THE SAFETY REPORT ASSESSMENT MANUAL

Sections 8 to 15

8. HOW TO USE THE CRITERIA

Scope

1 This section of the manual provides guidance on principles and the approach to using the assessment criteria. The assessment criteria are contained in subsequent parts of the manual and are used by assessors to examine safety reports, submitted under the COMAH regulations, to reach conclusions on the extent to which reports meet their purposes under the regulations. The conclusions are then used to inform the intervention strategy for the establishment and/or its installations.

Principles of assessment criteria

2 For the purposes of a safety report, Schedule 4 Part 1 paras (1) to (4) of the regulations identifies 4 elements that need to be demonstrated by the operator. The extent of the information required for each demonstration to be made depends on the type of safety report required by Regs. 7 or 8.

3 The different report types that may be submitted for assessment include:

- the initial report for each existing establishment,
- pre-construction reports
- pre-operation reports for new establishments,
- modification and periodic updated reports for all establishments throughout their life.

4 **Assessment criteria provide a framework to promote consistent consideration of matters to be examined during assessment.** The criteria do not constitute a mandatory process for assessment and assessors are not obligated to address every criterion, nor to the same depth of detail. Criteria are intended to be used with professional judgement and experience, based on their application to specific hazards and risk at establishments, and the demonstrations provided in reports. The aim is to achieve a consistent and proportionate approach to assessment within a framework.

5 The information required in a safety report, both for making the necessary demonstrations and for action by the competent authority and local authority, is written in terms of goals to be achieved. In doing this, the operator should ensure the links to the required demonstrations are properly made and clear. The assessment criteria help assessors gather information and understand how goals might be achieved.

6. The criteria are presented in Sections 9 to 14 of this manual. The links between the assessment criteria, the purposes in Schedule 4 Part 1of the regulations and the type of information required as a minimum by Schedule 4 Part 2 of the regulations can be seen in Figure 8.1.

7. The criteria are necessarily quite general. This reflects the broad nature of the type of establishment which is covered by COMAH and the range of hazards to be encountered. The criteria apply when assessing information relating to all health, safety and environmental issues.

8. A diagram showing the information required in a safety report can be seen at Figure 8.2.

Structure of the assessment criteria

9. The criteria are set out in 6 groups that are then divided into a number of “categories” as outlined in the following paragraphs. These “categories” are the main issues upon which the assessment team should come to a common view.

10 The criteria in SRAM are the primary guidance for assessors. These criteria are supported by explanatory text.

11 More detailed technical guidance supporting the topics covered by Sections 10, 12 and 13 of SRAM exists on the relevant agency Website and/or Intranet. This guidance is subject to review and development as part of the CA’s corporate knowledge base to address technical issues and practices.

12 Guidance to the criteria in SRAM appears in a 'tick list' style and should be interpreted as 'prompts' for an experienced assessor. The guidance is not a checklist for report writers and will not constrain assessors from considering or asking for other information if the circumstances dictate.

Use of the criteria

13 There are overlaps between a number of criteria in different chapters, but these reflect the fact that the same piece of information may be used to help more than one demonstration. However, where assessment by an assessor leads to areas that are likely to interface with another discipline assessor’s principal scope of assessment, assessors will, where appropriate, seek to reach an agreement at an early stage on who will lead on a topic or on issues arising. This is to avoid unnecessary duplication of assessment. (Note: further guidance to technical discipline assessors is provided in Section 12 of the manual.)

14. As a general guide on assessing COMAH safety reports, the following overview of the assessment process may be helpful to assessors in forming their overview of the demonstrations in the safety report.

Assessors should be able to:

a) Gain a clear understanding of the processes, plant and environs of the establishment (or installation).

b) Consider the hazards described, whether they are appropriate and representative of the activities carried out and the appropriateness of the measures identified to control them, i.e. there should be clear links between the measures provided and the major accident scenarios identified.

c) Focus on systems and outcomes that show how the operator has reduced risks to ALARP and how they achieve continuous improvement in relation to preventing and limiting major accidents.

d) Consider the operator's MAPP and SMS, and how it relates to the requirements of the COMAH regulations, taking into account the described adequacy and reliability of the measures when assessing whether the MAPP and SMS will work in practice.

e) Immediately pursue and verify any measures that, on reading, are suspected of being seriously deficient. These deficiencies should be resolved independently of reaching assessment conclusions.

15 Remember that the assessment of a safety report is not a discrete activity but leads to further action under the intervention plan for the operator at that establishment.

16 The individual assessment criteria are used in detail to come to conclusions about the measures provided and whether the purposes required of a safety report under COMAH have been met. Assessors should record details of their assessments on the templates provided on CA internal computer systems.

17 The effort put into the assessment should be sufficient solely for the CA to reach conclusions on the safety report, based on the questions in Appendix 8.2 (Overall Purpose).

Request for further information

18 Assessment does not result in a pass or a failure for a safety report but the CA will 'communicate' its conclusions to the operator.

19 Assessors may decide that there is insufficient information to conclude that the required purposes in Schedule 4 Part 1 of the regulations have been met. In making requests for further information, it is assumed that such information should already exist (or be rapidly produced) if the company has conducted the necessary work in preparing the demonstrations in the report. In this event, it is assumed that the operator can readily supply such information (typically within around 4 weeks, though longer may be agreed provided this does not impact upon the assessment schedule for completion).

20 An assessor may suspect with good reason that essential information is missing because it is not available and requires extra work to develop it. However, the operator must be given the opportunity to provide the required information – it may be available, but just not included for whatever reason, or they may be able to

produce it quickly. It is for the operator to say that they cannot produce information when required, not for assessors to assume they cannot provide it when required.

21 Information might be obtained in writing, or from a site visit, e.g. from interviews or from documents held on site by the operator, or other means that best achieve the required outcome in the time available. Information obtained following site visits, or other informal route should be formally requested or logged in writing with the company, via the Assessment Manager. This is because any further information which is obtained and contributes to the purposes of the report, such as the demonstrations to be made, will be kept with the safety report and placed on the Public Register (subject to the determination of an application for personal or commercial confidentiality, or because of national security). In all circumstances, assessors will be **obtaining information** to support or clarify the arguments in the safety report and **not undertaking inspection to verify statements made**. Additional information obtained by an assessor should be distributed to others in the assessment team. (For further guidance see also Procedures 5.1.)

22 If, following a request, the operator is unable to produce the required information without conducting significant additional work, thereby resulting in a delay in supplying the information such that the assessment cannot be completed within the required assessment timescales, the assessment should be concluded as further outlined in 'Concluding An Assessment' below.

23 Requested information SHOULD:

a) be directed at reaching an **assessment conclusion** on the demonstrations in accordance with the requirements of the regulations.

Requests for information SHOULD NOT be used to:

a) ask the operator to undertake additional work (i.e. such as would extend response to more than 4 weeks).

b) obtain information to resolve issues that would be regarded as inspection (i.e. **verification** of demonstrations).

24 When making written requests for further information, assessors should ensure that:

a) The issue under consideration is clearly explained, preferably with an outline of how the report fails to address the issue. Reference to the relevant assessment criteria to which the deficiency relates and to the relevant COMAH regulation(s) and/or schedule(s) should be made.

b) There is a clear link to how the further information relates to meeting the required demonstrations, with reference to the regulations.

c) The nature of the required information that is expected in order to resolve the issue(s) is indicated.

d) An indication of the importance of the information to the demonstration is given, i.e. necessary to make, or to clarify understanding of, the demonstration (medium/low); potential significant deficiency in the measures (major).

25 Assessors should **avoid** information requests that:

a) ask open ended or vaguely worded questions.

b) do not have a clear link to making a demonstration.

Failure to clearly define the requirements for further information is likely to result in inadequate or wrong information being received.

[Note: See Appendix 8.1 for examples relating to information requests.]

Serious deficiency and other deficiencies

26 The report may describe measures that appear to be seriously deficient for preventing or controlling a major accident. The assessment team will form a view about these measures and will balance them against the likelihood of the related major accident hazards and their consequences when considering serious deficiency as applicable to Regulation 18.

27 The CA has a duty to prohibit that part of the seriously deficient operation that could lead to a major accident. The CA will visit the site to check whether the measures signposted by the report are actually seriously deficient, before taking action under Regulation 18.

28 It is only the measures provided by the operator that can be considered 'seriously deficient' under COMAH and **not the report itself**.

29 There is no legal precedent in health and safety legislation as to what serious deficiency might mean. The dictionary definition of 'deficiency' refers to 'defect', and 'a lack of completeness'. The assessment team must form the consensus professional view that a major gap or defect exists in the measures provided, linked to prevention or limitation of a major accident, for serious deficiency to be determined.

30 Assessors should not consider a measure(s) to be seriously deficient just because it might be reasonably practicable to achieve higher standards of protection. This would be a matter that should be addressed during subsequent inspection.

31 Deficiencies in individual measures may be found, some of which might be considered significant, but not '*seriously deficient*' as described in the guidance to Regulation 18. Action to address measures that are considered to be deficient (but not '*seriously deficient*') should form part of the intervention strategy for the establishment, prioritised on a risk basis. Consideration should normally be given to the totality of measures to prevent and limit major accidents before proceeding to the issue of prohibition notices under Regulation 18.

32 In the context of the safety report, the assessment team may consider that the depth of information contained is so low that a decision may be reached to return the safety report to the site operator for resubmission, tied to an agreed plan for resubmission:

a) An omission of information leading to the return of a safety report would apply to significant or large-scale omission of information required to meet the demonstrations and not to smaller discrete omissions.

b) An example might include failure to provide sufficient information on the process used for identifying the listed major hazards. In this example, there might be a failure to describe who has identified the hazards, no description of the methods that were employed or how suitable methods were determined, and no information on how the identified hazards were developed into representative scenarios for further analysis. This omission would be a large gap in a significant area of the total risk assessment process and has strong implications for the assessment of later stages in the risk assessment cycle, including selection of measures.

c) Failure to identify a possible major accident scenario may not by itself be so deficient as to warrant return of the safety report as measures may exist that provide a level of protection that is not '*seriously deficient*'. Similarly, failure to describe risk assessment team competencies would not on its own be so deficient for return of the report if methodology for hazard identification and scenario selection and prioritisation were broadly described.

d) There should be no action to prohibit an activity, following a substantial omission in the information in the report leading to the return of the report, unless a 'serious deficiency' in applied measures were also established at a site visit.

Demonstration

33 There are a number of demonstrations to be made. These are linked to the criteria as outlined in Figure 8.1. The report should demonstrate the link between the measures taken and the 'major accident hazards'. Having examined the information in the report, the judgement about whether the report demonstrates that the necessary measures have been taken should be linked to the adequacy of the MAPP and SMS.

34 For the purposes of a safety report required by COMAH, '**demonstrate**' means '**show**', '**justify**' or '**argue the case**' by the information given. It is NOT taken to mean 'pursue by extensive in-depth scrutiny' or 'exhaustive examination to prove beyond reasonable doubt' whether the relevant criteria have been made and the demonstrations achieved.

35 The safety report should:

a) **Show** the application of due process for identification and analysis of hazards that is sufficiently rigorous, systematic and proportionate to risk.

b) **Show** how all measures necessary have been identified and linked to specified major accident hazards, and implemented to reduce risks to ALARP.

c) **Justify** why identified measures are not implemented by **argument** under ALARP principles (i.e. gross disproportion of effort or cost linked to risk benefit gained). '**Argument**' can be made using qualitative or quantitative statements appropriate to the level of risk.

d) **Show** that an on-site emergency plan is in place, based on sound principles and reflecting the major accident scenarios identified.

’Suitable’ and ‘sufficient’

36 The assessment criteria make references to information that is ‘suitable or ‘sufficient’. For the purposes of assessment these terms are taken to mean:

a) ‘Suitable’: Valid and appropriate for the operator's situation and circumstances as described in the safety report.

b) ‘Sufficient’: Supporting information and arguments are well developed and presented, proportionate to the described level of risk based on the circumstances outlined in the safety report.

Assessment of the demonstration of ALARP

37 The guidance to Regulation 4 (General Duty) describes the application of all measures necessary to reduce risk of a major accident to ALARP based on a hierarchical approach (inherent safety, prevention, control, mitigation). The assessment process seeks evidence of the application of this principle to the identified major accident scenarios.

38 Important elements of the ALARP demonstration include:

a) **Identification** of all **major accidents** and their probability of occurrence using appropriate and proportionate systems of analysis.

b) **Assessment** of **the consequences** (extent and severity) of identified major accident scenarios using appropriate and proportionate systems and methods of analysis.

c) The **linking** of specified **measures** to specific major accident scenarios, not just a statement, in isolation, of measures that exist at the establishment. [Note: it is important that the safety report does not simply state what measures exist, but that it also demonstrates how the company has examined the link between identified scenarios and the identified measures that address those specific hazard scenarios. and the identification and implementation of further reasonably practicable measures to reduce risks to ALARP.]

d) **Identification** of possible **further** measures that could be applied to lower the risk. [Note: it is important that the safety report demonstrates how the company has considered what else might be done in the context of further measures to address identified hazard scenarios. Hence, breadth and depth of assessment of reports also needs to focus proportionately towards ‘what more measures could be applied?’.]

e) **Justification** for **not implementing** identified further measures, based on gross disproportion between the benefit gained in reduced risk and the cost and effort required to implement the measures (reasonable practicability).

39 **Detailed guidance on the consideration of ALARP is provided on the HSE Website and HSE’s Intranet – see COMAH Home page**.

40 Conclusions on the demonstration of ALARP need to be reached by the assessment team at the end of the assessment process during the assessment

closeout meeting. It is unlikely that any one assessor will be in a position to form a complete opinion on the demonstration of ALARP in isolation without input from the rest of the team.

Concluding an assessment

41 Assessment of a safety report may be drawn to a conclusion, with issues arising from the assessment remaining unresolved at the time of conclusion.

42 The assessment process is only a part of the COMAH regime and examines at face value the factual information and examines arguments and demonstrations contained in the report against the requirements of the regulations. Criteria are used as a framework for assessment. Conclusions on the adequacy of the report in meeting the purposes identified in the regulations are reached at the end of the assessment process. These conclusions are used by the CA to inform and prioritise further intervention with the company.

43 The assessment conclusions reached by the assessment team need to clearly describe why a demonstration has not been met and refer to the relevant SRAM criteria to which the deficiency relates and to the relevant COMAH regulation or schedule. Appendix 8.2 lists the main questions to be asked to help the assessment team to reach conclusions.

44 Assessors may make a request for further information during assessment, raised on the assumption that such information should be readily available. Upon receipt of this information, the assessor should decide whether concerns have been adequately addressed or if further intervention is needed. A conclusion should be reached at this stage. If information is not readily available upon request (e.g. requiring further work by the company), the assessment conclusions should be drawn on the basis of information supplied.

45 Drawing assessment to an end at this stage with written conclusions sets a baseline for future intervention strategy for the site. This allows the work to be prioritised in context with any other work, not necessarily directly linked to the assessment process, that may need to be undertaken with the site. If the ‘further assurances’ sought by an assessor are simply about demonstration and do not have a likely outcome of further necessary measures, then this might be prioritised ‘low’ on the risk scale. If however, further measures linked to preventing a major accident are suspected to be a likely outcome, then it would be prioritised more highly, taking account of the scale of the consequence and risk.

46 Concluding assessment in this way reduces possible interference with progress on potentially more important intervention activity concerning other possible high risk issues affecting the site. It allows the relative importance of outstanding assessment issues to be programmed into the overall site intervention plan dealing with all outstanding matters for the site, not just assessment.

Revision plan

47 Where the assessment team concludes that significant further information is required to make adequate demonstrations then a revision plan will be required. The output from the plan is a revised safety report in which the demonstrations are made, or the assessors are satisfied that they have sufficient information to decide whether there are serious deficiencies, or the assessors are content that there are no longer significant shortfalls in the demonstrations made in the safety report. Measures that

are found to be deficient at this stage will be included in the intervention plan for the establishment.

48 The revision plan should specify the information required, the reasons why (e.g. In support of what demonstration and why it is thought lacking) and when the information is required by. The time for producing the required information will depend on the significance of the matters, any representations that the operator makes and the resources available to the CA in its assessment and intervention programme. The information can be supplied as revised pages of the report or in a separate letter. All required information received will form part of the safety report.

Intervention strategy

49 As an outcome of the conclusions of the assessment process the assessment team may make recommendations for inclusion in the intervention strategy for the establishment. Recommendations should identify topics for inspection or other intervention, estimate resources and indicate when such intervention should take place (prioritisation) over the following 5 year period until the next periodic resubmission of the safety report.

Human factors assessment

50 The consideration of human factors potentially affects all disciplines. The criteria in Section 10, 11 and Section 12 of SRAM include outline guidance on areas where human factors may be an issue relevant to specific disciplines. Additionally, guidance on human factors is covered in a stand-alone Appendix 4 in Section 12 in respect of technical measures and is available for use by all assessors during assessment.

51 Not all safety reports will necessarily receive a dedicated assessment by a Human Factors specialist assessor (to be agreed when setting the target assessment agenda). This is because the most effective assessment of human factors issues is often achieved by direct contact with the site as part of the intervention strategy. It will also depend upon the nature and depth of human involvement in safety critical functions at the establishment or site.

52 Assessors of all disciplines should therefore take account of human factors as it affects their discipline, using the guidance provided. This approach does not prevent assessors seeking the specialist support of the Human Factors team during assessment if deemed appropriate.

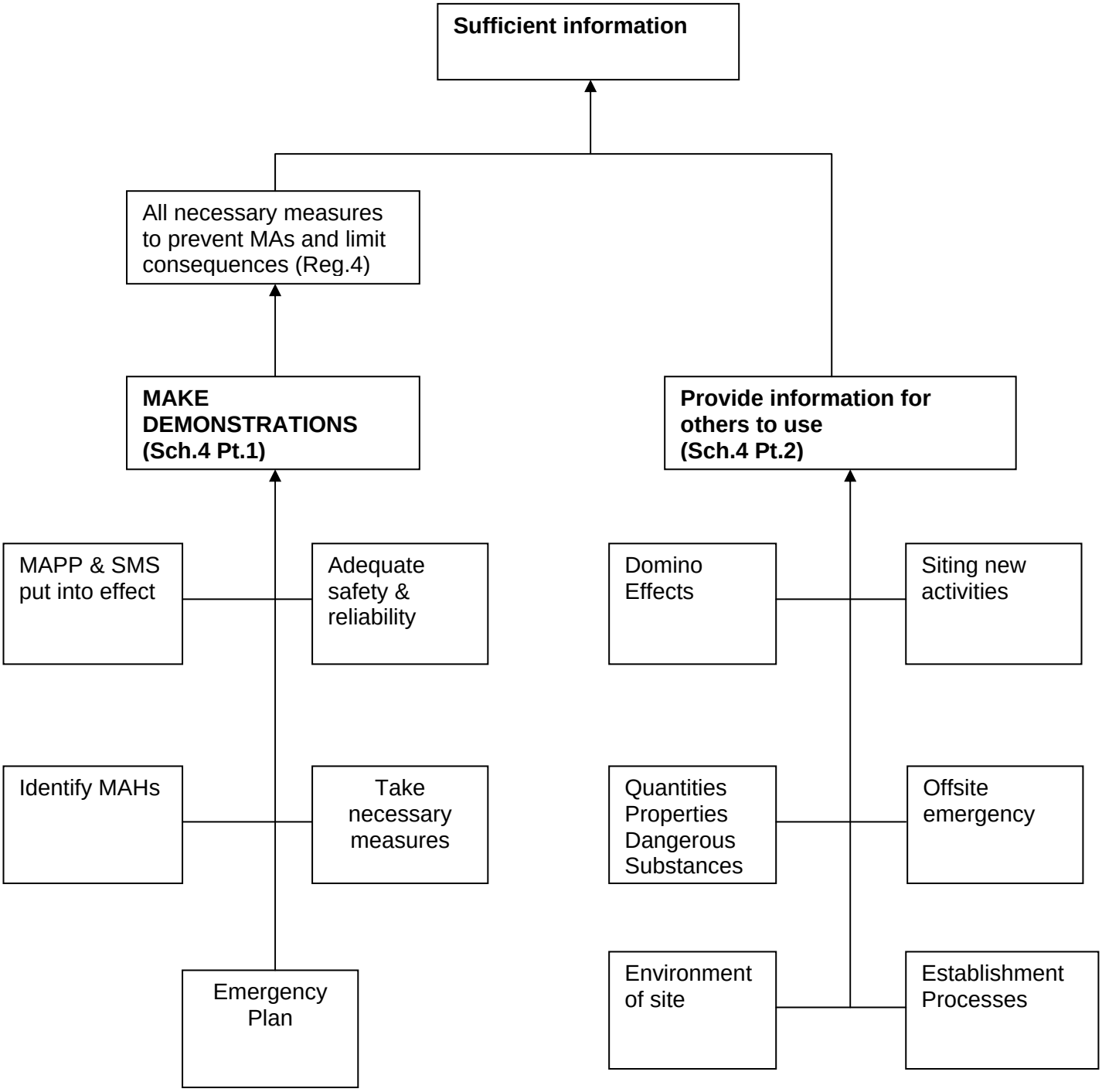
Figure 8.1 Links between schedule 4 and assessment criteria

The figure below shows the links between the relevant Schedules of the COMAH Regulations in terms of the purposes contained in Schedule 4, Part 1 and the information required by Schedule 4, Part 2 and the primary blocks of assessment criteria. Paragraph numbers in column 1 (Purpose) and column 3 (Information required) relate to paragraph numbers in the respective parts of Schedule 4.

PURPOSE (Sch4 Pt 1)	ASSESSMENT CRITERIA	INFORMATION REQUIRED (Sch4 Pt 2)
Para1. Demonstrate MAPP and SMS put into effect.	**MANAGEMENT OF RISK**	Description of MAPP and SMS in place (Sch 2). Para1. Information on management system and organisation re major accident prevention.
Provide knowledge to help CA with each of the demonstrations. Basic understanding Para 4. Supplying information to enable off-site emergency plan to be drawn up. Para 5. Provide sufficient information to CA for land use planning purposes.	DESCRIPTION AND OTHER INFORMATION	Para 2. Presentation of 'environment' of establishment (2a, b, c). Para3. Description of installation (3a, b, c(i), (ii), (iii)).
Para 2. (1st part). Demonstrate major accident hazards identified.	MAJOR ACCIDENT SCENARIOS	Para 4a. Probability or conditions under which they occur. Summary of initiating event for each. Para 4b. Consequence assessment - severity and extent.

