risk reduction measures has taken place.***

85 It is not in the spirit of risk assessment to use it solely to demonstrate that existing controls or the adoption of current good practice make the risks ALARP. Risk assessment is an opportunity to systematically assess the current situation or decide the best option for designing a new facility. It is a chance to take account of technological advance, to seek inherently safer designs, and to take account of improvements in assessment methods and views on good practice etc. Whatever additional measures are identified as being reasonably practicable they should be implemented. The justification for rejecting possible risk reduction measures needs to be well argued and supported with evidence.

Criterion 4.6.2 ***The main conclusions on the measures necessary to control risks should adequately take account of the sensitivity of the results of the analysis to the critical assumptions and data uncertainties***

86 The results of any risk assessment will be subject to uncertainty. Uncertainty in qualitative risk assessment arises from the validity of any assumptions made, the 'completeness' of the hazard identification and views on the likelihoods of hazardous events and associated consequences. Uncertainty in quantified risk analysis arises from assumptions, 'completeness', data inaccuracies, and the capability and appropriateness of the models employed. The greater the uncertainty the greater the need for a conservative approach supported by strong qualitative arguments based on sound engineering judgement and relevant good practice. In situations where good practice has yet to be established collateral evidence from analogous situations may be helpful For example if a novel design of storage vessel is adopted, failure modes and likelihoods can be developed by taking account of what is known about these parameters for current designs.

87 The interpretation of 'suitable and sufficient' risk assessment will depend on the complexity of the process, the scale of the hazards, and the degree of associated uncertainty. These factors also influence the balance between qualitative, quantitative and semi-quantitative evidence and arguments.

Criterion 4.6.3 ***The conclusions drawn from the risk analysis with respect to emergency planning are soundly based.***

88 The worst case scenarios for people and the environment must be considered. The analysis of these should not be overly optimistic or pessimistic as this could have resource implications for the emergency services. The consequence models and assumptions used therefore need to be appropriate for the scale and nature of the hazards (see also Criterion 4.5). The range of hazardous scenarios considered needs to be representative and suitable for emergency planning purposes. The consequences of catastrophic vessel failure and guillotine fracture of pipework need to be included. The levels of harm considered and the impact criteria/vulnerability models used need to be suitable for predicting the extent of areas where people might be fatally or seriously injured or require hospitalisation. For environmental impact assessment, corresponding levels of harm to the environment should be considered. A considered. For releases resulting in environmental damage a range of representative conditions need to be considered eg to cover the range of flow rates in water courses.

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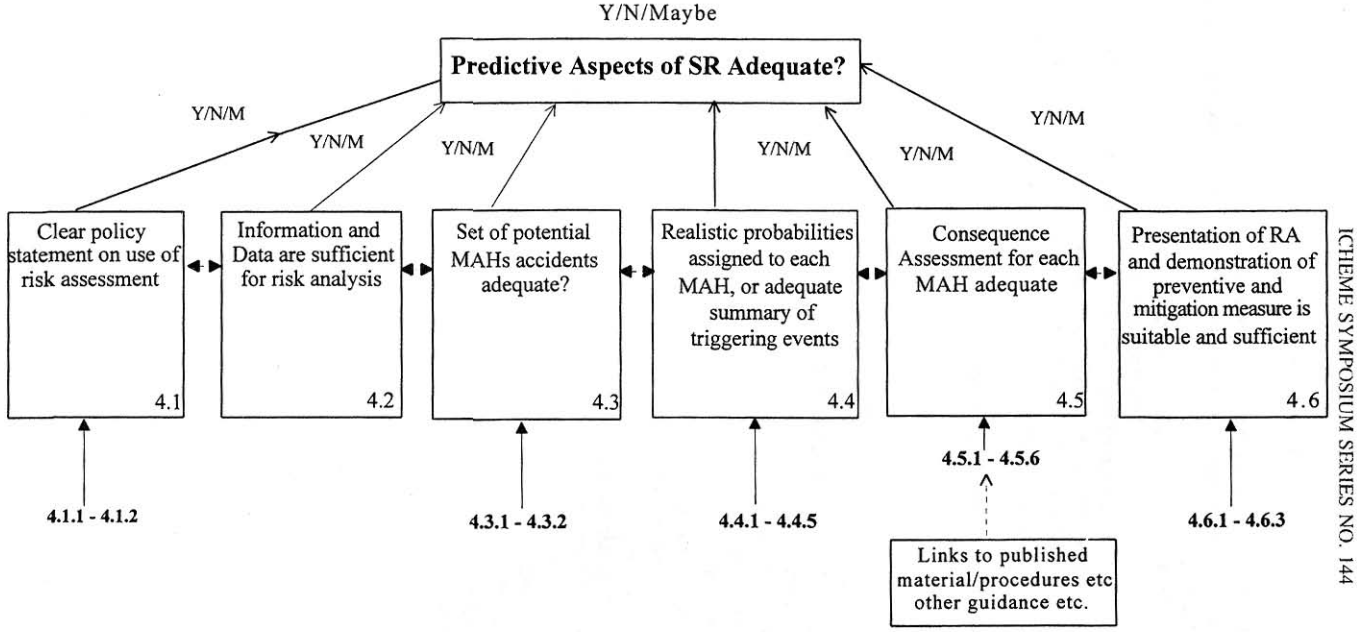
Acronyms

ALARP	as low as is reasonably practicable
BATNEEC	best available technology not entailing excessive cost
BLEVE	boiling liquid expanding vapour explosion
CA	competent authority
COMAH	control of major accident hazards
EA	Environment Agency
ETA	event tree analysis
EQS	environmental quality standard
FMEA	failure mode and effect analysis
FTA	fault tree analysis
HAZOP	hazard and operability study
LPG	liquefied petroleum gas
QD	quantity-safety distance
RA	risk assessment
SR	safety report
SRAM	safety report assessment manual
TOR	tolerability of risk



The extent to which the top level criteria (criteria 4.1 - 4.6) are met is determined by the extent to which the lower level criteria are satisfied.

Fig 4.1 Overview of Criteria for Predictive Aspects of Safety Reports.