PURPOSE (Sch4 Pt 1)	ASSESSMENT CRITERIA	INFORMATION REQUIRED (Sch4 Pt 2)
Para 2. (2nd part). Demonstrate necessary measures taken to prevent major accidents. Para 3. Demonstrate adequate safety and reliability incorporated into: (a) design and construction (b) operation and maintenance.	PREVENTION OF MAJOR ACCIDENTS	Para 4c. Technical parameters and equipment used for safety of installation. Para 5a. Equipment installed to limit consequences.
Para 2. Demonstrate necessary measures taken to limit consequences of major accident (2nd part). Para 3. Demonstrate adequate safety and reliability incorporated into: (a) design and construction (b) operation and maintenance. Para 4. Demonstrate on-site emergency plans drawn up.	LIMIT CONSEQUENCES OF MAJOR ACCIDENTS	Para 5b. Organisation of alert and intervention. Para 5c. Mobilisable resources (internal and external). Para 5d. Summary of 5(a), (b) and (c) for drawing up on-site plan.

Figure 8.2 - Information required in a safety report



Appendix 8.1 Requests for information – Examples

This appendix provides examples of requests for information (RFIs) that assessors of safety reports may make to operators during the assessment process. The expectation is that information requested should normally be available and therefore can be readily supplied by operators in support of their demonstrations.

Where possible, RFIs should be clearly stated, linked to the requirements of the regulations and should state or imply the nature of required information that is needed to resolve the issue being raised.

Example 1

The following is an example of an RFI request based on one that was made to, and on the response received from, an Operator. Comments on how the aims of information requests are met are included as comments within brackets.

Issue raised to Operator

'Pt 1, Management of Health & Safety, Section 3 , para7 in the safety report – Isolation Procedures: It is stated in the safety report that any isolation not meeting minimum recommended isolation standards must be risk assessed before the isolation is approved. The dutyholder is requested to clarify what practical steps and responsibilities are described in the isolation procedures (or related documents) to initiate a feasibility review to upgrade isolation provisions for future interventions.

Continued (i.e. repeated) interventions using less than minimum standards of isolation, albeit supported by a Level 2 risk assessment (as defined in the procedures), is not an acceptable longer term strategy for isolation, without reasonably practicable measures being taken to achieve minimum (or better) recommended standards to meet foreseeable future requirements (i.e. reduce the risk to ALARP of a major accident due to loss of containment during maintenance)

[Basis: Reg. 4; Sch. 4 Pt2 (1); SRAM Criterion 12.2.5.1. Importance 'Medium'.].'

[**Comment**: The above example describes the assessor's concerns by explaining in the 2nd paragraph what the issue is, viz. that if there is a deficiency in isolation arrangements, it is not sufficient simply to repeatedly exercise a fall back isolation assessment procedure to justify a substandard isolation every time the maintenance procedure needs to be carried out. It may be justified to adopt 'exceptional' arrangements the first time. However, once the deficiency has been identified, there should be follow up steps taken to improve the (isolation) arrangements for the future if reasonably practicable (i.e. the ALARP principle to take reasonably practicable measures to prevent major accidents). This could be planned at a suitable plant shutdown opportunity.

The first paragraph clearly states what information is sought in the SMS to address this concern. Details should be readily available and can be supplied, either as a statement in a letter from the Operator with reference to existing procedures, or the entire procedure could be provided. The basis of the request within the regulations and SRAM and an indication of the importance of the issue to the demonstration is stated.]

Operator's Submitted Response

A letter from the Operator explained:

'The Safe Isolation and Reinstatement of Plant Procedure (para 2.1) states: 'Any isolation which does not meet the minimum recommended isolation standard ……. must be assessed using the Level 2 Risk Assessment…… Should any non-compliant isolation have to be repeatedly justified by risk assessment, consideration shall be given to a permanently engineered solution.'

[**Comment**: This short response broadly meets the concerns expressed in the assessor's request for further information, with the exception that there is no clear definition that consideration of permanent solutions should be triggered following first non-compliance and where similar future intervention can be anticipated. The assessment of this issue can be drawn to a close at this point as there is no evidence to suggest a serious deficiency.

The text taken from the isolation procedures could be read to imply that several non-conforming isolations could be applied before action is taken to review potential design modification to upgrade the isolation to at least meet minimum required standards. (Risk Assessment could be repeatedly implemented to justify authorising the substandard isolation. This increases the risk of a failure leading to loss of containment if the risk assessment is not fully effective on every occasion – a human factors issue that can be readily remedied by strengthening the procedure to assign a clear responsibility on the isolating authority.)]

Assessment Conclusion

An assessment conclusion that can be drawn from the above is a recommendation for improvement to the isolation procedures to **place a responsibility** on the appropriate isolation authority to initiate a design / modification review whenever a non-conforming isolation is first presented for their authorisation. Action at this point should be taken to assure risks are reduced to ALARP at the earliest opportunity.

The implementation of this is a detail that can be noted for further examination as post assessment intervention activity (inspection).

Example 2

An assessor raised the following issues (shown in italics) following initial assessment of a safety report:

'Criterion 3.5.5
The worst case accident is stated to be a delayed ignition fireball following a catastrophic failure of an aniline reactor. It appears that the fireball calculations are based on a quantity of 2 x flash fraction in the fireball, although the quantity is not explicitly stated.

Please provide your evidence to support a "limited local flash immediately" following a reactor failure and the assumption of 2 x flash fraction (i.e. 34% at relief conditions) in the delayed ignition fireball. The information in CRR 277/2000, Review of RELEASE rainout model and the CCPS data (hse.gov.uk/research/crr pdf/2000/CRR00277.pdf) and particularly the De Vaull and King correlation, suggests that all the aniline, rather than only 34%, could remain airborne

[Basis: Sch.4 Pt 2(4b); SRAM Criterion 10.5. Importance – clarification issue - ‘Medium'.]‘

[**Comment:** The assessor’s references disagree with the work done by the company and the request is looking to see what information they have to back up their assumptions. This could reasonably be put to the company as a further information request. The company should not need to conduct further work to explain its assumptions used in the assessment of this event. The basis of the request within the regulations and SRAM and an indication of the importance of the issue to the demonstration is stated.]

The assessor went on to request:

‘Please consider the effect on the fireball and toxic gas cloud calculations in the report of assuming that all the aniline remains airborne. What would be the impact on the hazard/risk ranges and numbers of people affected? ‘

[**Comment**: the assessor wants to get an idea of the significance of what he/she feels is an error in the report. However this is actually asking the company to do some more work and this doesn't fit in with the aim of a further info request (readily available information). The reality is that the company only need to do this work if they can't back up their assumption of 34% airborne aniline. Therefore there should be no RFI at this stage, as presented. If the company can justify the assumption, the matter drops. If not, then the assessment of this issue concludes on the basis that there is a flawed assumption and that further work needs to be done via a revision plan to accompany the assessment team’s conclusions letter. The assessment conclusion are made and are not delayed while the assessor waits for the company to do further consequence assessment work].

A further request from the assessor was:

‘Criterion 3.5.5
The distance to LFL is used in the report for assessing flammable gas dispersion. In order to take account of pockets of gas being above the centreline or average concentration and modelling uncertainty, the hazard range can be taken to be 0.5LFL. Please discuss your choice of LFL, and comment on whether a 0.5LFL criterion would have any significant impact on the assessed risks.’

[Comment: The assessor wants to get an idea of the significance of the change from LFL (Lower Flammable Limit) to 0.5LFL, before deciding how far to pursue the issue. However, this may appear as something of an information fishing exercise, and may be seen as a request for further work rather than a request for readily available information. If the assessor can accept LFL, then this is fine. If not the assessment team may conclude that a possible error is made and again reach conclusions on this basis and recommend that further work should be done linked to a revision plan.]

Appendix 8.2 – Main questions to be answered

The following questions should be considered, where relevant to the scope of the safety report and the assessment target agenda, by the assessment team when reaching their conclusions from the assessment of safety reports. Normally, for reports where assessment of all topics is required, all questions should be considered prior to completion of the Team Assessment Conclusions Record in Appendix 4.5. For reports where only a selective scope of assessment is undertaken, it is possible that not all questions are relevant (e.g. a revision report where only management changes have been made, and there are no material technical changes affecting major accident scenarios or technical measures, may not require assessment by all disciplines).

MAIN QUESTIONS TO BE CONSIDERED BY ASSESSMENT TEAM
Q8.1 Does the report contain: (a) sufficient information for the purposes of Schedule 4 Part 1; (b) at least the information required by Schedule 4 Part 2?
Q8.2 Is there: (a) a major accident prevention policy (MAPP) and (b) a safety management system (SMS) for implementing it?
Q8.3 Does the report demonstrate that: (a) the MAPP and (b) the SMS have been put into effect, in accordance with the information set out in Schedule 2?
Q8.4 Does the report demonstrate that the major accident hazards have been identified?
Q8.5 Does the report demonstrate that the necessary measures have been taken to prevent and limit the consequences of major accidents?
Q8.6 Does the safety report demonstrate that a systematic and sufficiently comprehensive approach to the identification of risk reduction measures has taken place?
Q8.7 In coming to conclusions on the measures necessary: (a) are there any assumptions, (b) are these clear, and (c) are the conclusions valid, taking into account any uncertainties in the data provided?
Q8.8 Are conclusions drawn from the risk analysis with respect to emergency planning soundly based?
Q8.9 Does the report demonstrate that adequate safety & reliability have been incorporated into: (a) the design, (b) construction, (c) operation, (d) maintenance, linked to the major accident hazards in the establishment?

MAIN QUESTIONS TO BE CONSIDERED BY ASSESSMENT TEAM
Q8.10 Do the findings and conclusions in the safety report show that the measures adopted to prevent and mitigate major accidents make the risks from a major accident ALARP? *[If the answer is NO, then at least one of the questions in Q8.4 to Q8.9 will also be answer NO].*
Q8.11 Does the report demonstrate that an internal emergency plan has been drawn up?
Q8.12 Does the information supplied enable the local emergency planners to draw up an off-site emergency plan which will take the necessary measures in the event of a major accident?
Q8.13 Is there evidence that there is a serious deficiency in the measures taken to prevent, limit and mitigate a major accident?
Q8.14 Does the report provide sufficient information to the competent authority (CA) to enable decisions to be made in terms of siting of new activities and developments around existing establishments?
Q8.15 Does the report give sufficient information to enable the CA to identify establishments or groups of establishments where the likelihood or consequences of a major accident may be increased by their proximity because of the "domino effect?

9. DESCRIPTIVE ASPECTS

Introduction

Scope

1 This guidance is for assessors concerned with the description of the establishment; the dangerous substances and activities on it, and the environment surrounding it. This descriptive information provided by the operator plays an essential part in achieving the purposes of a safety report.
Relevant Requirements of the COMAH Regulations

2 The descriptive information covered by this set of criteria is needed to satisfy the demonstration of safety required by Schedule 4 Part 1.
The minimum information required is given in Schedule 4 Part 2, para 2 “Presentation of the environment of the establishment” and para 3 “Description of the installation”.

General guidance for assessment of the descriptive elements

3 It is possible that the description of the installation, the demonstration of safety and the major accident scenarios are not presented separately. The operator may decide to amalgamate information relating to the installation description and the demonstration of safety to better make the case, or aid the logical flow of the safety report. In this situation, assessment against this criterion would need to be done in conjunction with any other criteria that apply.

4 Some of the information required to assess the impact on the natural environment may already have been prepared for environmental impact assessment or other authorisation procedures. It is permissible for the operator to refer to this information. However, assessment is made easier and more efficient if it is submitted as part of the COMAH safety report, rather than by reference to authorisations sent separately to the Agencies.

Pre-construction and pre-operation safety reports

5 Pre-Construction Safety Reports (PCSRs) and Pre-Operation Safety Reports (POSRs) should normally be able to provide details on all criteria in this section, though some revision may be required in POSRs to reflect design development since the PCSR.

6 Descriptions of the environment and surrounding populations should reflect expected conditions once the site becomes operational. Where commencement of operations is phased, reports should describe circumstances (including temporary arrangements such as use of temporary offices and buildings, inclusion of construction contractor populations, etc.) as they apply to each phase.

7 Overview descriptions of the establishment, particularly where relevant to major accident hazards, emergency response, monitoring etc. should be described as far

as information is available at the time of submission of the report. Significant gaps in required information should be justified. Principles and design philosophies which will govern the eventual choice of equipment should be stated where detailed final arrangements are not known.

Appendix 9.1 - Descriptive assessment criteria and guidance

Descriptive Criteria	Guidance
General	
Criterion 9.1 **The safety report should give details to allow communication with the competent authority**	The safety report should include, as a minimum: • the name of the operator; • if the operator is a company, the address of the registered office; • if the operator is a trading partnership, the names and addresses of all trading partners, together with the name and address under which the partnership operates; • the name and address of the establishment and if necessary the installation covered by the report; • the name(s), address, telephone & fax number and e mail address for contact(s) within the operator's organisation for communication about the report.
Dangerous Substances	
Criterion 9.2 **The safety report should identify the maximum quantities of every dangerous substance present, or potentially present, on the establishment** **[Schedule 4 Part 2, Para 3 (c) (i)]**	Dangerous substances are those which are either, • listed in Schedule 1 Part 2 of the Regulations, or • meet the criteria laid down in Schedule 1 Part 3. Those to be identified are: • all dangerous substances at or above lower tier and upper tier threshold quantities; • other dangerous substances below these quantities, if they are capable directly or indirectly of being involved in a major accident; Sources of the materials include: • raw materials, intermediates, finished products, by products and wastes; • substances produced during process excursions, or other unplanned but foreseeable events; • any other dangerous substances which may be anticipated to be present on the establishment (including substances present on road and rail vehicles). The following principles should be considered: • where certain dangerous substances have not been included in the inventory, the reason for

Descriptive Criteria	Guidance
	their omission should be provided; • where an establishment has a large number of different dangerous substances present, it may be necessary to group them into representative categories (in line with Schedule 1 Part 3), for the purpose of quantification. In such cases the safety report should explain and justify the basis for the groupings chosen; • the maximum inventories calculated should take into account fluctuations in business activity and the established quantity under the Planning (Hazardous Substances) Regulations 1992,[1] as updated by the Town and Country Planning, England and Wales - The Planning (Control of Major Accident Hazards) Regulations 1999. There may be other legal authorisations which refer to quantities (e.g. IPPC or IPC); • where a number of different dangerous substances are present on an establishment at less than their qualifying quantity, the safety report should show how individual quantities have been aggregated. • to allow the assessors to establish if all substances arising from foreseeable excursions have been identified, then operators are advised to give details of measures taken to identify such substances.
Criterion 9.3 **For each dangerous substance identified, the safety report should describe its chemical name (including common use chemical name) and CAS number, according to IUPAC nomenclature** **[Schedule 4 Part 2 para 3 (c) (iii)]**	The safety report should include, for each dangerous substance or class of dangerous substances (including those present as impurities or additives or constituents of preparations): • its chemical name (for example, propane, butane) and where appropriate, its common chemical name (for example, LPG); • identification of the substance (for example, chlorine) or class of substances (for example poly chloro-di-benz dioxines), according to the IUPAC system of nomenclature; • the CAS number for the substance or class of substances; • the concentration of any impurity or additive and proportion of each constituent in a preparation. The safety report should also provide any additional information useful to help identify the dangerous substance. For explosives, including stored process intermediates, the following additional information will

[1] Name of Scottish equivalent is the Town & Country Planning (Hazardous Substances)(Scotland) Regs 93

Descriptive Criteria	Guidance
	normally be required: • the name and description corresponding to the UN Number assigned to the explosive on classification under the Classification and Labelling of Explosives Regulations 1983, where applicable; • which definition of an explosive in Part 3 of Schedule 1 to COMAH it falls within; • its behaviour on accidental initiation described in terms of Hazard Type as used in licences issued by the Health and Safety Executive under the Explosives Act 1875.
Criterion 9.4 **The safety report should describe the physical and chemical behaviour of each dangerous substance identified, relevant to normal operating conditions and foreseeable accident conditions** **[Schedule 4 part 2 para 3 (c) (ii)]**	This may include, for example; flash points (by an identified method), ignition temperatures, flammable limits, vapour pressure, density, boiling point, data on reactions, rates of decomposition, and data on sensitiveness of explosives. The following principles should be considered: • only those physical and chemical properties relevant to the various demonstrations of safety contained in the safety report need to be presented; • information presented in the safety report should be sufficient to describe the behaviour of the dangerous substances under all normal operating conditions, process upset conditions and foreseeable accident conditions.
Criterion 9.5 **The safety report should describe the immediate and delayed harm to man and the environment for each dangerous substance identified** **[Schedule 4 part 2 para 3 (c) (ii)]**	The information presented should include the physical, chemical or toxicological characteristics of the dangerous substances that may cause harm and an indication of the hazards posed. The information presented should address both the short and long term effects and may include for example: • health hazards such as irritation, asphyxiation, cancer or genetic damage; • lethal concentrations; • harm caused by fire or explosion; • effects on the environment, including building damage, the ecosystem and relevant sensitive species. • outlines of the routes to harm, (e.g. via airborne discharge, seepage into groundwater, formation of an explosive cloud, or accidental initiation of explosives giving rise to blast); • characteristics such as bio-accumulation,

Descriptive Criteria	Guidance
	persistence, dispersal mechanisms and known antagonistic or synergistic effects. The following principles should be considered: • the information presented should consider acknowledged acceptable limits, in terms of concentration, distance from source, time of exposure, or any other relevant parameters; • references to scientific literature to justify the harmful effects, hazardous concentrations and acceptable limits are expected; • where information is not known, assessors should expect operators to evaluate the significance of that lack of knowledge and describe their policy for dealing with it.
Environment	
Criterion 9.6 **The safety report should describe the environment of the establishment in sufficient detail to allow the consequences of a major accident to be assessed** **[Schedule 4 part 2 para 2 (a)]**	The information to be provided fits into a number of categories as follows: **General** information is expected to include a map to a suitable scale (usually at least 1:10,000) showing the establishment and its surroundings. On such maps the land use pattern (ie industry, agriculture, urban settlements, environmentally sensitive locations etc) and the location of the most important buildings and infrastructures (i.e. hospitals, schools, other industrial sites, motorway and railway networks, stations and marshalling yards, airports, harbours etc) should be clearly indicated. Also on the maps, access routes to the establishment should be clearly indicated as well as the escape routes from the establishment and other traffic routes significant for rescue and emergency operations. Separate maps may be required to identify the surrounding population and the surrounding natural environment. It may be necessary to have different scale maps when the operator mentions long distance effects. Information on **the surrounding population,** is expected to include: • approximate numbers of residents; • estimated numbers of people who may use the area (for example: present at workplaces, present as tourists, or to attend football matches or motorway services); and • groups of people who may be particularly vulnerable either on account of their sensitivity to the hazards in question (e.g. schools and hospitals) or because of the population density.

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	Consideration should also be given to allow assessment of the indirect impact of a major accident on the public. For example, as a result of contamination of drinking water. Information on **the surrounding environment** should that may influence the impact of a major accident. Examples may include: • the topography if it could have an effect on the dispersion of toxic or flammable gases or combustion products, (this should include buildings, underground workings or other structures where appropriate, e.g. a pedestrian subway); • historical local weather records, including: wind speed; wind direction; atmospheric stability and rainfall. The relevance of this information to the behaviour of releases of dangerous substances should be described; • a description of the underlying and surrounding geology and hydrogeology if it is appropriate to the consideration of a major accident; • a description of the surrounding water courses (under various flow conditions), underlying aquifers and any drinking water extraction points should be given in relation to the dispersion of liquid contaminants or leachate from solids deposited on the surrounding land; • description of surrounding water and land quality; • information on sewerage and rainwater systems if they could be involved in the dispersal of liquid contaminants off-site; • information on tides and currents that might influence dispersion or accumulation if marine or estuarine habitats are at risk; • a description of features of the surroundings that may hinder emergency response or mitigation measures. Information on **the built environment** is expected to include: • each listed building and monument; • any sections of the infrastructure, such as major transport routes or utilities (e.g. electricity, gas, telephone, water sewers and treatment plant); that may be vulnerable to the effects of a major accident. Information on **the natural environment** is expected to include a description sufficiently detailed to allow the

Descriptive Criteria	Guidance
	significance of the impact of major accidents to be assessed. This should include details of any: • Sites of Special Scientific Interest (SSSI); whether they are Special areas of Conservation (SAC) or Special Protection Areas (SPA); or Ramsar sites; • marine nature reserves; • marine sensitive areas, under English Nature's marine strategy; • and the significance of these features in either a national or international context should be explained, for example the flora or fauna particularly at risk.
Criterion 9.7 **The safety report should describe the environment of the establishment in sufficient detail to allow the contribution of external factors to major accidents at the establishment to be assessed** **[Schedule 4 part 2 para 2]**	• The information itself is a requirement under Schedule 4 part 2 para 2 of the Regulations, and is an essential precursor to assessment of the major accident scenarios, provided under Schedule 4 part 2 para 4 (a) of the Regulations. • The contribution of the external factor to the major accident could be as an initiating or exacerbating event. Factors for consideration under this criteria include: • the physical environment surrounding the establishment may have an effect on certain initiating events. For example, the underlying geology should be described to allow the consideration of seismic events and subsidence as accident initiators; • the history of the land on which the establishment is located, together with its surroundings, may be significant to the consideration of major accident initiating events. For example, history of mining, other mineral extraction activities or land reclamation, may lead to subsidence; previous land use, may be important in respect of contaminated land or water; • historical evidence of other external events that might act as accident initiators such as: seismic events; flooding; and extreme weather conditions including: temperature; rain; snow; wind; and lightning; • other major hazard installations and pipelines in the area capable of initiating or influencing a major accident; • current land use under the establishment, including current mining or mineral extraction

Descriptive Criteria	Guidance
	activities; • air traffic movements over and around the establishment, including civilian and military, fixed wing and helicopters; • transport activities that may have an impact including shipping, major transport routes and dangerous substance movements; and • other human activities that might lead to major accidents such as arson, vandalism, theft, and criminal damage; • high voltage overhead electric power distribution lines; • radio transmission masts in the area that produce fields which could interfere with safety control systems or communication systems, or initiate electro explosive devices.
• Establishment	
Criterion 9.8 **The safety report should identify installations and other activities of the establishment that are relevant to major accident hazards** **[Schedule 4 part 2 para 4(b)]**	• This information is expected to include identification of: • main storage facilities; • process installations; • location of relevant substances and their quantities; • relevant equipment (including vessels and pipes); • utilities and services; • means of access and egress; • control rooms, offices and other occupied buildings which could be vulnerable in a major accident.

Descriptive Criteria	Guidance
Criterion 9.9 **The safety report should** describe the process(es) being carried out within every installation which could give rise to a major accident [Schedule 4 part 2 para 3 (b)]	The Safety Report should include descriptions of: • the purpose of the installation; • the conditions under which the dangerous substance is normally held; • what happens to the dangerous substance in terms of physical and chemical changes arising from the designed purpose of the plant; • what happens to the dangerous substance in terms of physical and chemical changes arising from foreseeable deviations from the designed purpose of the plant; • the discharge, retention, re-use and recycling or disposal of residues and waste liquids and solids, or the discharge and treatment of waste gases.
Criterion 9.10 **The safety report should describe the area on each installation where a major accident scenario could happen** **[Schedule 4 part 2 para 2(c)]**	The Safety Report should clearly identify plant and activities where a major accident could happen. It should: • include a plant diagram which unambiguously identifies key control systems, reaction vessels, storage vessels, pipework systems, valves and significant connections; • contains a plan which unambiguously identifies the location of activities where a major accident could happen (e.g. storage in packages, processing of explosives).
Criterion 9.11 **The safety report should provide focused information about each installation, in sufficient detail to support the demonstration that major accident hazards will be prevented or the effects mitigated** **[Schedule 4 part 2 para 3 (a)]**	The purpose of the focused information is to provide enough detail for assessors to understand the operator's demonstration of safety. Therefore, safety reports should provide descriptive information pertinent to the demonstration being made, and at a level of detail so that assessors can understand the arguments presented. The safety report should contain plan(s) or map(s) or diagram(s) plus descriptions, which clearly set out information about the installations with major accident potential. The description should allow determination of the purpose, location and function of equipment within the installation that has a bearing on major accident prevention and control. In particular, information about items of plant such as: • vessels (e.g. location, type, size, pressure, purpose, contents); • pipework systems (e.g. routes, types, size, pressure, purpose); • services (e.g. steam, air, electricity, fuel,

Descriptive Criteria	Guidance
	hot water); • drainage (e.g. routes, purpose [e.g. foul water, fire fighting run-off water]); • stacks, flares and gas cleaners (e.g. location, purpose); • safety (or environment) critical valves, instruments, control loops and detection systems; • fire fighting and supply arrangements; • monitoring equipment, e.g. for toxic products in air, sewers, discharges to water; for fires or explosive atmospheres; • incorporators, rolling mills, manual and power presses, sieves, granulators, mixers. Safety reports should also include information about: • the normal operating parameters of plant; • the designed maximum working capacities, temperatures, and pressures and maximum explosive inventories; • relevant qualitative and quantitative information on energy and mass transport in the process (i.e. material and energy balances) in: ♦ normal running ♦ start up or shut down periods ♦ abnormal operations; ♦ dangerous substance locations, and (at each location) an indication of the chemical and physical state and quantity of the dangerous substance.
Criterion 9.12 **For sites that are part of a domino group, designated by the competent authority, the safety report should confirm whether there has been information exchange between the operator and other operators in the domino group** **[Regulation 16(3)]**	NB it is the duty of the CA designate and notify operators in domino groups. • Where this duty applies, then the operator would be expected to include information on; • What information they have exchanged and to which other COMAH establishment operators; • What information they have received and what conclusions they have come to including whether they had to amend their MAPP, have or will have to amend the safety report and whether changes are required to the on site emergency plan.
Criterion 9.13 **The safety report should include the names of any relevant organisations**	Paragraph 6 of schedule 4 part 2 was added by regulation 17(3) of the COMAH Regulations 1999 (As Amended).

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involved in drawing up the report [Schedule 4 part 2 para 6]	Simple clarification of the names of those organisations involved is all that is required to meet this criterion. Confirmation of where no other organisations were involved is required to explain to the CA any absence of information.

10 Predictive aspects

Introduction

Scope

1 This guidance is for assessors completing the predictive assessment and is relevant to all types of safety report. The criteria assess the fitness-for-purpose of the site operator's major accident risk assessment. 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 risk assessment so that it is fit-for-purpose in relation to their site-specific circumstances and the demonstration required.

Relevant requirements of the COMAH Regulations

2 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".

3 The criteria in this section assess whether the operator's risk assessment is both suitable and sufficient for the purposes of Schedule 4, Part 1 paragraph 2, 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. Schedule 4, Part 2 defines the minimum information requirement.

General guidance for the assessment of the predictive aspects

All measures necessary

4 Dutyholders are required 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,
- the adoption of inherently safer designs,
- whether good practice has been, or is to be adopted,

- the application of risk-reducing measures where relevant good practice is not yet established.

5 In general the Tolerability Of Risk (TOR) framework is applied:

- 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 Cost Benefit Analysis (CBA) suggests otherwise.
- 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. Professional judgement is not an arbitrary process but is supported by appropriate education, training and experience, applied with specific analysis where necessary.

6 The issue under COMAH is whether any necessary measures have been excluded. If all reasonably practicable measures are in place, and the risks are tolerable, then there is nothing more that needs to be done – Individual Risk and Societal Concern must be ALARP.

7 The key is to be able to decide:

- when any possible further measures are reasonably practicable (ie necessary), and
- when any possible further measures are not reasonably practicable.

8 A good demonstration in a Safety Report will provide:

- an amount of evidence and
- a depth of argument

that are proportionate to the risk posed by the establishment.

9 The assessor needs to assess the demonstration, particularly the analysis of possible further risk reduction measures. All the information needed to assess an ALARP demonstration must be available (or referenced and summarised where appropriate) in the Safety Report.

Risk assessment

10 The Competent Authority (CA) uses the predictive criteria to assess the site operator's major accident risk assessment.

- Risk Assessment is fundamental to the demonstration that all measures necessary have been taken to reduce and control risks.
- Risk Assessment is a step towards demonstrating that risks are ALARP.

11 Additional measures:

- Whenever additional measures are identified as being reasonably practicable they should be implemented.
- Whenever possible risk reduction measures are rejected the case needs to be well argued and supported with evidence.
- Risk reduction cannot be looked at without first doing a risk analysis.

12 Operators therefore need to present their approach to risk assessment. The approach and the depth of the analysis will be influenced by site-specific circumstances and the level of risk attaching to the site.

13 The risk assessment needs to address:

- risks to people on-site individually and collectively,
- risks to people off-site individually and collectively,
- risks to the environment.

14 The risk assessment needs to be:

- a logical and systematic process – the Safety Report needs to identify the tools and competences the company is using to undertake the risk assessment.
- Presented as an integrated whole. The steps in the risk assessment process have to be linked together.

15 The risk assessment needs to identify:

- a representative set of major accident scenarios,
- the consequences and likelihood of major accident scenarios,
- all the necessary measures taken to prevent major accidents,
- all the necessary measures taken to limit consequences of major accidents,
- domino effects where relevant.

16 For new establishments and modifications to existing establishments the risk assessment needs to include:

- consideration of the elimination of hazards,
- inherently safe approaches to reduce the scale of hazards,
- prevention, control and mitigation measures to limit risk.

17 Risk assessment steps that should be demonstrated in the safety report are:

- understand the site operations, the materials involved and the process conditions;
- identify the hazards to people on-site and off-site and the environment;
- analyse the different ways the hazards can be eliminated, reduced in scale, realised and controlled;
- 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;
- predict the corresponding consequences both when mitigation measures work and fail;
- analyse the risks associated with the remaining hazards and the options for reducing them.

- decide which measures need to be implemented to make the risks to people (individually and collectively) and the environment as low as reasonably practicable (ALARP);
- 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.

18 The predictive criteria are structured in the same way as the above steps. They are designed to analyse:

- how an operator identifies the major hazards on site,
- how this information is used to make decisions on the necessary measures to prevent a major accident or limit its consequences.

The end point of this group of criteria forms the starting point for the SMS, technical and emergency response criteria.

19 New plant:

- Analysis of the hierarchy of measures (para 14 above) of the risk assessment 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.

20 Existing plant:

- As new plant but the scope for elimination and reduction in scale may be less.

Proportionality

21 The depth of the analysis in the operator's risk assessment should be proportionate to the hazards and risks presented by the establishment. Further guidance on proportionality is included in Section 7 of the manual.

22 Where explosives facilities and operations do not meet accepted quantity-safety distances (QD's), the safety report should:

- Provide a justification that all measures necessary to control the risks are applied.
- Normally include a quantified risk assessment.

Fitness for purpose

23 Fitness for purpose of the risk assessment depends on:

- Expertise/competence of those identifying and analysing hazards (human factors issue).

- Methods used in the risk analysis.
- Data and assumptions.
- How the significance of the risk was assessed.

Early predictive assessment

24 During the early stages of the predictive assessment, the focus is on whether the report appears to contain the minimum key information required by Schedule 4 Part 2 para 4(a) and 4(b) that shows:

- a proportionate approach to hazard and risk analysis,
- identification of the extent and severity of a representative set of scenarios,
- proportionate consideration of risk reduction measures and the ALARP demonstration.

25 Apparent large omission of key information in these areas is likely to have a major impact for further assessment of the safety report across all disciplines and therefore needs to be identified at an early stage. When the safety report is received the AM and Predictive Assessor will decide if it is necessary for the Predictive Assessor to conduct an initial assessment before the report is passed to other members of the team for assessment. Circumstances where this may be appropriate include:

- First safety reports for a particular site, particularly for sites that keep a range of dangerous substances, have very large quantities and/or a range of processes.
- Where there are any indications from any source that the operator's major accident risk assessment may be insufficient.

26 In cases where an initial assessment is deemed appropriate, Appendix 10.2 provides examples of the types of minimum key information that may be required. An Early Predictive Assessment Record (word template) is available for use if required.

Appendix 10.1 Predictive assessment criteria and guidance

Predictive Criteria	Guidance
Criterion 10.1 **The safety report should clearly describe how the operator uses risk assessment to help make decisions about the measures necessary to prevent major accidents and to mitigate their consequences.** **[Schedule 4 part 1 para 2; Regulation 4]**	Risk assessment is sufficiently systematic and detailed for the operator to identify necessary measures. This criterion summarises the **description** in the safety report of the company's **general approach** to the use of risk assessment in the process of identifying necessary measures. The assessment of the **application** of this approach is covered by the remaining criteria (10.1.1. to 10.5.6). Criterion 10.6 draws summary conclusions on the assessed overall adequacy of the **application** of risk assessment described in the report for actual site conditions. • Description of how a balance between qualitative, semi-quantitative and quantitative arguments, based on risk, is adopted. • Summary of the methods used to analyse risks. • Criteria used to judge the significance of the residual risks when control measures have been implemented. • Link between hazards identification, risk assessment and its use in the selection of risk reduction measures described (See Technical Assessment Criteria for further details on measures). ♦ Eliminating and reducing the scale of hazards. ♦ Reduce event likelihood and mitigate the associated consequences. • Use of current thinking on: ♦ Inherently safer design options and the hierarchical approach to selection of measures. ♦ Relevant good practice. ♦ Engineering and procedural standards. • Basis for making decisions about adoption or rejection of identified measures is provided. • Description of the role that risk assessment has in the demonstration that the risks are ALARP for on-site personnel, people off-site and the environment. • The depth and detail of the analysis is proportionate to and takes into account: ♦ The scale and nature of the hazards.

Predictive Criteria	Guidance
	♦ The associated risks. ♦ The site-specific circumstances e.g. size and nature of installation. ♦ The proximity of population or sensitive environments. • Approach to making the risk assessment a living document described. • Arrangements for periodic review described. • Description of how human actions or omissions affect risk and link to suitability of measures.
Criterion 10.1.1 **It should be clear that human factors have been taken into account in the risk analysis** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a), Schedule 2 Para 4(b)]**	How people can contribute to and mitigate the occurrence and impact of major accidents. • The safety report describes a process for identification of human failures, actions, or other involvement as contributor to major accident causation which is: ♦ Systematic and integrated with the overall risk assessment. ♦ Competently applied. ♦ Showing how human failure contributes to major accident initiation or escalation. • The probabilities of human actions and omissions which contribute to major accidents **and** the reliability of measures dependent upon human action: ♦ Are addressed and are realistic. ♦ Recognise different categories of human failure including omissions, mistakes, decision failures, violations, sabotage and rule breaking.
Criterion 10.1.2 **Any criteria for eliminating possible hazardous events from further consideration should be clearly justified** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a)]**	The intent of this criterion is to ensure no important hazardous events go unconsidered • Risk dominating accidents are identified and include: ♦ The worst case scenario. ♦ Low probability events such as aircraft impact, lightning strike, cold catastrophic failure of a pressure vessel, guillotine rupture of pipework. ♦ Smaller releases which could trigger other events leading to event escalation. • Criteria for eliminating accident sequences from

Predictive Criteria	Guidance
	further analysis are given such as: ♦ Use of representative scenarios. ♦ Use of equivalent hole sizes of releases. ♦ Limited hazard ranges/cut-offs. ♦ Frequency cut-off (frequencies for highly improbable accidents may not need to be as detailed as that for risk dominating sequences). • Justification for eliminating possible hazardous events from further consideration: ♦ are clearly presented and well argued. ♦ Criteria have been applied (early) to limit the scope of the predictive aspects.
Criterion 10.2 **The safety report should demonstrate that the operator has used information and data that are suitable and sufficient for risk analysis** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a)]**	Meteorological conditions that are appropriate for the site, including: • Process and location specific weather data: ♦ from an appropriate Meteorological Office climatological weather station, ♦ data obtained over a suitable recent period (e.g. at least five years.), ♦ if modelling of the transmission of thermal radiation from fireballs and jet fires,use of likely minimum, likely maximum, and average humidity at a specified temperature. • Appropriate stability/wind speed combinations: ♦ a minimum of two combinations representative of daytime and night time conditions (eg, D5 and F2). ♦ if buoyant plumes are modelled (eg warehouse fires), high wind speeds are considered, e.g. D15. ♦ on a directional basis for at least 12 sectors. [NB most flammable hazardous events are only marginally affected by meteorological conditions, However there are two key exceptions, 1) unignited drifting flammable clouds 2) thermal radiation from fireballs and jet fires] • Assumptions made in tailoring data to site specific circumstances are realistic. • If the data are sparse, any adjustments err on the side of safety i.e. ‘cautious best estimates’ in line with the ‘precautionary approach’. • Consideration of a range of suitably applied harm levels (e.g. toxic, thermal, pressure effects)

Predictive Criteria	Guidance
	to people and the environment. • Use of current maps, off-site population data and surrounding environmental features.
Criterion 10.3 **The safety report should identify all potential major accidents and define a representative and sufficient set for the purposes of risk analysis** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a)]**	• All potential major accidents (MAs) are identified, and • if these MAs are put into groups to make the risk analysis feasible, the coverage of the different types of MA hazards is suitable and sufficient for risk assessment and emergency planning purposes, i.e.: ♦ They dominate the on-site and off-site risk. ♦ They encompass the complete spectrum of severity (i.e. include the worst case foreseeable scenario). [See criteria 3.3.1 & 3.3.2]
Criterion 10.3.1 **The safety report should demonstrate that a systematic process has been used to identify all foreseeable major accidents** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a); Schedule 2 para 4(b)]**	A systematic hazard identification process has been used to identify **all** major accident scenarios, including worst case and lesser events. A comprehensive process should have considered loss of containment derived from all reasonably foreseeable on-site operations and also external events that may impact upon site operations. The report should outline how major accident hazards are identified and show that a suitable range of events has been identified for further assessment. • **On-site Events** where relevant may include: ♦ Loss of containment accidents due to equipment, vessel, pipe work and pipeline failures. ♦ Explosions. ♦ Condensed Phase Explosions relating to explosives. ♦ Large fires (Warehouses, pool fires, jet fires, etc.). ♦ Events influenced by emergency action or adverse operating conditions etc.. ♦ Other types of major accident hazard or abnormal discharge. • **External Events** where relevant may include: ♦ Aircraft impact. ♦ Seismic event; land slips, subsidence. ♦ Extreme environmental conditions (e.g. abnormal rain, snow, temperature, wind, floods, lightning). ♦ Vehicle/train impact or other external

Predictive Criteria	Guidance
	missiles. • Scenarios ranked and analysis proportionate to the scale and nature of the hazards. • The range of MA scenarios affecting people and the environment is sufficient for identifying necessary measures and includes: ♦ Local incidents: may seriously harm workers or escalate into a more serious incident. ♦ Major incidents: harm is mainly confined to the site, but affects more than one area of the site (e.g. an explosion) - potential for killing more than one worker - possibly with limited off-site impact, no fatalities but possible hospitalisation of 1 or more people. ♦ Catastrophic incidents: potential for multiple on-site and/or off-site fatalities. • The scenarios include events where planned or installed measures fail.
Criterion 10.3.2 **The hazard identification methods used should be appropriate for the scale and nature of the hazards** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a)]**	• Hazard identification methods appropriate and proportionate to the type of plant and circumstances and the scale and nature of hazards are identified and described. • The relevant expertise of the hazard identification team involved is described. • Methods that might be used include: ♦ HAZOP (Hazard and Operability Studies). ♦ Safety reviews and studies of the causes of past major accidents and incidents. ♦ Industry standard or bespoke checklists for hazard identification. ♦ FMEA (Failure Mode and Effect Analysis). ♦ Job safety analysis (e.g. Task Analysis). ♦ Human error identification methods. ♦ HAZARD Study 2 or PHA type assessments.
Criterion 10.4 **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**	The likely frequency or probability of major accidents is considered. • The likely frequency or probability of major accidents is considered: ♦ Their probability, or the conditions under which they occur. ♦ A summary of the events which may trigger each of these scenarios (i.e. causes - whether internal or external to the installation).

Predictive Criteria	Guidance
or external), which may play a role in triggering each scenario **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a)]**	• Depth of the analysis of event likelihood is proportionate to the scale and nature of the hazard. • The use of operational experience in analysis is described. • **Failure rates**. The safety report: ♦ Justifies the failure rate values used. ♦ Includes references and methods of derivation (where appropriate). • Safety critical events. The safety report: ♦ Defines 'safety critical event' and the basis for the choice of definition. ♦ Applies the definition systematically. ♦ Presents a list of safety critical events. ♦ Includes events that may be low risk, but can escalate to a more serious event.
Criterion 10.4.1 **The safety report should demonstrate that a systematic process has been used to identify events and event combinations which could cause major accident hazards to be realised** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a)]**	Use of a systematic process for scenario generation. Demonstration should show that the identification of events or event combinations take appropriate account of: • Insights gained from the study of previous accidents and incidents. • Causes of accidents in other industries which present societal risks. • Assessment of the effects of failure of plant and equipment designed to prevent, detect, or mitigate the hazardous conditions. • Human error as an accident-initiating event. • Human error in intervention activities. • Escalation pathways, the key steps that might prevent them and time for actions to be taken.
Criterion 10.4.2 **All safety critical events and the associated initiators should be clearly identified** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a)]**	• The identified Safety Critical Events or event sequences are those that dominate the contribution to risk at different distances from the plant. • The likelihood of the various MAH's and the associated consequences has been used in determining safety critical events. • Appropriate methods for assessing the probabilities of each major accident have been used.

Predictive Criteria	Guidance
	• Rejection of identified control measures for safety critical events is justified.
Criterion 10.4.3 **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** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a)]**	• The quantitative or qualitative arguments presented in the safety report should: • Be realistic, well reasoned and plausible. ♦ Justify significant departure from arguments currently accepted by risk assessment media. ♦ Be backed-up by credible performance data. • Qualitative arguments need to be: ♦ Based on accepted good standards for engineering and safe systems of work. ♦ Supported by evidence on the likely demand on the various control measures and systems and what the consequences might be if these fail. [Note: reliance on manual isolation when automatic isolation fails will require justification if less than 20 minutes is assumed for operator action to be implemented.]
Criterion 10.4.4 **The methods used to generate event sequences and estimates of the probabilities of potential major accidents should be appropriate and have been used correctly** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a)]**	Demonstration that frequency and probability estimates are reasonable. • Appropriate methods (used individually or in combination) to generate event sequences and estimates of major accidents probabilities include: ♦ Relevant operational and historical data. ♦ Fault tree analysis. ♦ Event tree analysis. • The safety report should describe: ♦ The methods and assumptions actually used. ♦ Any failure rate data used. ♦ Justification for data in terms of the site-specific circumstances. ♦ Data suitability, unless shown that risks analysis conclusions are not sensitive to the data. ♦ The process and methods (including human error identification and analysis) adopted to generate any probabilities or event sequences. ♦ Checks against company benchmarks should be included when appropriate.

Predictive Criteria	Guidance
	♦ Sensitivity of the conclusions to the assumptions where necessary.
Criterion 10.4.5 **The safety report should provide adequate justification for event probabilities that are not consistent with historical or relevant generic industry data** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(a)]**	• The operator's justification may include quality procedures, plant experience, or other acceptable evidence. A conservative approach should be evident for arguments used. [Note: the CA may: Compare event probability estimates with values commonly used and accepted by experienced risk analysts. Identify the most important parts of the predictive aspects where the justification needs to be further evaluated – possibly by use of sensitivity analysis.]
Criterion 10.5 **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** **[Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(b)]**	The intent of this criterion is to ensure valid and appropriate consequence assessment. • The safety report describes: ♦ For people, harms that include fatality, serious injury and hospitalisation. ♦ A range of potential harms to the environment. ♦ A systematic process for assessing consequences of major accidents. ♦ A detailed consequence assessment for dangerous substances present in quantities sufficient to cause a major accident hazard. ♦ Assumptions stated and justified. ♦ As appropriate, whole tank failure, BLEVE, fireball. flash fire or vapour cloud explosion. ♦ Outcomes developed using Event Tree Analysis. ♦ The worst-case scenarios. ♦ The models that have been used and a justification of their suitability. ♦ Well-validated models for significant hazards. • Proprietary Models. ♦ References the pedigree and basis of such models, especially where there is the potential for large numbers of people to be killed or injured in a single major accident because of the long hazard range or the proximity of a large population. ♦ Proprietary models used are up to date and take account of the current physical knowledge about the phenomena.

Predictive Criteria	Guidance
	♦ Are bench marked against available data or other models which were known to have been bench marked. ♦ Have been written in a quality assured process. ♦ [Note. Assessors may also make use of the Gas Dispersion Guidance for COMAH safety report assessors.] • Hazard ranges. ♦ A demonstration on the appropriate choice of the models, and the expertise of the user, proportionate to the significance of the hazard being modelled. [Note 1: Assessors should consider the following: a) For a low proportionality site containing specific substances covered by the SRAGs, comparison with the appropriate SRAG graphs. b) For low proportionality sites not covered by SRAGs and medium proportionality sites, issues such as model quality and the expertise of the user are more important and some checking (Sampling) is recommended. c) In high proportionality cases there should be no doubt as to the validity and quality of the model or the expertise of the user and these should be demonstrated in the report. Some analysis of the sensitivity of the predicted consequences to the key assumptions might be expected. d) Use of professional judgment and experience when deciding if consequence distances appear inconsistent. Note 2: Overly conservative hazard ranges have implications for both offsite emergency planning and for prioritisation of risk reduction measures. Operators need to recalculate hazard ranges if: a) this significantly affects ALARP arguments and the allocation of resources for risk reduction b) the offsite plan will be significantly affected. c) the CA is concerned about the training, experience and competence of the model user.]

Predictive Criteria	Guidance
Criterion 10.5.1 **Source term models used should be appropriate and need to have been used correctly for each relevant major accident hazard** **Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(b)]**	• Loss of containment accidents (releases) are correctly modelled. • The nature, size, and duration of releases are identified. • For releases to atmosphere, the influence of obstacles on jets and air entrainment is described. [Note In the criterion, 'Appropriate' means 'fit for purpose'.]
Criterion 10.5.2 **The material transport models used should be appropriate and need to have been used correctly for each relevant major accident hazard** **Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(b)]**	• The safety report shows appropriate use of models where relevant for: ♦ Passive (neutrally buoyant) or a heavier-than-air clouds. ♦ A cloud containing aerosol which reacts with ambient moisture entrained into the cloud. ♦ Releases giving rise to large hazard distances. ♦ Dispersing clouds interacting with obstacles or terrain features. ♦ Considers a range of weather conditions. ♦ Sensitivity tests for significant events (in terms of assumptions about the source term).
Criterion 10.5.3 **Other consequence assessment models (e.g. BLEVE, Warehouse fire etc.) used should be appropriate and need to have been used correctly for each relevant major accident** **Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(b)]**	• The safety report identifies and describes consequence models and justifies their suitability.
Criterion 10.5.4 **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** **Schedule 4 part 1 para 2;**	• The safety report shows, where the scale and nature of the hazard and risks is significant: ♦ The sensitivity of results to the choice of harm criteria or model, or the way it is used, may be needed. ♦ Justification for the approach to environmental impact assessment and data used.

Predictive Criteria	Guidance
Schedule 4 part 2 para 4(b)]	
Criterion 10.5.5 Assumptions used are justified, realistic, and not unduly optimistic **Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(b)]**	• The safety report shows the sensitivity of the results to assumptions (particularly when the scale and nature of the hazard and risks are significant).
Criterion 10.5.6 Estimates of the severity and extent of each major accident consequence are realistic **Schedule 4 part 1 para 2; Schedule 4 part 2 para 4(b)]**	Extent and severity is concerned with who (people) or what (environment) might be harmed, how badly, and how many (people) or how much (environment) are affected by major accidents. • Predictions are realistic by comparison with published assessments and with company benchmarks. • The safety report: ♦ Combines harm criteria, predicted hazard ranges , specific data for on/off site populations with the likelihood of the major accident scenarios. ♦ Presents severity information in a suitable form, e.g.: ▪ Numbers of fatalities, serious injuries, hospitalisations. ▪ Banding of events in terms of consequence to people (eg 1 - 5, 5 - 20, 20 – 100, etc). ▪ Effects distances on maps of the site and surrounding area (with identified estimations of numbers, centres and types of populations both on and off site). ▪ Discusses the importance of typical cloud widths, wind direction, atmospheric conditions and location of on-site and off-site personnel for effect on extent and severity.
Criterion 10.6 The risk assessment should be suitable and sufficient **Schedule 4 part 1 para 2; Schedule 4 part 2 para**	This criterion summarises **assessment** conclusions on the described **actual** outcomes of the risk assessment process applied to **actual** site circumstances and is an assessed view of whether the application of the general approaches to the use of risk assessment outlined in Criterion 3.1 appears suitable and sufficient. Conclusions on Criterion 3.6

Predictive Criteria	Guidance
4(a), 4(b); Schedule 2 Para 4(b)]	can only be reached at the end of assessment. • The applied risk assessment methodology: ♦ Is proportionate to the scale and nature of the hazards. ♦ Is proportionate to the estimated risks. • The safety report pulls together the information from the risk assessment such that it: ♦ Draws together the likelihood and consequence assessments in an appropriate way to make estimates of the risks. ♦ Recognises that high consequence low risk events warrant attention for further risk reduction on a case by case basis. ♦ Considers both individual and (where appropriate) societal risk. ♦ Compares the risks against suitable criteria, and takes account of aversion to large scale serious events where necessary, in the selection of necessary measures. ♦ Draws conclusions about the tolerability of risks from the site. ♦ Considers sensitivity and uncertainty in the risk assessment. ♦ Demonstrates that risk assessment has been used in an appropriate way as part of the process to reduce risks to ALARP. ♦ Includes consideration of risk reduction options. ♦ Describes the decision making process.

Appendix 10.2 Predictive aspects - key information requirements

CRITERION	KEY DATA
Principles of risk assessment	
10.2 The safety report should demonstrate that the operator has used information and data that are suitable and sufficient for risk analysis.	• Wind rose for at least 12 direction sectors. • Representative day & night conditions for gas dispersion – D5; F2. • Conservative weather e.g.D15 for knock down of buoyant smoke plumes from warehouse fires involving toxic substances. • Current maps with offsite land & populations. • Detail of location and quantity of hazardous materials and storage conditions • Current information & maps showing surrounding environment including environmentally designated sites (SPA, SAC, SSSI etc.).
Identification of major hazards & accident scenarios	
10.3 The safety report should identify all potential major accidents and define a representative and sufficient set for the purposes of risk analysis.	Examples include: • BLEVE from above ground LPG storage vessel. • Flash fire following catastrophic failure of refrigerated storage tank. • VCE following release of flammable liquids and gases at high P&T. • Catastrophic failure of large(st) storage tank or vessel containing toxics. • Catastrophic failure of a reactor.
Likelihood OR conditions under which a major accident can occur	
10.4 The safety report should contain estimates of the probability (qualitative or quantitative) of each major	• Range of 'engineered' (human initiated) failures beyond the control of the operator, e.g. aircraft or other onsite impacts such as cranes, affecting utility

CRITERION	KEY DATA
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.	failure such as power loss. • Range of natural events, e.g. seismic, flooding, weather extremes. • Failures in engineered and human responses and accident control. • Consider effects of MAs on neighbouring establishments, e.g. missiles.
Consequence assessment	
10.5 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.	• Reference to methods and models for source terms. • Reference to methods and models for dispersion. • Reference to methods and models for hazard phenomena, e.g. BLEVE, VCE, fireball. • Harm criteria, e.g. ♦ Toxic doses (concentration and time of exposure) with effects on people and their significance. ♦ Thermal fluxes and duration of exposure likely to lead to harm to people, plant where the effects could lead to failure or escalation on/off site (Reg. 16 Domino effects). ♦ Environmental harm in terms of dose and significance for receptors, with justification/derivation as appropriate. • Extent & severity – who might get hurt, how badly, how many.

11. MAJOR ACCIDENT PREVENTION POLICY & SAFETY MANAGEMENT SYSTEMS ASPECTS

Introduction

All measures necessary

1 The criteria and guidance presented in this chapter are concerned with the operator's Major Accident Prevention Policy (MAPP) and the rest of the Safety Management System (SMS) for implementing it.

Relevant requirements of the COMAH Regulations

2 COMAH Regulation 7(7) requires the operator to produce a safety report. Schedule 4 Part 1 paragraph 1, indicates that one of the purposes of the safety report is for demonstrating that a major accident prevention policy and a safety management system for implementing it have been put into effect in accordance with the information set out at Schedule 2 of the Regulations.

3 Schedule 4 Part 2 of the Regulations specifies the minimum data and information to be covered in the safety report. Paragraph 1 of Schedule 4 Part 2 requires that information on the management system and the organisation should contain the elements given in Schedule 2. Schedule 2 therefore sets the framework for these assessment criteria.

General guidance for the assessment of the MAPP and SMS elements

4 The elements of an SMS for implementing the MAPP listed at Schedule 2 of the Regulations, are compatible with the model given in the publication HS(G)65 “Successful health and safety management”. The criteria and guidance which follow are set out under headings which link to the HS(G)65 model, and the derivation given under each criteria provides a link back to the elements of the SMS required by Schedule 2 of the Regulations.

5 It is important to remember, however, that there are alternative models describing the interrelationship between the key elements of a successful safety management system. Operators may have chosen these alternatives when describing their SMS in company documents. Although we may wish to encourage operators to present information about their MAPP’s and SMS’s using the HS(G)65 format, there is no legal requirement for them to do so. The operator's approach to providing the MAPP and presenting information about the associated SMS is likely to reflect the overall management philosophy, system and culture and we should be careful to avoid the impression that we are seeking to impose a particular management model or framework. This means we may have to search, sort and assemble information from the operator's safety report into the HS(G)65 elements at the start of the assessment process.

6 Under each of the criteria guidance is given which indicates the information expected to be provided in a safety report, to meet the criteria. Typically this is the minimum information expected. In circumstances where the hazards and complexity of the establishment suggest that a rigorous demonstration is required, further information or detail may be needed to meet the criteria (see section 1 for further information on proportionality). Therefore the guidance should not be seen as exhaustive.

Pre-construction and pre-operation safety reports

7 Pre-Construction Safety Reports (PCSRs) and Pre-Operation Safety Reports (POSRs) should demonstrate adequate management of design, construction and commissioning processes prior to the introduction of dangerous substances. Plant design often undergoes considerable development before and during the construction period and effective management and communications interfaces between operator, contractors and subcontractors is required. Particular issues affecting PCSRs or POSRs, as appropriate, include:

- Key safety design criteria.
- Design process control and change management (hazard identification and risk assessment, design management and change approval, document control, etc.) during construction and commissioning.
- Competency of designers, construction teams, contractor teams, specialists.
- Management of temporary arrangements or constraints during design, construction and commissioning.
- Construction verification systems and commissioning controls. Post commissioning checks.
- Identification of key roles and responsibilities for management of major hazards.
- Communications between operator, designers, construction personnel, commissioning personnel, CA and other affected parties.
- Design, construction and commissioning planning controls.
- SMS review and revision process prior to operation.

Appendix 11.1 MAPP & SMS assessment criteria and guidance

MAPP & SMS Criteria	Guidance
MAJOR ACCIDENT PREVENTION POLICY (MAPP) The following criteria, and guidance, refer to the MAPP. It should be remembered that operators of top tier sites are not required to produce a MAPP which is a separate document, but that the major accident prevention policy is required to be part of the safety report.	
Criterion 11.1 **The safety report should include a commitment to achieve a high standard of protection for people and the environment** **[Regulation 5(2)]**	A simple statement, in the policy document or safety report, of commitment should be sufficient to meet this criterion.
Criterion 11.2 **The safety report should show that the MAPP sets out the operator's overall aims and principles of action with respect to the control of major accident hazards** **[Schedule 2 para 2]**	This is a high level requirement, more detail will be required for subsequent criteria, but for the purposes of this criterion, simple reflection of the aims of COMAH regulation 4 (take all measures necessary to prevent major accidents and limit their consequences to persons and the environment) should be sufficient.
Criterion 11.3 **The MAPP should include a commitment to provide and maintain a management system which addresses the following issues:** **a) organisation and personnel;** **b) identification and evaluation of major hazards;** **c) operational control;** **d) management of change;** **e) planning for emergencies;** **f) monitoring performance; and** **g) audit and review.** **[Regulation 5(3), by reference to schedule 2 paragraph 4]**	If operators include a statement of commitment to achieving a high standard of protection for people and the environment and support this broad aim by including in the MAPP appropriate objectives under each of the elements listed in criteria 4.3 (a) to (g), then their MAPP is likely to be adequate. It is important to note that, for this criterion, we are only looking for the policy statements. Subsequent criteria look the detail under each heading to demonstrate that there is the SMS to support the MAPP. Under each heading the operator would be expected to cover the following, respectively; • the roles and responsibilities of personnel involved in the management of major hazards at all levels in the organisation, including contractors where appropriate, and the provision of training to meet identified training needs; • the arrangements for systematically identifying major hazards arising from normal and abnormal operation and the assessment of their likelihood and severity; • the arrangements and procedures for safe operation, including maintenance of plant,

MAPP & SMS Criteria	Guidance
	processes, equipment and temporary stoppages; • the arrangements for planning modifications to, or the design of new installations, processes or storage facilities; • the arrangements for identifying foreseeable emergencies by systematic analysis and to prepare, test and review emergency plans to respond to such emergencies; • the arrangements for the ongoing assessment of compliance with the objectives set out in the MAPP and SMS and the mechanisms for investigation and taking corrective action in the event of failing to achieve the stated objectives. These should include the operator's system for reporting major accidents and near misses, particularly those involving failure of protective measures, and their investigation and follow up on the basis of lessons learnt, and; • the arrangements for periodic systematic assessment of the MAPP and the effectiveness and suitability of the SMS, the documented review of performance of the MAPP and SMS and their updating by senior management.
Criterion 11.4 **The MAPP should be set at a senior level in the operator's organisation**	The written statement of the operator's MAPP is signed and dated by the appropriate director or senior executive would satisfy this criterion.
Criterion 11.5 **The safety report should show that the MAPP has been established in writing** **[Schedule 2 para 2]**	Inclusion in the safety report of the operator's current MAPP, noting that it does not have to be separate document, would satisfy this criterion.
ORGANISING HSE publication HS(G)65 categorises the activities necessary for successfully organising in health and safety into the four elements (the 4Cs) of control, competence, cooperation and communication. These categories have been used in producing these criteria	
Control	
Criterion 11.6 **The safety report should include sufficient explanation of how the SMS fits into the overall organisational**	This criterion recognises that operators may have a SMS that does not follow the HS(G)65 model, or even if it does, the SMS will have to fit into the overall management arrangements for the site and company that follow other models. This criterion offers the opportunity for the operator to describe the arrangements for

MAPP & SMS Criteria	Guidance
arrangements	management of safety and demonstrate that the operator's SMS fits in with the overall management system. There should be confirmation that safety management (particularly the management of major accident hazards) forms an integral part of the operator's overall company management and organisational arrangements. In meeting this criterion, the opportunity exists for the operator to give an overview of their SMS and how it fits to overall organisational arrangements, to aid assessment of the safety report.
Criterion 11.7 **The safety report should show that all necessary roles in the management of major hazards have been clearly allocated** **[schedule 2 para 4(a)]**	To meet this criterion the report should include: • description within the safety report of what use has been made of allocation of roles, in the management of major accident hazards, illustrated where appropriate with organisation charts; • information to confirm that the control of major accident hazards is a management function; • an explanation indicating that safety and environmental professionals act in support of line management; • description of a structured attempt to identify all safety critical and safety related human tasks, so that responsibilities in the measures for prevention, control and mitigation can be assigned.
Criterion 11.8 **The safety report should show that the responsibilities of everyone involved in the management of major hazards have been clearly defined** **[schedule 2 para 4(a)]**	To meet this criterion the report should include; • reference to job descriptions, or other documents detailing individual responsibilities; • identification of post holders with key responsibilities; • references to the way in which the operator has set out how particular jobs should be done e.g. by using performance standards (rules stating who does what, how, when and with what expected result).
Criterion 11.9 **The safety report should describe how the operator allocates resources to implement the MAPP** **[schedule 2 para 4(a) and regulation 4]**	To meet this criterion the report should include: • description of a process to determine and maintain the minimum staffing levels required to deliver the necessary measures under all foreseeable operating conditions; • reference to the arrangements for filling key posts; • explanations of systems for identifying absences of key personnel and arranging competent cover; • brief explanation of the arrangements for securing

MAPP & SMS Criteria	Guidance
	financial resources to meet the demands of any improvements or upgrades that may be identified by the risk management process.
Criterion 11.10 **The safety report should show that the performance of people having a role to play in the management of major accident hazards is measured and that they are held accountable for their performance** **[schedule 2 para 4(a)]**	To meet this criterion the report should include: • explanation of how the responsibilities are made clear to the jobholder e.g. in job descriptions or other documents; • reference to performance review and appraisal systems; • effective compliance checking arrangements for safety critical procedures. Where more detailed and rigorous demonstrations are deemed necessary, the report should provide; • information about procedures for identifying and taking action on failures to achieve satisfactory performance; • reference to disciplinary procedures and incentive and reward schemes; • summaries of arrangements for setting performance standards and targets for line managers.
Competence	
Criterion 11.11 **The safety report should show that the operator has in place a system for providing and maintaining appropriate levels of management and employee competence** **[schedule 2 para 4(a)]**	To meet this criterion the report should include: • outlines of the arrangements for the selection, recruitment, training and placement of employees and managers at all levels including, where relevant, contractors; • indications of arrangements for provision, validation and evaluation of training and instruction; • reference to the arrangements for providing specialist and expert advice whether from in-house professionals or from external sources; • outlines of arrangements for identifying personal development needs including needs for improving individual skills and the arrangements for meeting those needs. Where the more detailed and rigorous demonstrations are deemed necessary, the report should also include: • descriptions of the relevant qualifications, skills and experience required for post-holders and teams or groups having a significant role to play in the management of major accidents (at all levels); • reference to the arrangements for identifying the training needs of all those having a role to play in

MAPP & SMS Criteria	Guidance
	the control of major accident hazards, including their deputies, from directors or senior executives, down to operators and including contractors and their employees; • details of training relevant to the individual's profession, discipline or trade and training in relation to each relevant aspect of the operator's systems for preventing and mitigating major accidents.
Co-operation	
Criterion 11.12 **The safety report should show that the operator has systems for ensuring that those working in the establishment are actively involved in the control of major accident hazards [schedule 2 para 4(a)]**	To meet this criterion the report should include: • summaries of the work of consultative bodies (e.g. committees) involving the workforce; • reference to the mechanisms that the operator has in place to secure the involvement of those working in the establishment in; ♦ hazard studies (e.g. HAZOP) and risk assessments; ♦ setting standards relevant to the control of major accident hazards; ♦ devising, reviewing and revising operating and emergency systems, procedures and instructions for the control of major accident hazards; ♦ the design and procurement of new equipment including the human machine interface to ensure human factors and usability are taken into account; ♦ performance measuring activities including accident, incident and near miss investigations; ♦ audit and review activities. • outline of the arrangements for upward reporting of information relevant to the control of major hazards. Where the more detailed and rigorous demonstrations are deemed necessary, the report should also include; • summaries explaining how the operator has set about developing a culture which encourages the active participation of the workforce, including contractors and their employees, in the health, safety and environment effort.
Criterion 11.13 **The safety report should show that the operator has in place arrangements for co-operating with, and securing the**	To meet this criterion the report should include outlines of the operator's arrangements for co-operating with: • operators of other establishments which might be affected by the major accident hazards; • contractors and their employees;

MAPP & SMS Criteria	Guidance
co-operation of, other organisations [schedule 2 para 4(a) and regulation 9(3)]	• the emergency services; • county and other authorities responsible for preparation and maintenance of external emergency plans; • local authorities for other matters e.g. hazardous substances consent; • enforcing authorities; • employers associations; • other relevant bodies.
Communications	
Criterion 11.14 **The safety report should show that the operator has arrangements for gathering intelligence needed for the control of major accident hazards from external sources**	Operators cannot manage major accident hazards properly or achieve compliance with relevant legal requirements unless they are able to obtain important intelligence about these issues from external sources. Also, Regulation 8(1) requires the operator to review the safety report when it is necessary to do so to take account of new technical knowledge and developments in knowledge concerning the assessment of hazards. Descriptions of the operator's arrangements for ensuring that important safety intelligence such as changes in legislation, developments in technical standards and management practices and information about incidents with major accident potential occurring elsewhere in the world is obtained from: • enforcing authorities; • professional bodies; • industry associations; • emergency services; • other companies; • local authorities etc.
Criterion 11.15 **The safety report should show that the operator has arrangements for communicating information important for the control of major accident hazards within the operator's organisation [schedule 2 para 4(a)]**	To meet this criterion the report should include descriptions of the use of the following methods; • written communications, • visible behaviour, and • face to face discussions, to cover communication of the following information; • the meaning and the purpose of the MAPP; • the visions and beliefs which underlie the MAPP; • the commitment of senior management to the implementation of the MAPP;

MAPP & SMS Criteria	Guidance
	• plans, standards, procedures and risk control systems relating to implementation and measurement of performance; • comments, suggestions and ideas for improvement from individuals and teams; • performance monitoring and auditing activities; • lessons learned from accidents and other incidents • staff handover and other critical communications.
Criterion 11.16 **The safety report should show that the operator has arrangements for communicating information relevant to the control of major accident hazards to external organisations [regulations 9(3), 10(3)&(5), 14, 15 and 16]**	To meet this criterion the report should include outlines of the operator's arrangements for: • communicating with other establishments in the vicinity including exchanging information about major accident hazards and emergency plans; • communicating with the emergency services and local authorities in relation to emergency plans; • communicating with county and other local authorities responsible for preparation and maintenance of off-site emergency plans; • supplying the information required under Regulation 14 to people, and establishments serving the public (such as schools and hospitals), off-site who are liable to be affected by a major accident; • making the information mentioned at (d) available to the general public; • communicating with relevant enforcing authorities including HSE and EA/SEPA.
PLANNING AND IMPLEMENTING There are four elements of the SMS listed in Schedule 2 (4) of the Regulations which address planning and implementing issues. These are all considered in this section.	
Hazard Identification	
Criterion 11.17 **The safety report should show that the operator has arrangements for systematically identifying major hazards, assessing the risks arising from normal and abnormal operations and determining necessary control measures [schedule 2 para 4(b)]**	To meet this criterion the report should include: • explanation of the formal hazard identification and risk assessment techniques (HAZOP, FMEA… etc.) actually used at each stage of the life cycle of the process plant or storage facility and applied to the operator's activities and from the substances and materials purchased, stored, processed or produced; • explanation of the formal hazard identification and risk assessment techniques used to provide continuing review (eg PHR, PHA etc); • descriptions of how the operator's arrangements for

MAPP & SMS Criteria	Guidance
	risk assessment take account of human factors including human behaviour and reliability and the potential for human error in relation to safety-critical activities; • descriptions of how the outcomes of hazard identification and risk assessment have been used to determine the physical control measures and management risk control systems needed for the prevention and mitigation of major accidents. Where more detailed and rigorous demonstrations are deemed necessary, the report should include; • explanation of how the elements of a life cycle were considered, particularly abnormal conditions; • reference to the techniques used to identify the hazards and assess the risks arising from external factors; • outline of arrangements for determining the skills and knowledge (practical and theoretical) required by the hazard identification and risk assessment team members.
Criterion 11.18 **The safety report should show that the operator has systems for identifying areas for necessary improvement in relation to the control of major accident hazards** **[schedule 2 para 4(b)]**	Following on from the requirements of schedule 2 para 4(b), the assessor needs to be assured that systems for evaluating risks extend to identification of any necessary improvements. The report should include outlines of the operator's arrangements for improvement planning, including methods for identification of necessary measures. This should include description of how the operator makes decisions on what is reasonably practicable. Reference to the operator's current improvement plans may be useful.
Criterion 11.19 **The safety report should show that the operator has systems for determining priorities to achieve the objectives of the MAPP and scheduling necessary improvement work in relation to the control of major accident hazards** **[schedule 2 para 4(b)]**	Following on from the requirements of schedule 2 para 4(b), and criterion 4.18, we must accept that operators do not have unlimited resources and cannot make all the improvements they may have identified immediately. The work needs to be prioritised and scheduled accordingly. To meet this criteria we would expect to see the following; • explanation of how priorities are decided e.g. based on considerations of hazard or risk. Where more detailed and rigorous demonstrations are deemed necessary, we would also expect to see; • explanations of how improvement work relevant to the control of major accident hazards is scheduled, how the work is resourced, co-ordinated, allocated to individuals or teams to carry out and how

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	timescales for completion are set; • reference to any current backlogs of improvement work including overdue maintenance schedules indicating how these are being tackled.
Key Risk Control Systems – Operational Control	
Criterion 11.20 **The safety report should show that the operator has adopted procedures and instructions for safe operation, including maintenance, of plant, processes, equipment and temporary stoppages [schedule 2 para 4(c)]**	To meet this criterion the report should include descriptions of the risk control systems which the operator has in place for controlling the risks which arise at each stage of the life cycle of the plant, processes or storage facilities in question. These would include the systems for controlling the risks at each of the following stages as appropriate: • *construction and commissioning* of plant, processes, equipment and facilities; • *operation* of plant and processes (including as appropriate, start-up, steady state running, normal shutdown, detection of departures from normal operating conditions and responses to them including emergency shutdown and temporary and special operations); • *safe operation under maintenance conditions* (including carrying out risk assessment for decontamination and maintenance work, generating safe methods of working for maintenance and using permit-to-work systems to control it); • selection and management of contractors; • *inspection, test and maintenance* of plant, equipment and facilities; • *decommissioning* of plant, processes, equipment and facilities. Where more detailed and rigorous demonstrations are deemed necessary, the report should include; • links between the identification of safety critical and key safety related tasks, and the development of procedures; • description of a process for developing procedures that are not only technically correct, but are useable, clear and unambiguous.
Key Risk Control Systems – Management of Change	
Criterion 11.21 **The safety report should show that the operator has adopted procedures for planning modifications**	To meet this criterion the report should include the description of procedures which cover changes to the following (wherever they may be capable of affecting the control of major accident hazards): • organisation, including staffing levels, people

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to, or the design of new installations, processes or storage facilities [schedule 2 para 4(d)]	methods of work; • plant and equipment; • processes, work methods and process variables, such as materials, procedures, and process controls (including software); cover the full range of possible types of change, including: • permanent; • temporary; • urgent; and include the basic elements of: • defining change; • allocation of responsibility for authorising and initiating work on the proposed change; • allocation of responsibility for authorising and initiating implementation of the actual change at the establishment; • identification and recording the change; • assessment of the implications of the change by competent persons; • identification and implementation of control measures deemed necessary as a result of the change; • pre commissioning, or pre implementation, checks and reviews • post change checks and reviews.
Key Risk Control Systems – Planning For Emergencies	
Criterion 11.22 **The safety report should show that the operator has arrangements in place to** **- identify foreseeable emergencies by systematic analysis** **- prepare, test and review emergency plans, and** **- provide specific training for all persons working in the establishment.** **[schedule 2 para 4(e)]**	To meet this criterion the report should include a description of the operators procedures for emergency planning which include the following: • arrangements for identification of foreseeable emergencies; • arrangements to determine the planned response to such emergencies; • arrangements for testing of emergency plans; • arrangements for the review of emergency plans, based on information gained through testing and other changes which may influence the plan. • arrangements to provide realistic training and preparation for all those likely to be involved in the response to an emergency;

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	• arrangements to communicating plans to all those who may be affected by an emergency.
MEASURING PERFORMANCE	
Active Monitoring	
Criterion 11.23 **The safety report should show that the operator has devised proactive means of performance measurement, which provide information on whether the measures taken to guard against major accident scenarios are operating as intended.** **[schedule 2 para 4(f)]**	This criterion recognises that in the case of major accident hazards, a low incident rate is no guarantee that risks are being effectively controlled. To meet this criterion, the report should include a description of a process for performance measurement, which includes the following elements; • identification of key risk control systems necessary for the control of major accidents; • development of means by which the performance of key risk control systems can be monitored; • setting of leading indicators which provide information on whether those key risk control systems are operating as intended; • tolerance levels set against each indicator; • reporting to senior management on a routine basis; • involvement of senior management in the setting of performance indicators and tolerance levels; It is not expected that performance indicators are set against all elements of all risk control systems on a complex installation, or that collection and analysis of data is resource intensive. This would lead to an overload of indicators. It is more important to have manageable number of carefully selected and targeted good quality indicators, to provide assurance across the whole business.
Reactive Monitoring	
Criterion 11.24 **The safety report should show that the operator has adopted a system for reporting incidents and near misses, particularly those involving failure of the protective measures for control of major accident hazards** **[schedule 2 para 4(f)]**	To meet this criterion the report should include descriptions of arrangements to produce lagging performance indicators, ensuring that the following are recognised and reported to management: • major accidents as defined in COMAH; • other relevant injuries and cases of ill health; • other significant events leading to loss or environmental harm; • incidents - including individual behaviour - with the potential for harm or loss or environmental damage, particularly those with the potential for major accidents; • hazardous conditions, including process deviation

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	or loss of containment.
Investigation and Response	
Criterion 11.25 **The safety report should show that the operator has adopted mechanisms for investigation and taking corrective action:** **(a) in cases of the proactive performance measures showing a deterioration in risk control measures; and** **(b) in relation to any incident or event with the potential to cause a major accident.** **[schedule 2 para 4(f)]**	There should be a clear follow on from criteria 11.23.and 11.24 To meet this criterion the report should provide a description of arrangements for investigation, which include the following: • initiation which can be based on of failures identified through either the active or reactive performance monitoring systems; • early evaluation to identify immediate risks; • taking prompt action on immediate risks; • decisions made on the level and nature of investigation based on considerations of potential rather than actual outcome; • determining the immediate causes; • determining the underlying human and management-related causes; • trending of information collected through investigation, to highlight common or wider problems in the prevention and mitigation measures; • reporting to senior management.
AUDIT AND REVIEW	
Audit	
Criterion 11.26 **The safety report should show that the operator has adopted a procedure for systematic assessment of the MAPP and the effectiveness and suitability of the SMS** **[schedule 2 para 4(g)]**	It should be noted that here the term ‘auditing’ involves fundamental assessment of the validity and reliability of the SMS itself. It should not be confused with some operator's use the term "auditing" to refer to activities such as safety tours, physical conditions inspections and behaviour observation carried out by line managers as part of their active performance monitoring activities. To meet this criterion it is expected that descriptions of the operators arrangements for audit will contain the following; • the resources and personnel required for each audit, bearing in mind the need for expertise, operational independence and technical support; • the audit plan indicating how it has been prioritised; • the audit protocols to be adopted (which might include the use of questionnaires, checklists, open and structured interviews as well as checking

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	documents and measurements and observations); • the procedures for reporting the audit findings; • the procedures for following up the recommendations shown to be necessary by audits.
Review	
Criterion 11.27 **The safety report should show that the operator has adopted a review process which uses information from performance measurement and audit** **[schedule 2 para 4(g)]**	To meet this criterion the report should include a description of arrangements for review, which include; • involvement of senior management; • consideration of the results of performance measurement and audit; • consideration of the suitability and adequacy of the current arrangements for performance measurement (including suitability of the performance indicators used); • consideration of the suitability and adequacy of the current arrangements for performance measurement.
Criterion 11.28 **The safety report should show that results of review are documented** **[schedule 2 para 4(g)]**	To meet this criterion the report should include descriptions of the operator's arrangements for publishing the results of the review within the organisation.
Criterion 11.29 **The safety report should show that the operator has adopted a system under which the MAPP and SMS is updated by senior management** **[schedule 2 para 4(g)]**	To meet this criterion the report should include a description of how the review process (see criteria 4.27 & 4.28) is used by senior management to carry out necessary updates of the MAPP and SMS.

12. Technical aspects

Introduction

Scope

1 This guidance is for assessors completing the technical assessment and is relevant to all types of safety report. These criteria contribute to the assessment of the measures taken to prevent major accidents and to limit their consequences for people and the environment. They also concern the incorporation of adequate safety and reliability into the design, construction, operation and maintenance of the establishment and are presented in a way that identifies the different concerns during the life cycle of an establishment.

2 These criteria interface with those specific aspects of the Safety Management System which are directly relevant to the technical measures taken; e.g. periodic examination of pressure systems, operating procedures, etc. They are the outcomes which are determined or influenced by the SMS. The criteria reflect both the probability and consequences (i.e. risk) of major accidents. The starting point for these criteria (12.1) is in fact the end point of the predictive criteria 10.6.

Relevant requirements of the COMAH Regulations

3 Paragraph 3(a) of Part 1 of Schedule 4 requires a demonstration that adequate safety and reliability have been incorporated into the design and construction of the installation. Part 2 of Schedule 4 to the Regulations specifies the minimum information to be included in a safety report and includes a description of the technical parameters and equipment used for the safety of the installations and a description of the equipment installed in the plant to limit the consequences of major accidents.

General guidance for the assessment of technical aspects

The assessment approach

4 The CA's approach to assessment is that it be:

- consistent
- proportionate
- targeted
- transparent
- based on prima facie evidence.

5 The first step in the assessment approach is an examination of the risk assessment to see whether the Duty Holder understands the risks and has identified all measures necessary to limit those risks. Discipline specialists then assess the demonstration of whether the measures described provide appropriate safety and reliability given the risks.

The specialist disciplines covered by this manual are:

- Process Safety (PS)
- Mechanical (M)
- Control and Instrumentation (CI)
- Human Factors (HF)

6 All measures necessary means all those measures intended for eliminating, reducing, controlling and mitigating risk as required by relevant codes and standards, PLUS any additional measures necessary to reduce risks to As Low As Reasonably Practicable (ALARP) (i.e the sacrifice would not be disproportionately high for the achieved risk reduction).

7 The assessment process stops when the CA is satisfied on the basis of prima facie evidence that:

- there is sufficient evidence that risks have been reduced ALARP, supported by signposts (to what can be verified on-site) or valid arguments that the measures are of suitable safety and reliability to achieve the risk reduction,

  or

- requests for further information have been adequately responded to.

NOTE: Measures that achieve larger risk reductions should get more attention.

8 The information in the Safety Report is examined at face value to determine whether these measures meet current well supported codes or standards AND

whether the arguments for not adopting further measures demonstrate that the ALARP principle have been adequately justified and applied.

Generally it is not necessary to carry out a Cost Benefit Analysis in order to demonstrate ALARP but in some cases it may well be required.

Proportionality

9 The breadth and depth of the assessment of the operator's risk assessment and the determination of all necessary measures should be proportionate to the hazards and risks presented by the establishment. Further general guidance on proportionality is included in Section 7 of the manual.

10 Rather than describing many individual measures the Safety Report can sometimes more efficiently refer to systems, with examples of their application to a sample of plants / processes. Wider application of these systems can then be verified on-site by inspection. These are systems which deliver measures appropriate to the hazards and risks throughout the life cycle of:

- Design
- Construction
- Operations
- Maintenance, Inspection and testing
- Modifications
- Decommissioning

Further information will be required when life cycle systems of measures are not addressed in the Safety Report or described in sufficient detail to identify how they deliver measures of sufficient safety and reliability proportional to the risk to people and the environment.

11 The effects of Loss Of Containment (LOC) may be more extensive and severe for some scenarios that for others. The safety and reliability of the safety critical parts of the identified measures should be targeted for a depth and breadth of assessment that is proportionate to how extensive and severe the consequences of a release could be.

Summary of technical measures demonstration requirements

12 The CA expects the justification for why further measures are not necessary to be more detailed the greater the extent and severity of the potential major accident hazard. The greater the extent and severity, the more the Duty Holder should be considering alternative measures.

Issues within and between technical disciplines

Key philosophy for technical assessment

13 The safety report should provide clear justification of the applied measures for:

- Control of the processes, taking account of foreseeable normal and abnormal operations (Process Safety, Control and Instrumentation).

- Prevention of Loss Of Containment (LOC) by the adequacy of the initial integrity and continuing integrity of the containment boundary. Direct causes of failure include: Corrosion, Erosion, External Loading, Impact, Overpressure, High/Low Temperature, Low Pressure, Vibration, Wrong/Defective Equipment (Mechanical Engineering) and Human Failings (all disciplines).
- Risk reduction using safety instrumented systems and their reliability (Control and Instrumentation and Process Safety).
- Hazardous Area Classification and suitability of equipment within designated hazardous zones (Process Safety and Control and Instrumentation).
- Adequate human integrity of the measures for prevention, control and mitigation of LOC and its effects. These measures depend upon human reliability no matter how automated the plant. Human Factors include the workplace environment, organisational, job and individual characteristics that influence understanding and decision making, rule following and skilled behaviour (human factors).

Process safety assessment

14 General approach to process safety assessment.

The assessor is looking for evidence of:

Identification of the credible hazards. This will focus on the quantities and properties of hazardous substances and the consequence of LOC, the operating conditions within the plant, control function and process operating philosophy, and the impact these have on-site and off-site to exposed populations.

- Determining whether measures match the hazards. This may focus on evidence on suitable ranges of process design, control, protective systems and human measures to provide diversity.
- The derivation of appropriate performance standards linked to safety criticality. It should be possible to see the link between identified major accidents and the range of selected measures chosen to prevent and limit them.
- Whether there is correct identification of process and external loads and duties. This addresses the process internal operating conditions under normal and abnormal operating states and expected future demands.
- Potential for deviations and excursions from normal operating conditions.
- The external effect of the environment on the process and its operation (e.g. temperature, hazardous atmospheres, etc.) should be addressed.
- Effect of other failures to initiate major accident scenarios.
- Whether the company has identified the demands on the safety systems.
- Potential for knock-on effects.

15 Key technical issues for process safety assessment.

- Loss of containment arising from a range of initiating events (such as process operating excursions from normal / safe operation, uncontrolled chemical reactions, external events, etc.)

- How these are systematically assessed.
- How these are prevented, controlled and mitigated against.
- Measures the duty holder relies on as the main control to make the process safe (e.g., venting, pressure relieving, inerting).
- Compatibility issues of the materials involved.
- Scale up - awareness of the hazards in scaling up (eg, heat transfer considerations if increasing the volume).
- Separation and segregation.
- Safe operating envelopes and safety margins.
- Safe operations measures to prevent excursions/loads.

- Control system performance in relation to desired function (not limited to hardware).
- Process control philosophy for management of hazards:
  - balance of reliance on manual or automated control.
  - control room operation interface with the process.
  - in normal and abnormal operating modes and emergencies.
  - Fail to 'safety' philosophy for control and isolation devices.
- Installed process control measures and how they are designed:
  - Evidence of appropriate recognised standards.
  - Coverage of safety functions.
  - Suitable alarm systems for deviations.
  - Determination that integrity is suitable and sufficient.
- System integrity under identified hazardous scenarios (including worst case scenario).
- Redundancy, diversity, availability.
- Hierarchical approach to selection of measures:
  - Inherent safety.
  - Reduction of the hazard.
  - Prevention (corrective systems), Control (shutdown/shutoff control, venting and disposal), Mitigation (e.g. deluge systems, fire fighting systems).
- Management issues:
  - Systematic review processes.
  - Inherent safety a principle of the SMS and a selection of measures philosophy.
  - Safe operating systems and assurance they are followed.
  - Change management.
- Flammables and toxics:
  - Sources of ignition in possible flammable atmospheres (consider static and hot sources) – Hazardous Area Classification.
  - For toxics, consideration of ventilation and where material is stored.

Mechanical systems assessment

16 General approach to mechanical systems assessment:

The assessor is looking for evidence of:

- Adequate initial mechanical integrity. The focus is on adherence to suitable design principles, often embodied in codes and standards.
- Suitable controls on manufacture and construction for the delivery of design intent.
- Adequate continuing integrity through operating the plant within its normal operating envelope as well as through appropriate maintenance and periodic examination regimes.
- Procedures to ensure modifications will not compromise integrity.

17 Key technical issues for mechanical systems assessment:

- New plant and initial integrity. In new plant initial integrity is very important before the inspection cycle begins.
- Suitable design principles, codes and standards.
- Consideration of:
  - Design details.
  - Operating and fault conditions.
  - Materials properties.
  - Potential failure modes.
  - Provision, inspection and maintenance of protective systems.
  - Design of equipment secondary containment.
- Design criteria:
  - Prevent and control of releases
  - LOC direct causes
  - Adequate structural integrity
  - Operational and extreme loading
  - Suitable materials
  - Excursions beyond design conditions
- Construction criteria
  - Construction standards
  - Verification of construction systems
  - Controls on manufacture (particularly welding)
  - Inspection and testing of initial integrity
  - Management of design changes during construction (including safety assessment)
- In service integrity:
  - Operating within limits.
  - Appropriate maintenance and inspection by competent person(s).
  - Procedures for modifications.
- Maintenance/inspection criteria:
  - Appropriate maintenance by competent workforce

- Examination by independent competent persons
- Assessment of examination/maintenance results
- Written Schemes of Examination linked to performance / maintenance history.

- Ageing plant - As plants and equipment age there is an increasing likelihood of time related ageing damage from fatigue, corrosion, erosion, creep and other degradation mechanisms. The safety report should describe:
  - The specified design basis and the assessment that has been made of the impact for continued operations, inspection, testing and maintenance.
  - Equipment condition derived from known inspection history e.g. the corrosion history; operational performance; how the plant has degraded.
  - Processes that need to be gone through for determining and carrying out more detailed inspections and to positively justify what is needed to keep the plant going (as opposed to rebuilding it).
  - Reviews to compare the original design with up to date design principles and the consideration of measures to risk reduced ALARP where appropriate.
  - Any use of fitness-for-service and remnant life assessment techniques in re-evaluation of structural integrity.

Control and instrumentation systems assessment

18 General approach to assessment:

The Control and Instrumentation Systems assessor is looking for evidence of:

- Suitably designed process control systems which will deliver the control philosophy of the process in a reliable manner and minimise impingement on safety related protection systems such as Safety Instrumented Systems (SIS). The report should also clearly describe areas where human interaction is necessary and how risk assessment has played a part in determining the overall control strategy.
- Suitably designed Safety Instrumented Systems (SIS). The report should demonstrate that SIS have been designed to suitable standards and that requirements for the safety system have been underpinned by suitable risk assessment processes. For legacy systems the report should state how the Company are reviewing these systems against current standards and how they intend demonstrating that they have suitable levels of safety and reliability.
- Suitable initial design of electrical systems and utilities. This equipment includes EX equipment, fixed electrical systems (HV &LV), earthing systems, fire & gas detection systems, and supply systems such as instrument air. With these systems the focus is on adherence to suitable design principles, often embodied in codes and standards.
- Suitable procedures in place to ensure that electrical/control equipment is operated within its design requirements.
- Continuing integrity of control and instrumentation systems ensured by suitable maintenance/inspection/testing regimes.

- Suitable procedures in place to ensure that modifications to systems are carried out in a controlled manner and subject to suitable hazard identification/analyses and associated risk assessment techniques.

19 Key technical issues for control and instrumentation systems assessment:

- Process Control Systems

  Design and implementation of the process control system should be based on suitable process hazard analyses. The CI assessment should ensure that the process control system in terms of hardware and software is suitable for delivering the requirements of the process in a reliable fashion, thus minimising demand rates on safety related protection systems. Information should be provided on key systems linked to major accident scenarios and should include the following:

  - Procedures/ standards used to ensure hardware/software meets the requirements of the process
  - Details of Process Control Strategies (manual, on/off, PID, cascade, predictive etc.)
  - Required human interaction with the process
  - Process based alarms/trips.
  - Safety related alarms and trips. (e.g. SIL rated systems)
  - Final protection systems (often not instrumented systems e.g. Pressure Relief Systems)

- Safety Instrumented Systems (SIS)

  Lifecycle Approach: A selection of SIS linked to major accident scenarios should be provided in the report. Information provided should be as indicated below. For SIL rated systems, providing the identified information should be straightforward, however, for legacy systems there will be gaps. The Company should identify these information gaps and state how they have reviewed, or intend to review, these systems in accordance with current standards, and also to demonstrate that risks have been reduced to ALARP. For higher claims of risk reduction (e.g. SIL2 or SIL3 rated systems) more detail should be provided.

Information about SIS should include:

- Design and Standards used for achieving functional safety of SIS (e.g. in house, BSEN 61508/61511 or other).
- How safety Safety Requirements Specification can be traced to a structured Hazard identification/Analyses process (e.g. HAZOP or similar).
- Clear specification of what the system is designed to do.
- How target reliability has been determined from suitable risk assessment.
- How the safety requirements specification has been achieved via hardware and software from sensor to final element.
- How is it achieved by initial design/installation and by subsequent proof testing.
- Suitable maintenance of system.
- Suitable modifications procedures.

- Utilities, especially power supply.
    - ♦ Design basis.
    - ♦ Continuing integrity of electrical distribution systems including earthing, HV&LV (non hazardous areas).
    - ♦ Load shedding and effects on plant stability.
    - ♦ Lifecycle integrity of instrument air system

- Electrical systems in hazardous areas.
    - ♦ Suitable Hazardous Area Classification
    - ♦ Electrical/instrumentation equipment suitably protected for designated zone.
    - ♦ Suitable proactive maintenance system in place

- Fire & Gas detection systems.
    - ♦ Technology description
    - ♦ Safety requirements specification.
    - ♦ Reference to design standards.
    - ♦ Rationale for positioning of detectors
    - ♦ Measures in place for protecting detectors against poisoning.
    - ♦ Maintenance and testing procedures for systems.

- Management issues:
    - ♦ Competence in assessing the control system.
    - ♦ Competence demonstration (where an operator is part of the control system).
    - ♦ Competence of proof testing and maintenance personnel.
    - ♦ Specific technical training for maintenance (electrical systems, control systems).
    - ♦ General Safety Management System for proof testing.
    - ♦ Competence in analysing effects of loss of power.
    - ♦ Safety Management System for software design teams.

Human factors assessment

20 General issues for assessment:

Looking for evidence of:

- Identification of the parts that people play in protection, prevention, potential initiation, and recovery from major accidents.
- Human performance requirements being addressed with the same degree of rigour traditionally expected for process and engineering issues.

21 Key technical issues for human factors assessment:

- Human systems (manual measures) and the justification of the allocation of safety critical function to humans.
- Performance standards for all safety-critical and key safety-related human tasks in the measures for prevention, control and mitigation of major accidents:

- Human performance requirements identified e.g. speed, accuracy, vigilance, communications, detection, diagnosis, physical actions, skills.
- Performance requirements within the limits of human capability.
- Performance requirements supported by workplace design, i.e. supported by information, controls and access for the operators, alarm systems design, ergonomics of process control interface, ergonomics of machinery and equipment.
- Exercises of infrequent tasks to maintain performance standards.

- Evidence of physical and mental fitness assurance:
  - Of safety critical staff
  - Including consideration of fatigue from shiftwork and overtime.

- Manning and supervision philosophy:
  - Roles and responsibilities for authorisation, decisions, communications for safety critical tasks.
  - Justification of demanning.

- Activities relying on human decisions and actions are supported by procedures:
  - Procedure design.
  - Task analysis.

- Staff selection, training, refresher training and competence assessment.
- Reliability and monitoring of human performance.
- Speed of response.
- Availability.
- Workload.
- Consideration of demands in abnormal conditions.

Demonstration requirements

22 Assessment is about reaching conclusions on the demonstration. The onus is on the Duty Holder to justify the measures in place. The demonstration requires:

- Justification of a particular design. Explain how this links to the reduction of major accident risks to ALARP, and how this is achieved through diversity and integrity of selected measures.
- Description of in-service inspection and maintenance regime.
- Compliance with guidance. If the offsite risk is small then compliance with guidance can be sufficient but if larger populations can be affected then additional measures will need to be considered.
- The depth of protection measures are proportional to risks arising from major accident scenarios.
- Further risk reduction options are considered and arguments that are proportionate to the hazard and risk are provided where options were not implemented.

- Specification of not just what but also why measures are provided i.e. the link between measures and their role in major accident prevention or mitigation. The arguments justifying a particular design are important to the ALARP demonstration.
- A description of the site development history from conception to the present.

Judgements

23 If demonstration requirements are missing, the assessor may ask for further information. This information will be deemed part of the report at that stage and conclusions will be reached as to whether or not the demonstration has been made. Information not, or inadequately, supplied may become an issue for resolution within the planned intervention strategy for the establishment.

24 Triggers leading to requests for further information might include:

- Insufficient evidence to justify not providing an identified measure.
- Missing or vague information such that a judgement cannot be made, including inadequate definition of terms.
- Lack of a philosophy or system such that it is not clear if the measure is systematically applied.
- Incorrect information.
- Failure to comply with relevant legislation.
- Failure to comply with guidance or meet good industry practice.
- Missing systems or major components of a system which can be shown to lead to a major accident hazard.
- No indication of checking, testing, inspecting, monitoring of condition of measures.
- Failure to comply with guidance or use of inappropriate standards.
- Unsuitable materials.
- Inadequate measures.
- Absence of maintenance priorities or regime.
- Inadequate inspection regime.
- Incompatibilities between data.
- Overconfidence in performance standards.
- Performance standards not given.
- Over-reliance on correct and timely human responses.
- Inconsistencies within the safety report.
- Conflicts with the CA’s knowledge of the establishment and its operations.

Pre-construction and pre-operation safety reports

General

25 All technical assessment criteria are available for consideration of Pre-Construction Safety Reports (PCSRs) and Pre-Operational Safety Reports (POSRs) in so far as information is available. However, the timing of these reports will, in practice, limit the available information. The following outlines some of the principal assessment focus elements relating to PCSRs and POSRs.

26 Assessment of PCSRs should focus on the 'front end' design aspects in the assessment criteria and, in particular, the approach to considering the adoption of inherent safety principles in the proposed design. The conceptual design option selection process and the consideration of potential major hazards in reaching the selected final design should be described. Specific design issues relating to the prevention of accidents during the construction and commissioning phase, considered prior to the introduction of dangerous substances, should also be addressed.

27 **Justification** of the chosen design and how it reduces risks to ALARP is an important element of the PCSR as the options for necessary change and improvement are more easily addressed at this early stage. The link between identified major hazards and the proposed key technical measures is an important part of this justification. Description of the chosen design, without some indication of key decisions (linking hazards and measures) behind the rejection of other considered principal design features or options, only addresses the chosen design and fails to explain why other options do not offer better opportunity to reduce risk to ALARP. Assessment will necessarily be limited to information that is reasonably available at the time the report is submitted

28 Assessment of POSRs should focus on amendments made to the design and construction, and any additional information since the PCSR, and whether the plant meets the design intent. Commissioning controls will also be an important assessment issue.

29 The combined information contained in the PCSR and POSR report should be equivalent to that contained in a safety report for an existing establishment.

PCSR and POSR specific issues

30 The boundaries between PCSRs and POSRs and the information they contain will depend upon the timing of submission and the information available for inclusion. The following guidance should be applied to the PCSR or POSR as appropriate to the time of submission of the report and the depth of information contained.

- The impact of features and integrity of the design, specific to meeting the needs of the construction or commissioning process and the assessment of their impact for major accident hazards should be described. (e.g. extraordinary loads imposed by water pressure testing, temporary arrangements affecting layout, utilities, etc. during construction and commissioning phases.).
- The impact for temporary isolation and connections to contribute to potential loss of containment or other major hazard during or after commissioning, and the arrangements in place for their control should be

described (e.g. planned management controls for design, construction and commissioning; designed integrity of temporary systems.).

- Account taken of Human Factors controls associated with a period of high activity using a large body of contracted personnel may pose specific issues to be addressed by safety management arrangements.
- Planned maintenance arrangements during the commissioning period may differ from those expected during normal plant operation (e.g. use of contractors, changed responsibility arrangements, etc.).
- The level of detail design change during the construction and commission period is potentially significant and requires effective change control management systems. In normal operation, modification procedures will typically form part of the operator's management system. However, during the design, construction and commissioning phases, other systems for change management may be applied (e.g. design contractor's in-house systems, other contractor systems, etc.). The dovetailing of temporary arrangements prior to operation and the company's own management systems should be described where appropriate.
- The PCSR should identify key activities that are yet to be undertaken during the development of the design. Whilst details of these activities may not be well developed, the key areas of the design that are likely to be affected and the potential sensitivity of described arrangements to the planned future work should be described as far as is reasonably practicable. It should be possible for the assessor to readily cross-reference changes between the PCSR and the POSR.

Technical assessment criteria and guidance

31 The following appendices contain tables of technical assessment criteria for each of the primary technical disciplines (Process Safety, Mechanical, Control and Instrumentation, Human Factors). Guidance to the criteria is provided in bullet point format to provide a checklist of issues that may require consideration by CA assessors.

32 Assessors should use the guidance as appropriate in relation to:

- The site specific circumstances described in the safety report.
- Their professional experience and judgement.
- The scope of assessment in the agreed Target Agenda.

Assessors are not obliged to address every criterion or its guidance in full.

33 The full guidance for technical assessment is formed by the contents of all four technical discipline appendices. Where no guidance has been indicated for a discipline against any particular criterion, this does not infer that the criterion has no relevance to that discipline, but means that the criterion is not a primary focus area for that discipline. Assessors are not obliged to address solely the criteria and guidance in the Appendix relevant to their specific discipline as the boundaries of discipline interest in assessment criteria may overlap. However, where assessment by a discipline assessor leads to areas that interface with another discipline assessor's principal scope of assessment, assessors should, where appropriate,

seek to reach an agreement at an early stage on who will lead on a topic or on issues arising. This is to avoid unnecessary duplication of assessment.

34 The guidance to the criteria provides a framework for assessment and is not intended to provide detailed topic specific technical guidance. Detailed topic technical guidance exists on the relevant Website and/or Intranet. This guidance is available as part of the CA's corporate knowledge base addressing technical issues and practices

Appendix 12.1: Process Safety Criteria and Guidance

Process Safety Criteria	Guidance
Criterion 12.1 **The safety report should show a clear link between the measures taken and the major accident hazards described** **[Schedule 4 Part 1 para 2; Schedule 4 Part 2 para 4(a), 4(c), 5]**	This is the core of the Safety Report from the technical point of view and provides the link between identification and analysis of hazards and the selection of measures. • The operator recognises the hazards/scenarios. • Control measures are **linked** to specific scenario(s). • It is clear how decisions are made for reducing risks ALARP. • The safety report explains decision criteria for selecting measures. For a representative set of scenarios from the predictive analysis: • The report demonstrates how risks have been reduced to ALARP and are tolerable. • The report demonstrates adequate diversity and redundancy in the control measures (appropriate to the SIL). • The report demonstrates there are no further reasonably practicable risk reduction measures the operator could take.
Criterion 12.2 **The safety report should demonstrate how the measures taken will prevent foreseeable failures which could lead to major accidents**	This is effectively a summary of all the other criteria, looking at the overall picture. The assessor should come back to this when the other criteria have been considered, and then consider: • Whether all the assessed criteria have been met. • How significant the failure of one or more criteria is to the overall safety justification. • Any failure to recognise appropriate standards. • Full application of standards and any deviations from the standards.
Criterion 12.2.1.1 **The safety report**	The Safety Report specifies the standards and codes of practice used as the basis for the design of the

Process Safety Criteria	Guidance
should show that the establishment and installations have been designed to an appropriate standard. **[Schedule 4 Part 1 para 3; Schedule 4 Part 2 para 4(c), 5(a)]**	plant and the selection of appropriate risk control measures. The Safety Report recognises that some of the design is outwith the standards and codes and describes the process for managing deviations and exceptions to ensure that safety and environmental protection is not compromised. • The safety report specifies: • Potential demands placed on systems such as: ♦ Trip systems ♦ Operators responding to alarms • Performance standards for on-demand systems: ♦ Accuracy and speed of response of operators. • The Safety Report shows that the performance standards are adequate: ♦ That the measure has a sufficiently high availability. ♦ That performance standards (reliability, availability, accuracy, speed of response etc.) have been verified such that the operator can demonstrate the measures work according to the standards.
Criterion 12.2.1.2 **The safety report should show that a hierarchical approach to the selection of measures has been used.** **[Schedule 4 Part 1 para (3); Regulation 4]**	This is an important criterion which has a closely defined 4 stage hierarchy: **eliminate** (inherent safety), **prevent**, **control**, **mitigate**, in that order of priority. • The Safety Report considers reducing the quantities of hazardous substances stored or used in the process: ♦ Consideration is given to using alternative less hazardous substances. ♦ A case is made for the amount and type of each hazardous substances. • Consideration of intensified processes, e.g. smaller semi continuous processes instead of large batch processes. • Alternative inherently safer processes have been considered, e.g. to eliminate or reduce the risk of a runaway reaction.

Process Safety Criteria	Guidance
	• The Safety Report identifies the operational measures which prevent excursions/loads. • For preventive measures the Safety Report demonstrates: ♦ Redundancy, diversity and availability of these measures ♦ A safety management system. • Where there are hazards there are control systems (hardware) including: ♦ Corrective systems. ♦ Shutdown/shutoff. ♦ Venting and disposal. • Where there are no control systems, the Safety Report shows that there are adequate preventive measures: ♦ e.g. if a runaway reaction cannot be controlled are there good (standard, best practice) measures for prevention of runaway? • Priority is given to passive measures over active measures. • It can be concluded that the Safety Report demonstrates an approach to selecting measures that is proportional to the risks.
Criterion 12.2.1.3 Layout of the plant should limit the risk during operations, inspection, testing, maintenance, modification, repair and replacement. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	Layout issues for process will link to the ability to conduct process operations during normal and emergency situations. • Layout plans show relative layout of process equipment, hazardous inventories and the separation of hazardous and less/non operational hazardous areas. • Plans show location of emergency utilities (e.g. firewater). • Layout considers hazardous interaction between released materials. • Layout considers human emergency response to process events (i.e. can operators do what they need to do in identified emergencies?), etc • Where there is venting (e.g. to mitigate exothermic runaway) the Safety Report demonstrates that any vented material goes to a safe and suitable location. • Layout considers access for process operator

Process Safety Criteria	Guidance
	functions, e.g. location of key manual process isolations. • The risks associated with equipment being adjacent to each other been considered: ♦ There is a justification for not having extra barriers or changing the layout. ♦ Segregation of reactive materials in storage or transport. **Note:** for an operating plant, redesign is much more difficult than adding control systems for reducing risks ALARP (e.g. routeing and location cannot be easily retrofitted).
Criterion 12.2.1.4 Utilities that are needed to implement any measure defined in the safety report should have suitable reliability, availability and survivability. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c), 5(a)]**	• The Safety Report presents an evaluation (where relevant) during normal and abnormal operation of: ♦ Loss of power. ♦ Loss of air. ♦ Loss of nitrogen. ♦ Loss of cooling. ♦ Loss of heating. ♦ Fire water supply. ♦ Other safety critical utility (e.g. fuel / purge). • The Safety Report presents an evaluation of the significance of the different utilities to the particular processes (eg cooling water important for an exothermic process). • The Safety Report demonstrates how utilities have been designed in relation to minimising the consequences of major accident scenarios. • Independent supplies are provided where necessary (eg mains water supply is avoided where water pressure and reliability of supply is critical).
Criterion 12.2.1.5 The safety report should show that appropriate measures have been taken to prevent and effectively contain releases of dangerous substances. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c), 5(a)]**	Where there could be releases, the Safety Report adequately describes measures such as bunding or other forms of secondary containment and controlled disposal systems such as venting into dump tanks (see also 5.2.1.7). • The safety report shows that the proposed measures are adequate, e.g.: ♦ Overtopping of bunds has been considered through suitable sizing criteria and structural design. ♦ The consequences of overtopping has been

Process Safety Criteria	Guidance
	considered.
Criterion 12.2.1.6 The safety report should show that all foreseeable direct causes of major accidents have been taken into account in the design of the installation. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	Direct causes of loss of containment should be considered during design. For process safety considerations, the report should address (where applicable) the following direct causes: • Corrosion: ♦ Systems for selection of materials for process equipment and systems exposed to corrosive environments (internal and external). ♦ Consideration of the effects of foreseeable changed process conditions or contaminants in the corrosion prevention arrangements. ♦ Special corrosion monitoring philosophy and arrangements. • Erosion: ♦ Design for solids or abrasive flow conditions, cavitation, phase changes, etc. • Pressure: ♦ Identification of sources of overpressure or underpressure (vacuum), e.g. high/low pressure interfaces, failure of control devices, external fire, failure of safety devices, reactions, thermal expansion, utility failure, etc.. ♦ Designed systems to prevent overpressure described linked to recognised standards. • Temperature: ♦ Identification of sources of excessive high or low temperature, e.g. fire, freezing, loss of utility, failure of control devices, external environment, rapid differential thermal effects, etc.. ♦ Designed systems to prevent temperature excesses and effects, e.g. insulation, tracing, deluge, protective barriers, layout, etc.. • Vibration: ♦ Identification of process driven vibration sources with the potential to cause a major accident, e.g. water hammer, reciprocating systems, cavitation, phase changes, etc. and how this has been considered in

Process Safety Criteria	Guidance
	design. • Human Error: ♦ Identification of sources of human error in process operations, e.g. maloperation of valves and equipment, lack of process hazard awareness, misunderstood commands, unrealistic demands, lack of specific training or process knowledge, etc.. ♦ Identification of measures aimed at minimising human error, e.g. dedicated storage and transfer systems, coupling design to prevent cross connection, etc.. ♦ Identification of extent of safety criticality attached to human actions and how this is catered for in design. Realistic performance standards for safety critical functions during normal and emergency conditions, etc.. ♦ Defence in depth to minimise the effect of human failure. ♦ Control of process design functions to minimise design error. Note: It is unacceptable for the safety report to have no explanation of how the identification of direct causes of LOC has been conducted.
Criterion 12.2.1.7 **The safety report should show how structures important to safety have been designed to provide adequate integrity.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.8 **The safety report should show how the containment structure has been designed to withstand the loads experienced during normal operation of the plant and all foreseeable operational**	• Details of foreseeable plant normal and abnormal operating conditions, including internal and external conditions, start-up, shut-down, turnaround, regeneration, degradation, emergencies, etc.. • Description of philosophy for setting design margins over foreseeable operating conditions. Tight operating margins may require justification where they are relevant to safety of

Process Safety Criteria	Guidance
extremes during its expected life. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	operation. • Identification of significant high / low pressure interfaces or differential pressures affecting design and overpressure protection arrangements (there have been spectacular failures due to a failure to appreciate this issue). • Recognition of high / low temperatures and impact on permitted operating pressures. Design conditions should take account of foreseeable coincidental extremes of pressure and temperature. Recognition of the possibility of low temperatures creating a vacuum.
Criterion 12.2.1.9 **The safety report should show that materials of construction used in the plant are suitable for the application.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.10 **The safety report should show that adequate safeguards have been provided to protect the plant against excursion beyond design conditions** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	In general terms, the safety report should: • Give details of the physical parameters of possible conditions: flows, temperatures and pressures with respect to excursions, runaway, worst case scenarios, etc.. • Demonstrate that the design standards and other applied codes of practice are appropriate to the conditions under which the design must work. • Show that hazard identification has covered the possibility of beyond design conditions. For process systems, the use made of code allowable short-term overstress conditions should be identified and justified and any links to the predictive analysis made where appropriate. • Describe the evaluation of excursions in chemical reactions, process operations, etc. and justify the sufficiency of the controls. • Describe the philosophy for the required failure modes of valves (i.e. fail to safety).

Process Safety Criteria	Guidance
	• Show that accident history for a type of plant has been considered where relevant. • Justify non-use of recognised safeguards. • Normal operating limits: ♦ Appropriate manual or automatic control systems to maintain normal operating conditions. ♦ Appropriate use of alarms to warn operators of operating excursions beyond normal ranges. • Safe operating limits: ♦ Identification of *safety related controls and alarms* designed to prevent or warn of excursion beyond safe operating limits and upon which the safety of the plant is based. ♦ Integrity of safety related controls (functionality, reliability, vulnerability, survivability, dependence on other systems). ♦ Pressure relief and emergency venting arrangements, dump systems. ♦ High integrity pressure protection systems (HIPPs) used in place of, or in conjunction with, mechanical overpressure protection systems and other control measures should be justified and shown to be of adequate integrity. ♦ Interfaces with other measures such as shut-off of systems, flushing, reaction inhibitors, cooling systems, venting systems, etc. to limit excursions beyond safe operating limits should be described.
Criterion 12.2.1.11 The safety report should describe how safety-related control systems have been designed to ensure safety and reliability **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.12 The safety report should show how systems which require	The Safety Report shows: • Any safety critical operations carried out by operators.

Process Safety Criteria	Guidance
human interaction have been designed to take into account the needs of the user and be reliable **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	• How the operator knows when to intervene to carry out such an operation. • That assumptions regarding the availability and integrity of required human response during foreseeable normal and emergency operating states are justified. In particular, that important process safety critical control actions will not be jeopardised by changes in staff arrangements, that time to achieve operations has been taken into account, or that the safety of the design is otherwise not critically compromised by failure of required operator response due to foreseeable causes (e.g. lack of training, human response under high stress, exposure to hazards preventing required action, etc.). • That suitable performance standards have been developed and are monitored for safety critical operator functions. • An adequate and achievable response where operator intervention is a safeguard e.g. for detection and correction of deviations. • For batch plant operations: consideration of possibility of steps being omitted / repeated / carried out in the wrong order. **Note:** If human response is safety critical, the assessor should seek evidence that the company has examined the costs and benefits of having an automated system and justified the suitability of the adopted approach.
Criterion 12.2.1.13 The safety report should describe the systems for identifying locations where flammable substances could be present and how the equipment has been designed to take account of the risk. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	The Safety Report shows (ie, the Operator understands): • The procedures and policies for identifying hazardous areas are based on established codes and standards (ie the operator is aware of them). The procedures and policies for identifying hazardous areas are consistently applied. • Releases of flammables through vents, from leaks from gaskets and when equipment is opened have been considered (i.e. where the leaks are likely to occur and what are the release parameters and flammable properties of release materials are likely to be). • A diagram with hazardous area classification for the site.

Process Safety Criteria	Guidance
	• The hazardous area classification data is used in the selection and location of equipment and its maintenance and in considering plant and process changes. • The relevance and understanding of the Dangerous Substances and Explosive Atmospheres Regulations (DSEAR). **Note:** Process Safety assessors are mainly checking what the company is doing with regard to the physical area. Control and Instrumentation assessors are looking at the electrical equipment. Mechanical assessors may also have input for equipment with the potential to generate hot surfaces sufficient to be a source of ignition).
Criterion 12.2.2.1 **The safety report should show that the installations have been constructed to appropriate standards to prevent major accidents and reduce loss of containment** **[Schedule 4 Part 1 para3(a)]**	
Criterion 12.2.2.2 **The safety report should describe how the construction of all plant and systems is assessed, and verified against the appropriate standards to ensure adequate safety.** **[Schedule 4 Part 1 para3(a)]**	
Criterion 12.2.3.1 **The safety report should show that safe operating procedures have been established and are documented for all reasonably foreseeable conditions.**	• There is sufficient description about the safety management aspects of developing safe operating systems to avoid a major accident. • There is evidence of operational procedures which cover all reasonably foreseeable situations. • Procedures should be readily available to operators and be current.

Process Safety Criteria	Guidance
[Schedule 4 Part 1 para3(b)]	• There is explanation of how the operator develops, maintains and reviews procedures. • The Safety Report describes the process for development of procedures. It is a team exercise involving people with different skills (ie, technical input to the content to ensure hazards are properly identified and controlled). **Note:** There is quite a big overlap with SMS in relation to integrating process safety knowledge into procedures
Criterion 12.2.4.1 **The safety report should show that an appropriate maintenance scheme is established for plant and systems to prevent major accidents or reduce the loss of containment in the event of such accidents.** **[Schedule 4 Part 1 para3(b)]**	
Criterion 12.2.4.2 **The safety report should show that there are appropriate procedures for maintenance that take account of any hazardous conditions within the working environment.** **[Schedule 4 Part 1 para3(b)]**	
Criterion 12.2.4.3 **The safety report should show that systems are in place to ensure that safety critical plant and systems are examined**	

Process Safety Criteria	Guidance
at appropriate intervals by a competent person. **[Schedule 4 Part 1 para3(b)]**	
Criterion 12.2.4.4 **The safety report should show that there is a system in place to ensure the continued safety of the installations based on the results of periodic examinations and maintenance.** **[Schedule 4 Part 1 para3(b)]**	
Criterion 12.2.5.1 **The safety report should describe the system in place for ensuring modifications are adequately conceived, designed, installed and tested.** **[Schedule 4 Part 1 para3(a); Schedule 4 Part 2 para 4, 5(a); Schedule 2 para 4(d)]**	• The safety report demonstrates that there is a system for dealing with: ♦ Modifications which are changes in process parameters, i.e. a robust change management system that looks at hazard and risks. ♦ Modifications which are changes in supplier. ♦ Whether a process change needs a HAZOP or other suitable technique. ♦ Updating operating procedures and other documentation. • The system includes **criteria** for determining when a process change is sufficient to need to go through a formal management of change process.

Appendix 12.2: Mechanical criteria and guidance

Mechanical Criteria	Guidance
Criterion 12.1 **The safety report should show a clear link between the measures taken and the major accident hazards described** **[Schedule 4 Part 1 para 2; Schedule 4 Part 2 para 4(a), 4(c), 5]**	This is the core of the Safety Report from the technical point of view and provides the link between identification and analysis of hazards and the selection of measures. • The findings from the hazard identification process have been used to identify the safety critical equipment for both pressurised and non-pressurised plant, including: ♦ Vessels. ♦ Tanks. ♦ Pipework. ♦ Seals. ♦ Joints and flanges. ♦ Protective systems e.g. relief devices, emergency isolations. ♦ Secondary containment. ♦ Rotating machines including pumps, compressors, turbines, agitators, conveyors, etc.. • The scenarios are representative. They can be used for focussing on: ♦ Low probability high consequence events e.g. failure of pressure vessels. ♦ Higher probability generally lower consequence events e.g. failure of small bore pipework. ♦ Direct causes of failure e.g., corrosion, mechanical impact, overpressure, etc.. • Maintenance and inspection: ♦ Maintenance system described is appropriate for the identified measures. ♦ The operator has a suitable and sufficient inspection regime.
Criterion 12.2 **The safety report should demonstrate how the measures taken will prevent foreseeable failures which could lead to major accidents**	This is effectively a summary of all the other criteria. The assessor should come back to this when the other criteria have been assessed, and then conclude: • Whether all the assessed criteria have been met. • How significant the failure of one or more criteria is/are to the overall safety justification.

Mechanical Criteria	Guidance
	• Any failure to recognise appropriate standards. • Full application of the standards and any deviations.
Criterion 12.2.1.1 The safety report should show that the establishment and installations have been designed to an appropriate standard. **[Schedule 4 Part 1 para 3; Schedule 4 Part 2 para 4(c), 5(a)]**	The safety report should describe relevant codes and standards. Where these deviate from recognised codes or standards, the following information should be in the Safety Report. • List of all deviations/exceptions. • Justification why these have been adopted. • Demonstration that the deviation or exception provides a level of integrity at least as high as that provided by the relevant code. This criterion is related to criterion 12.2.1.7.
Criterion 12.2.1.2 The safety report should show that a hierarchical approach to the selection of measures has been used. **[Schedule 4 Part 1 para (3); Regulation 4]**	This is an important criterion which has a closely defined 4 stage hierarchy: **eliminate** (inherent safety), **prevent**, **control**, **mitigate**, in that order of priority. For mechanical discipline assessment: • The identification of suitable management system controls for maintenance and inspection schemes as prevention measures. • The appropriate selection of equipment to minimise or prevent the likelihood or consequences of failure (e.g. use of sealless pumps, use of corrosion resistent materials, etc.).
Criterion 12.2.1.3 Layout of the plant should limit the risk during operations, inspection, testing, maintenance, modification, repair and replacement. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	Good layout in design may be influenced by equipment features: • Evidence that catastrophic failure of equipment has been considered in setting equipment layouts, (e.g. what might fail, would it create missiles and where might they go? Could the fallout from equipment failure be reduced by careful layout considerations (e.g. orientation)?) • Consideration of dropped objects arising from construction and maintenance. • Consideration of lifting restrictions relating to equipment maintenance and the impact for layout design. • Consideration of access limitations for maintenance and inspection.

Mechanical Criteria	Guidance
Criterion 12.2.1.4 **Utilities that are needed to implement any measure defined in the safety report should have suitable reliability, availability and survivability.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c), 5(a)]**	The utilities issues typically include failure of services which could lead to a major accident • The impact that the failure of utilities could have on the mechanical systems is assessed, including provision and integrity of back-up systems • Demonstration of the reliability of back-up systems through monitoring, alarm and testing regimes.
Criterion 12.2.1.5 **The safety report should show that appropriate measures have been taken to prevent and effectively contain releases of dangerous substances.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c), 5(a)]**	Initial integrity. Measures for prevention and containing releases. • The Safety Report describes suitable means for preventing loss of containment through the identification of integrity (function, reliability, vulnerability, survivability) of mechanical equipment such as: ♦ ESDVs ♦ Manually operated isolations in safety critical duty ♦ Excess flow valves and non-return valves ♦ Protection arrangements for rotating equipment, (e.g. cavitation, dry running, deadhead conditions, seal protection.) ♦ Joint integrity (flanged, screwed, couplings, etc.). ♦ Temporary repairs (e.g. clamps, wraps). ♦ Dry break couplings ♦ Bellows and flexible joints. ♦ Secondary containment.
Criterion 12.2.1.6 **The safety report should show that all foreseeable direct causes of major accidents have been taken into account in the design of the installation.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	Initial integrity Direct causes of loss of containment should be considered in the design of suitable measures. For mechanical considerations, the report should address (where applicable) the following direct causes of LOC: • Corrosion: ♦ Systems for selection of materials for process equipment and systems exposed to corrosive environments (internal and external). ♦ Consideration of the effects of foreseeable changed process conditions or contaminants in the corrosion prevention

Mechanical Criteria	Guidance
	arrangements. ♦ Corrosion monitoring philosophy and arrangements. Specific threats such as: Corrosion under insulation, deadlegs, buried or masked systems, soil/air interfaces etc. • Erosion: ♦ Design for solids or abrasive flow conditions, cavitation, phase changes, etc. • External loading: ♦ Equipment loadings, e.g. design of equipment and piping system supports for use during construction and normal operation. • Impact: ♦ Consideration in design for foreseeable sources of impact damage, including missiles, dropped objects and swinging loads during construction and maintenance, blast loadings. • Pressure: ♦ Designed systems to prevent overpressure or vacuum described linked to recognised standards. • Temperature: ♦ Designed systems to prevent excess mechanically induced temperature excursions described linked to recognised standards. ♦ Design for low temperature effects (e.g. brittle failure avoidance, freezing, etc.) • Vibration: ♦ Machine induced vibration ♦ Consideration of small bore connections and their supports. ♦ Consideration of process induced vibration, e.g. water hammer, reciprocating systems, cavitation, phase changes, etc. and how this has been considered in design. • Wrong Equipment: ♦ Equipment supply standardisation and management approaches to minimise LOC (e.g. small bore fittings).

Mechanical Criteria	Guidance
	• Defective equipment. • Human Error: ♦ Control of maintenance and inspection activities to reduce human contribution to LOC during system invasive activities. ♦ Training implications for LOC, hazard awareness, equipment specific training, etc.. **Note**: It is unacceptable for the safety report to have no explanation of how the identification of direct causes of LOC has been conducted.
Criterion 12.2.1.7 The safety report should show how structures important to safety have been designed to provide adequate integrity. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	Initial integrity This criterion applies to all major vessels, pipework, rotating machines (e.g. pumps, compressors, etc.) and valves if they feature in major accident scenarios. • There is demonstration of adequate initial integrity: ♦ By reference to international codes and standards. ♦ By reference to principal design parameters (e.g. design pressure and temperature) and category of construction if applicable. ♦ Relevance and applicability of codes and standards. In-house codes and standards should be assessed for their relevance (a suitably robust description of how the company has validated them) based on prima facie evidence. • When no standards have been used, or design parameters are not known: ♦ the company demonstrates fitness for purpose showing how it has conducted design reviews (for novel designs, mixing of standards, non-standard approaches). The impact of such novel design approaches on required systems for monitoring, maintenance, etc. should also be described to depth consistent with the potential risk of adopting such designs.
Criterion 12.2.1.8 The safety report	Initial integrity.

Mechanical Criteria	Guidance
should show how the containment structure has been designed to withstand the loads experienced during normal operation of the plant and all foreseeable operational extremes during its expected life. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	This criterion is related to criterion 5.2.1.7. • Compare design conditions with expected operating conditions for equipment and assess the margin: ♦ Adequate margins are demonstrated where appropriate. ♦ Where more extreme conditions might occur they have been accounted for in the design. ♦ Evidence is sufficiently proportionate to the risk and complexity of the process. Continuing integrity: • Demonstration of how the operator monitors and ensures the plant continues to operate within designed limits. Changed operating conditions may affect the intended performance of some plant, introducing additional hazards or integrity management requirements.
Criterion 12.2.1.9 **The safety report should show that materials of construction used in the plant are suitable for the application.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	• The Safety Report should demonstrate the compatibility between operating conditions and the material of the containment systems (eg, for known corrosive agents). (See Criterion 5.2.1.6.). The report should link the aggressive nature of the operating environment and operating conditions to the material selection process for specified equipment. • The report demonstrates a consistent approach in the choice of materials rather than just a catalogue of material specifications for the whole plant. • Description of Parent Metal Inspection (PMI) regime for verification of bought-in raw materials or equipment where applied (may be important for pre-construction of modification reports). [Note: Detailed issues about the suitability of certain materials may be carried forward to the inspection programme for existing sites, but may require raising directly for pre-construction or modification reports during the assessment stage.]
Criterion 12.2.1.10 **The safety report should show that adequate safeguards have been provided to**	Initial and in-service integrity. • Mechanical measures in place to prevent excursion conditions are described.

Mechanical Criteria	Guidance
protect the plant against excursion beyond design conditions **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	• Demonstration that appropriate provision has been made for excursion relief, through: ♦ Pressure or vacuum relief devices, or other pressure protection arrangements. ♦ Description where the nature of the process fluid may compromise effective operation of the relief devices (e.g. fouling). ♦ Description of relief system testing regimes. ♦ Description of potential excursions (e.g. overfill / underfill, starvation, cavitation, deadheading of pumps, etc.) ♦ Reverse rotation / overspeed of compressors or turbines. ♦ Provision of suitable measures within packaged units. (Proprietary packaged equipment may not meet the same standards adopted elsewhere in the overall design philosophy for the site).
Criterion 12.2.1.11 **The safety report should describe how safety-related control systems have been designed to ensure safety and reliability** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.12 **The safety report should show how systems which require human interaction have been designed to take into account the needs of the user and be reliable** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.13 **The safety report should describe the systems for identifying locations where flammable substances**	• The report identifies where mechanical equipment may generate an ignition source. (e.g. equipment hot surface generation potential, spark generation potential, etc.).

Mechanical Criteria	Guidance
could be present and how the equipment has been designed to take account of the risk. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.2.1 **The safety report should show that the installations have been constructed to appropriate standards to prevent major accidents and reduce loss of containment** **[Schedule 4 Part 1 para3(a)]**	Initial integrity This criterion is relevant to construction of new and recent (e.g. as part of a modification) plant so as to gain assurance that the construction phase will be effectively managed. This criterion likely to have a limited application for older plants because they are less dependent on the initial integrity issues. It is not unusual that construction or commissioning information is not be available for the old plant. Primary interest for established installations is more likely to be associated with modifications involving new plant integrated with old systems. For most equipment of interest to mechanical engineering, the Design Code (e.g. BS PD5500 for Pressure Vessels or BS2654 for Storage Tanks) will cover construction and inspection / test standards as well as design. This criterion will therefore generally be covered by assessment carried out against Criterion 5.2.1.7. • There is demonstration of adequate initial integrity: ♦ By reference to international codes and standards. ♦ By reference to category of construction if applicable. ♦ By explaining the relevance and applicability of codes and standards.
Criterion 12.2.2.2 **The safety report should describe how the construction of all plant and systems is assessed, and verified against the appropriate standards to ensure adequate safety.**	Initial integrity. Evidence has been provided to show that: • Initial inspection, testing and commissioning of the plant has been documented and the information is retrievable. [Note: Discussion of this topic should be provided

Mechanical Criteria	Guidance
[Schedule 4 Part 1 para3(a)]	even for older plant, where information may not be available, to indicate how the company has considered the implications for major accidents.]
Criterion 12.2.3.1 **The safety report should show that safe operating procedures have been established and are documented for all reasonably foreseeable conditions.** **[Schedule 4 Part 1 para3(b)]**	Continuing integrity. • Pre-operations and Operations safety reports should describe how it is assured that mechanical plant and equipment are always operated within safe limits?
Criterion 12.2.4.1 **The safety report should show that an appropriate maintenance scheme is established for plant and systems to prevent major accidents or reduce the loss of containment in the event of such accidents.** **[Schedule 4 Part 1 para3(b)]**	Continuing integrity. Not applicable to pre-construction reports Routine maintenance is a key issue (monitor, repair, replace mechanical plant and equipment). • The Safety Report indicates: ♦ There is a relevant proactive maintenance regime in place. ♦ There is a maintenance philosophy (e.g. time-based, reliability based, etc.). ♦ There a system of prioritisation of maintenance activity, especially relating to safety critical plant. ♦ Performance monitoring is in place. • The Safety Report describes: ♦ The maintenance administration system, including a department organogram, relevant job descriptions, roles and responsibilities. ♦ Overview of key maintenance activities. ♦ The safety critical activities where appropriate.
Criterion 12.2.4.2 **The safety report should show that there are appropriate procedures for maintenance that take account of any hazardous conditions within the working**	Usually only apply to the extent of identifying issues for the inspection programme where specific hazardous activities are identified.

Mechanical Criteria	Guidance
environment. **[Schedule 4 Part 1 para3(b)]**	
Criterion 12.2.4.3 **The safety report should show that systems are in place to ensure that safety critical plant and systems are examined at appropriate intervals by a competent person.** **[Schedule 4 Part 1 para3(b)]**	In-service integrity: Periodic in-service examination of safety critical plant. [Note: Not applicable to pre-construction reports.] Apply to all equipment containing hazardous fluids. • There is a system which enables learning from the results of maintenance and inspection and failure history (for impact on inspection frequency). • Inspection regime adequately described. • Inspection frequencies have been justified. • Inspection system shows appropriate prioritisation of safety critical equipment. • Inspection arrangements are described in the Safety Report such that: ♦ The indepenedence and competence of inspection staff is demonstrated, e.g. by reference to UKAS accreditation or compliance with relevant standards such as BSEN 45004. ♦ Where 1st, 2nd or 3rd party accredited organisations are employed. • Where there is Risk Based Inspection (RBI), the Safety Report: ♦ Gives an overview of system used (or reference). ♦ Indicates whether external consultants are used and in what capacity. ♦ Indicates how changes in inspection frequency indicated by the RBI process are managed (e.g. a cautious approach).
Criterion 12.2.4.4 **The safety report should show that there is a system in place to ensure the continued safety of the installations based on the results of periodic examinations and**	In-service integrity: This concerns the follow-up to inspections of Criterion 5.2.4.3. • Check for evidence of post inspection follow-up: ♦ Safety Report indicates that inspection findings are analysed with judgements on

Mechanical Criteria	Guidance
maintenance. **[Schedule 4 Part 1 para3(b)]**	continued fitness for service. ♦ The safety report indicates a system for reviewing inspection findings and a means of managing follow-up actions. ♦ Liaison and dialogue with independent inspection authorities, particularly where revisions of Written Schemes of Examination are necessary.
Criterion 12.2.5.1 **The safety report should describe the system in place for ensuring modifications are adequately conceived, designed, installed and tested.** **[Schedule 4 Part 1 para3(a); Schedule 4 Part 2 para 4, 5(a); Schedule 2 para 4(d)]**	Pre-construction and pre-operations report: • system in place for identifying and managing modifications during the design and build process Initial integrity: • Change may inadvertently reduce safety of plant: ♦ The modification concept has been properly addressed for mechanical integrity. ♦ The change control process addresses changes that might be made during construction that could affect mechanical integrity. In service integrity: • The modifications procedure integrates the integrity management of new mechanical plant and addresses the potential impact of new equipment on existing systems. • The modification procedure includes changes to existing plant.

Appendix 12.3: Control & instrumentation criteria and guidance

Control & Instrumentation Criteria	Guidance
Criterion 12.1 **The safety report should show a clear link between the measures taken and the major accident hazards described** **[Schedule 4 Part 1 para 2; Schedule 4 Part 2 para 4(a), 4(c), 5]**	• The report should provide links between the Major Accident Scenarios (MAS) and the risk reduction measures including, SIS. The level of demonstration should be proportionate to the consequence/severity of the MAS. • The choice of representative MAS should have been influenced by the requirement for the Company to demonstrate that risk reduction measures, including SIS, have suitable safety and reliability through design, and that this is maintained throughout the lifecycle of the system. • Where Safety Instrumented Systems are linked to reducing risk of MAS the report should clearly demonstrate how the reliability of those systems has been determined, and how this is commensurate with the risk analyses techniques used in the S.R for demonstration that risks have been reduced to ALARP. • For SIS designed to current recognised industry standards, such as BSEN61508/61511 it should be demonstrated that the risk assessment method used to determine Safety Integrity Levels (SIL) has been calibrated to take account of consequence/severity of major accident scenarios, and also that targets for acceptable residual levels of risk are at least as rigorous as those promoted in HSE guidance "Reducing Risks Protecting People". • For legacy systems (designed pre 61508/61511) it is often the case that initial requirements for SIS in terms of functionality and reliability have been determined from historical hazard identification processes, e.g HAZOPs. However, often the reliability of the SIS has not been determined from a risk assessment, or the risk assessment used at the time may not be suitable for COMAH purposes. The Company should clearly state what the current status is and any reviews they plan to carry out. • The assessor should note areas where there may be obvious SIS omissions. This should be discussed with appropriate members of assessment team and a decision made if it could be a credible further measure that the

Control & Instrumentation Criteria	Guidance
	Company should be implementing. In extreme cases this omission may be regarded as a serious deficiency. The risk assessment process should result in consideration of further measures for MAS. This should not be confined to the representative set.
Criterion 12.2 **The safety report should demonstrate how the measures taken will prevent foreseeable failures which could lead to major accidents**	See 12.1
Criterion 12.2.1.1 **The safety report should show that the establishment and installations have been designed to an appropriate standard.** **[Schedule 4 Part 1 para 3; Schedule 4 Part 2 para 4(c), 5(a)]**	• The S.R should include information on the standards used for: ♦ Safety Instrumented Systems ♦ Process Control Systems ♦ Hazardous Area Classification ♦ Standards used for design, maintenance/testing of EX equipment ♦ Design/maintenance/testing of: Fixed electrical systems H.V and L.V. ♦ Earthing systems ♦ Lightning protection systems ♦ Fire & gas detection systems The duty holder should identify and justify cases where the design of their installation fails to meet the established standards.
Criterion 12.2.1.2 **The safety report should show that a hierarchical approach to the selection of measures has been used.** **[Schedule 4 Part 1 para (3); Regulation 4]**	This is an important criterion which has a closely defined 4 stage hierarchy: eliminate (inherent safety), prevent, control, mitigate, in that order of priority. For electrical and control discipline assessment: • The report should describe the application of suitable layers of protection. A typical approach could be: ♦ Robust process control (including human interaction) ♦ Alarms to indicate excursions from normal operating envelope. ♦ Designated Safety Instrumented Systems. ♦ Final protection system (often mechanical, i.e. pressure relief systems, however, could be a high integrity SIS).

Control & Instrumentation Criteria	Guidance
	♦ Mitigation systems The number of layers and the amount of risk reduction for each layer should be relevant to the consequence/severity of the range of potential hazardous events.
Criterion 12.2.1.3 Layout of the plant should limit the risk during operations, inspection, testing, maintenance, modification, repair and replacement. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	The report should provide an overview of how the following has been considered. • How the layout of control, instrument and electrical equipment has taken account the needs of normal operations, maintenance and testing requirements, and emergency operations. • The location of control centres within the plant and their vulnerability to potential major accident events. This should have been subject to suitable risk assessments (including Occupied Buildings Assessments where applicable). • Layout of control room equipment to take account of normal and emergency control conditions (e.g. ergonomics of normal and emergency control panels). • Minimised vulnerability, and potential for common cause failure, of essential services to safety critical instrumented systems and key process control applications.
Criterion 12.2.1.4 Utilities that are needed to implement any measure defined in the safety report should have suitable reliability, availability and survivability. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c), 5(a)]**	• A description of each utility and its back-up systems should be provided. It should be identified which utilities are essential for operation of key safety systems. • The report should demonstrate that the effect of loss of key utilities has been considered as part of a structured hazard identification/analyses process. The assessment should have ensured that control systems and safety systems fail to a safe state and that the consequence of a utilities failure does not act as a major accident initiator. • Effects of loss of electrical supply on other utilities such as fire water provision, instrument and compressed air, nitrogen supplies should all have been considered in such an assessment. • Every power trip is a potential initiator. Suitable diversity and redundancy should be inherent

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	within systems to reduce the risk of common mode or common cause failures. Problems likely to be encountered include loss of internal generation, loss of hydraulic pressure to ESD valves, loss of air in air reservoirs on valves. • Consideration of the effects of dips in power supplies as well as full power loss. • Measures to detect failure of essential utilities should be described. • Demonstration that the electrical supply and associated protection systems have been designed and are being maintained to suitable industry standards. Electrical distribution systems should be designed to discriminate faults to prevent cascading the failure across the site. • Generators/UPS systems should be subject to suitable periodic maintenance/testing regimes. • Instrument air system should be described and quality specification should be included Normally ESD systems should fail to a safe state. However, safety related systems which rely on a positive power supply should be identified. Demonstrations should show that suitable provisions are in place to ensure that these systems achieve their required function under all foreseeable shutdown conditions.
Criterion 12.2.1.5 The safety report should show that appropriate measures have been taken to prevent and effectively contain releases of dangerous substances. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c), 5(a)]**	• Process failures to danger, including how instrumentation and control based failures can lead to loss of containment, should have been considered by suitable hazard identification and analysis techniques. • Demonstration that fire & gas detection systems are suitable for purpose should be made. Information should be provided on the following: ♦ Technology description ♦ Safety requirements specification. – i.e. what is it installed to do? ♦ Reference to design standards. ♦ Rationale for positioning of detectors ♦ Measures in place for protecting detectors against poisoning. ♦ Maintenance and testing procedures for

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	systems.
Criterion 12.2.1.6 **The safety report should show that all foreseeable direct causes of major accidents have been taken into account in the design of the installation.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	The report considers control, instrumentation and electrical systems and their use as a direct cause of failure, and discusses how this has influenced the selection of measures. Potential failure mechanisms for consideration include: • Corrosion ♦ Corrosion of electical and control systems which could lead to a direct failure, blockage of instruments by corrosion products. Materials selection should be suited to the process • Erosion ♦ Erosion of internal instrument components due to solids, abrasive flow conditions, cavitation, phase change, high pressure drop, etc. • External Loading ♦ Assessment of potential risks to plant from lightning. Suitable protection systems to prevent/mitigate fire/shock and to provide surge protection systems should be installed where necessary. References to suitable industry standards should be made. • Wrong Equipment ♦ The report addresses instrumentation as a direct cause of failure, e.g.use of wrong type of equipment such as transmitters, etc. • Human Error ♦ Failures derived from misuse of safety system overrides during normal operation or after maintenance, under temporary operating arrangements, etc.
Criterion 12.2.1.7 **The safety report should show how structures important to safety have been designed to provide adequate integrity.** **[Schedule 4 Part 1**	

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para3; Schedule 4 Part 2 para 4(c)]	
Criterion 12.2.1.8 **The safety report should show how the containment structure has been designed to withstand the loads experienced during normal operation of the plant and all foreseeable operational extremes during its expected life.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.9 **The safety report should show that materials of construction used in the plant are suitable for the application.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	Corrosion and the products of corrosion can impact on the reliability of safety instrumented systems: • Corrosion/erosion potential has been taken into account in material selection and affected the selection of equipment (e.g. Hi/Lo pressure letdown; entrained solids; use of protective barriers for transmitters, etc.). • Awareness that products of corrosion may be sourced remote from the location of affected instrumentation (i.e. system awareness is required in selecting measures) [Note see also Criterion 12.2.1.6]
Criterion 12.2.1.10 **The safety report should show that adequate safeguards have been provided to protect the plant against excursion beyond design conditions** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	• There is an appropriate overall process control strategy based on an understanding of the hazards associated with the processes, derived from structured identification and analysis of those hazards. There should be a system for determining, recording and reviewing safe operating limits and how these relate to control, alarm and trip settings: • There should be in place a system for reviewing settings based on operating history and accounting for any modifications. • The safety report describes how maintenance activities are prevented from overcoming

Control & Instrumentation Criteria	Guidance
	safeguards such as interlocks and the integrity of safety related control systems.
Criterion 12.2.1.11 The safety report should describe how safety-related control systems have been designed to ensure safety and reliability **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	• If the Safety Instrumented System (SIS) was designed after BSEN61508 standard was released (2000) it, or some suitable alternative, should have been used to design the system. OR • If the system has been designed prior to this date then evidence should be provided, which demonstrates that suitable levels of safety and reliability have been incorporated in the design of the system. The duty holder should also state the principles of design that were inherent within the legacy standard and were later incorporated in BSEN61508. • The SR should also state clearly the intention of the Company with regard to carrying out reviews of legacy systems to current standards such as BSEN61508/61511. • Demonstration of suitable safety and reliability may be achieved through use of examples of SIS linked to major accident scenarios. The information provided should include: ♦ A description of the safety related system and its functions. ♦ Details of the standards the system was designed to. ♦ The process by which the required risk reduction and safety integrity for the function was identified. ♦ How the Company ensures that the relevant safety integrity is achieved through design of the system, and is continued throughout its lifecycle by suitable proof testing and maintenance.
Criterion 12.2.1.12 The safety report should show how systems which require human interaction have been designed to take into account the needs of the user and be reliable **[Schedule 4 Part 1**	• The safety report shows that over reliance on operators to prevent, control or mitigate hazardous events is avoided. • Process control systems which are highly reliant on operator intervention to keep the process within safe operating envelopes should have suitable independent safety layers of protection to prevent, mitigate hazardous events. In arrangements such as these the assessor should examine the potential for high

Control & Instrumentation Criteria	Guidance
para3; Schedule 4 Part 2 para 4(c)]	demand rates on the safety related layers of protection. • Where the operator is part of a safety related control loop, and so has a performance function, the duty holder should have realistically assessed the reliability with which the operator performs the function. • The Company should provide information to describe how they have assessed effects of alarms experienced by operators in normal operation. This should also consider the potential for alarm flood situations in shutdown situations. (Note: EEMUA guidance is a widely recognised baseline standard.) •
Criterion 12.2.1.13 The safety report should describe the systems for identifying locations where flammable substances could be present and how the equipment has been designed to take account of the risk. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	• Examples of hazardous area assessments related to MAS areas should be included in the report. This should have been carried out to current industry standards (DSEAR, BSEN 60079-10). Assessment for dusts should also be provided. [Note: overlap with Process Safety] • • Other ignition sources should also have been considered. Look for mention of – lightning protection, radio frequency ignition, static electrical discharges (internal and external), vehicles and fork lift trucks, portable equipment (particularly visitor's). •
Criterion 12.2.2.1 The safety report should show that the installations have been constructed to appropriate standards to prevent major accidents and reduce loss of containment **[Schedule 4 Part 1 para3(a)]**	For control, instrumentation and electrical systems, the safety report: • Demonstrates appropriate construction controls to ensure plant is built in accordance with design and to appropriate construction standards. • Demonstrates competency of construction personnel. • Considers the impact of planned construction activity on existing facilities and their safe operation where relevant. • Describes systems to manage, assess and record changes arising during construction.
Criterion 12.2.2.2	For control, instrumentation and electrical systems,

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The safety report should describe how the construction of all plant and systems is assessed, and verified against the appropriate standards to ensure adequate safety. **[Schedule 4 Part 1 para3(a)]**	the safety report should demonstrate that initial commissioning information regarding inspection and testing of the plant is documented, and that the information is retrievable. Subsequent changes to settings etc. should be recorded and part of suitable modifications procedures. (See section 12.2.5.1). For Pre-Construction and Pre Operations reports: • Description of the verification processes applied during construction phase activities associated with relevant systems. • Description of arrangements for commissioning trials to confirm required performance, limits of operation and safety provisions. • Description of documentation arrangements for recording of verification activities and results associated with construction.
Criterion 12.2.3.1 **The safety report should show that safe operating procedures have been established and are documented for all reasonably foreseeable conditions.** **[Schedule 4 Part 1 para3(b)]**	All safety reports should describe how it is assured that electrical, control and instrumentation systems and equipment are always operated within safe limits.
Criterion 12.2.4.1 **The safety report should show that an appropriate maintenance scheme is established for plant and systems to prevent major accidents or reduce the loss of containment in the event of such accidents.** **[Schedule 4 Part 1 para3(b)]**	For control, instrumentation and electrical systems: • The Safety Report should provide relevant information and examples that demonstrate: ♦ There are suitable proactive maintenance/ testing / inspection regimes in place based on relevant industry standards. ♦ There is a suitable maintenance administration system. ♦ Planning of work is carried out in a structured fashion. ♦ There a system of prioritisation of work. ♦ Safety critical activities are clearly identified ♦ There is proof testing of safety instrumented systems. ♦ Fixed electrical & earthing systems are subject to suitable periodic inspection/maintenance and testing.

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	♦ Process instrumentation should also be subject to suitable maintenance/calibration and testing. ♦ Performance monitoring is in place • The duty holder should demonstrate that persons carrying out maintenance/testing are competent to do so and that: ♦ Recognised schemes for training are used. ♦ There is ongoing refresher training. ♦ In accordance with basic engineering standards, the duty holder uses recognised schemes for training in areas of specialised maintenance, inspection and testing. Test Equipment and Tools: • Suitable procedures should be in place to ensure that: ♦ test instruments and tools are suitable for purpose. ♦ Calibration of test equipment is carried out on a regular basis by competent persons. ♦ Accredited test houses are used to calibrate key test equipment.
Criterion 12.2.4.2 The safety report should show that there are appropriate procedures for maintenance that take account of any hazardous conditions within the working environment. **[Schedule 4 Part 1 para3(b)]**	• Demonstration should be made that suitable procedures are in place to ensure that maintenance /testing of electrical and instrumentation systems is carried out in a safe fashion. It is essential that the Company have considered the risks for both personal safety and for the potential hazardous effect the work may have in terms of initiators on the plant. • For potentially hazardous work suitable safety management procedures should be in place. This should be based on suitable risk assessments, or in the case of more hazardous situations be carried out under a suitable Permit To Work system. • Company should have a set of Electrical Safety rules based on current industry standards. (e.g. current editions of HSG85, Memorandum of Guidance, Electricity at Work Regulations should be used as benchmark).
Criterion 12.2.4.3 The safety report should show that systems are in place to ensure that safety	See also 12.2.4.1 and 12.2.4.2 • The safety report should provide examples of how proof testing for Safety Instrumented Systems (SIS) is carried out and how test

Control & Instrumentation Criteria	Guidance
critical plant and systems are examined at appropriate intervals by a competent person. **[Schedule 4 Part 1 para3(b)]**	intervals are determined and reviewed (taking account of performance).
Criterion 12.2.4.4 **The safety report should show that there is a system in place to ensure the continued safety of the installations based on the results of periodic examinations and maintenance.** **[Schedule 4 Part 1 para3(b)]**	Addressed in 12.2.4.1
Criterion 12.2.5.1 **The safety report should describe the system in place for ensuring modifications are adequately conceived, designed, installed and tested.** **[Schedule 4 Part 1 para3(a); Schedule 4 Part 2 para 4, 5(a); Schedule 2 para 4(d)]**	The site should have a procedure for the modification of safety instrumented systems. • There should be evidence that structured hazard identification/analyses process and associated risk assessment are carried out to assess the impact of the changes from a CI modification, or to CI systems from a process modification. Important areas which should have been considered are: ♦ The requirement for the modification process to look at all stages from inception through to final operation from the CI perspective, not just the later test and verification stages. ♦ Suitable methods for review of performance standards affecting safety critical instrumented systems and interrelated systems, both during the period of modification and thereafter. ♦ Use of overrides throughout the modification implementation period. ♦ Temporary loss, or change of availability, of other safety control functions during modification. The requirements for a successful demonstration of the CI aspects of modification is based on the provisions of clause 17 of BS IEC 61511. If a Company claim that they are conforming to the

Control & Instrumentation Criteria	Guidance
	standard, and can include documentary evidence to support this, then the demonstration will have been made.

Appendix 12.4: Human factors criteria and guidance

Human Factors Criteria	Guidance
Criterion 12.1 **The safety report should show a clear link between the measures taken and the major accident hazards described** **[Schedule 4 Part 1 para 2; Schedule 4 Part 2 para 4(a), 4(c), 5]**	• It is clear where human action or inaction is critical to the measures taken and how the reliability of the human action or inaction is assured.
Criterion 12.2 **The safety report should demonstrate how the measures taken will prevent foreseeable failures which could lead to major accidents**	• It is clear that the design of the safety critical tasks is matched to the human resource.
Criterion 12.2.1.1 **The safety report should show that the establishment and installations have been designed to an appropriate standard.** **[Schedule 4 Part 1 para 3; Schedule 4 Part 2 para 4(c), 5(a)]**	
Criterion 12.2.1.2 **The safety report should show that a hierarchical approach to the selection of measures has been used.** **[Schedule 4 Part 1 para (3); Regulation 4]**	• There is a clear policy and/or procedure to ensure application of inherent safety principles in new design and modifications. • Any critical high-hazard system that depends on manual intervention (for example manual emergency shutdown of a high-hazard continuous process): ♦ is robustly justified, or ♦ there is a time bound action plan to address this •
Criterion 12.2.1.3 **Layout of the plant should limit the risk during operations,**	

Human Factors Criteria	Guidance
inspection, testing, maintenance, modification, repair and replacement. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.4 **Utilities that are needed to implement any measure defined in the safety report should have suitable reliability, availability and survivability.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c), 5(a)]**	
Criterion 12.2.1.5 **The safety report should show that appropriate measures have been taken to prevent and effectively contain releases of dangerous substances.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c), 5(a)]**	
Criterion 12.2.1.6 **The safety report should show that all foreseeable direct causes of major accidents have been taken into account in the design of the installation.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	• The safety report identifies any cases where operator error could be a direct cause of LOC without structural failure of the primary containment boundary, e.g. ♦ Identification of sources of human error in process operations, e.g. maloperation of plant, lack of hazard awareness, poor communication, unrealistic demands, lack of specific training or knowledge, etc.. ♦ Identification of measures aimed at minimising human error, e.g. dedicated operating systems, etc.. ♦ Safety criticality attached to human actions and how this is catered for in design. Realistic performance standards for safety critical functions during normal and

Human Factors Criteria	Guidance
	emergency conditions, etc.. ♦ Defence in depth to minimise the effect of human failure. ♦ Control of design functions to minimise error. ♦ Control of maintenance and inspection activities to reduce human contribution to LOC during system invasive activities. ♦ Activity training, equipment specific training, etc..
Criterion 12.2.1.7 **The safety report should show how structures important to safety have been designed to provide adequate integrity.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.8 **The safety report should show how the containment structure has been designed to withstand the loads experienced during normal operation of the plant and all foreseeable operational extremes during its expected life.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.9 **The safety report should show that materials of construction used in the plant are suitable for the application.** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	

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Criterion 12.2.1.10 **The safety report should show that adequate safeguards have been provided to protect the plant against excursion beyond design conditions** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.11 **The safety report should describe how safety-related control systems have been designed to ensure safety and reliability** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	
Criterion 12.2.1.12 **The safety report should show how systems which require human interaction have been designed to take into account the needs of the user and be reliable** **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	• Where reliability of human action is critical, there is/are: ♦ References to design standards. ♦ Usability assessments. ♦ Indications of operator involvement in setting reliability criteria. ♦ Compatibilities with other systems. ♦ Consideration of improvement teams. ♦ Appropriate standards for ergonomic design that include control and alarm display interfaces. ♦ Workspace design considerations (such as heat, light, noise, interface, physical access). ♦ Alarm handling design and procedures (form, numbers, priorities, actions required, management of overrides). ♦ Evidence of correct allocation of function, especially of new plant and for emergency shutdown arrangements . ♦ Avoidance of undue reliance on special or rarely used automation or procedures or unusual or rare judgement. • The design process for manually operated

Human Factors Criteria	Guidance
	equipment and controls ensures that the needs of users are fully taken into account, including usability and maintainability assessments and operator participation from an early stage. • The design process includes identification of training needs. • Where reliable response to alarms forms part of the demonstration, the safety report shows that the duty holder has taken effective action to ensure usability and compatibility with suitable standards. [Note: Some sub-optimal alarm systems can give the operator too much unhelpful information and alarm flood during plant upsets.] • The safety report shows that the usability and error potential of existing safety-critical manual tasks or interventions (for example critical connections or disconnections, critical alarms and controls) are: ♦ Understood, and ♦ Action has been taken to minimise potential hazards that may arise. • There is a process for developing procedures that ensures that they are technically correct, useable, clear and unambiguous, and including user input. • There is regular review of documented safety-critical and safety-related procedures.
Criterion 12.2.1.13 The safety report should describe the systems for identifying locations where flammable substances could be present and how the equipment has been designed to take account of the risk. **[Schedule 4 Part 1 para3; Schedule 4 Part 2 para 4(c)]**	

Human Factors Criteria	Guidance
Criterion 12.2.2.1 **The safety report should show that the installations have been constructed to appropriate standards to prevent major accidents and reduce loss of containment** **[Schedule 4 Part 1 para3(a)]**	
Criterion 12.2.2.2 **The safety report should describe how the construction of all plant and systems is assessed, and verified against the appropriate standards to ensure adequate safety.** **[Schedule 4 Part 1 para3(a)]**	
Criterion 12.2.3.1 **The safety report should show that safe operating procedures have been established and are documented for all reasonably foreseeable conditions.** **[Schedule 4 Part 1 para3(b)]**	**Managing procedures** The safety report presents a structured approach to developing, producing and maintaining procedures. • The safety report describes the following aspects: ♦ A process to determine which tasks need procedures. ♦ An approvals process for procedures. ♦ The development of procedures (their usability, in addition to technical content). ♦ A process for ensuring that procedures are valid and remain up-to-date. ♦ End users involvement in the development of procedures. ♦ A process to ensure that procedures are appropriate to the nature of the task, its criticality and the users' experience. ♦ A formal process to ensure that staff are trained in new/updated procedures. • There is a system in place to ensure that all foreseeable circumstances are covered by procedures (e.g. high level statements, step by

Human Factors Criteria	Guidance
	step instructions for safety critical jobs, emergency response events, etc). • The safety report describes how compliance with critical procedures is assured. • The safety report describes how the duty holder checks that procedures are followed. [Note: It is often assumed that employees will always follow procedures or work instructions. However, procedures are not always adhered to for a variety of reasons (i.e. procedural violations) e.g. because they may be inaccurate, do not describe best practice, are out of date, too complex or time consuming to access.] **Competence of staff.** [Note: Information on competence may be provided in summary, and references made to other documents.] • The safety report shows a focus on major accident hazards / process safety rather than personal safety: ♦ The competency requirements for process safety are identified, including the underpinning knowledge of equipment, processes, hazards and consequences. ♦ The competency requirements are informed by the hazard and risk analyses. ♦ Safety critical roles, responsibilities and tasks at all levels are identified, including for management and contractors. ♦ The safety report addresses: ♦ Operational personnel competency ♦ management competency (not just front line personnel). ♦ Emergency response competency. ♦ Contractor competency. ♦ 'Soft' competencies such as team management, communications, event recognition, delegation etc. in addition to task specific / technical competencies. • The safety report identifies responsibilities and resources for the process of competence assessment. [Note: Training / competency assessment is often under-resourced]

Human Factors Criteria	Guidance
	Selection and training • The safety report shows: ♦ How the selection of key personnel ensures their ability to perform to the required levels of competence. ♦ Staff are recruited and selected against defined criteria for the job. ♦ Competency assurance systems do not rest solely on generic national standards (e.g. NVQs) unless these have been adjusted to match the duty holder's specific operations and risks. ♦ On the job training is well-structured with specific training/learning objectives. ♦ Trainers / assessors are 'trained trainers' and have relevant experience to undertake these duties. ♦ There is a clear link between competency and safety critical procedures. ♦ Staff are assessed (and re-assessed at suitable intervals) against the criteria. ♦ The skills, knowledge, behaviours and working practices against which performance is judged have been identified. **Audit and review** • The safety report describes how individual competency and the competency assurance process itself are reviewed. **NB** This is particularly important during any organisational change process, such as business restructuring, increased use of contractors, multi-skilling, or demanning. The safety report describes a suitable record system that can demonstrate competency, which includes: records for each person evidence of appropriate validation evidence of training & assessment **Communications** • The safety report shows: ♦ That arrangements for safety critical communications address the potential for communication failures (such as misunderstandings or incomplete / inaccurate / unnecessary).

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	♦ Safety critical communications addressed include: ▪ Communications during emergencies. ▪ Any form of remote communication between control room and outside operators e.g. during shutdowns. ▪ Permit-to-work procedures, particularly if the work continues over a shift change. ▪ Communication of hazards and risks to contractors. ▪ Use of radios. ▪ Plant labelling and identification. ▪ Communication of changes to procedures. • Failures in communications are considered in the event of an emergency or abnormal situation. • Communication needs are considered, for example: ♦ The information required. ♦ From and by what means information is obtained. ♦ The communication mode (e.g. voice, text/email, pager). ♦ The format of communication (use of phonetic alphabet). **Availability of adequate numbers of competent staff** • The safety report: ♦ Describes the process by which the operator ensures that there is adequate availability of competent personnel (including contractors) for safe operation and for the provision of an effective emergency response service. [NB this relates to determining whether the duty holder has the right numbers of the right personnel in the right place and at the right time. The safety report should refer to the arrangements for ensuring that this is the case, rather than detailing the actual numbers of personnel.] • Focuses on safe management of critical events / tasks / roles / responsibilities and emergency

Human Factors Criteria	Guidance
	response. • Demonstrates the arrangements are informed by the risk assessment. • Describes the arrangements for monitoring and review of the numbers of adequate personnel.
Criterion 12.2.4.1 **The safety report should show that an appropriate maintenance scheme is established for plant and systems to prevent major accidents or reduce the loss of containment in the event of such accidents.** **[Schedule 4 Part 1 para3(b)]**	• There are measures in place to detect, monitor or avoid maintenance error. • The safety report describes /demonstrates: ♦ What maintenance work can lead to a major hazard accident. ♦ Robust defences to make sure these accidents are very unlikely, including: ▪ Physical barriers and guards. ▪ 'Administrative' controls (permits, procedures, checklists). ▪ Management controls (supervision and checking of tasks). ♦ Competent maintenance teams. ♦ Well designed maintenance tasks (eg, interesting, no time pressure, comfortable conditions). ▪ How the maintenance programme is based on major accident risk assessment. ▪ How communications are controlled well during shifts and between shifts. ▪ Special arrangements for the care of temporary or inexperienced maintenance technicians and contractors. ▪ Inspections of maintenance tasks in progress. • The safety report describes: ♦ How the ease of maintaining systems and continual improvement is achieved. ♦ How early signs of problems are monitored (e.g. a large backlog of jobs; excessive repair times; adverse feedback from staff. ♦ How the investigation of near misses and accidents is used to learn from human failure in maintenance and to improve the systems.

Human Factors Criteria	Guidance
Criterion 12.2.4.2 **The safety report should show that there are appropriate procedures for maintenance that take account of any hazardous conditions within the working environment.** **[Schedule 4 Part 1 para3(b)]**	
Criterion 12.2.4.3 **The safety report should show that systems are in place to ensure that safety critical plant and systems are examined at appropriate intervals by a competent person.** **[Schedule 4 Part 1 para3(b)]**	
Criterion 12.2.4.4 **The safety report should show that there is a system in place to ensure the continued safety of the installations based on the results of periodic examinations and maintenance.** **[Schedule 4 Part 1 para3(b)]**	
Criterion 12.2.5.1 **The safety report should describe the system in place for ensuring modifications are adequately conceived, designed, installed and tested.** **[Schedule 4 Part 1**	• There is a structured process for involving operators in the raising, design and implementation of modifications • Organisational change and transition management. • The safety report describes a robust procedure for management of organisational change with: ♦ With clear objectives. ♦ With clear leadership /accountability (senior

Human Factors Criteria	Guidance
para3(a); Schedule 4 Part 2 para 4, 5(a); Schedule 2 para 4(d)]	management). ♦ Which is structured, to a prescribed, consistent process, thorough and well documented / communicated. • The safety report describes an assessment process that: ♦ Identifies and maps all changes to both tasks and personnel that could have an impact on MH prevention, no matter how small the change. ♦ Is facilitated by well-trained persons independent of the facility being assessed. • The safety report describes how changes may impact on human reliability as assessed, including as necessary: ♦ Workload (including non-productive work). ♦ Competence. ♦ Work priorities. ♦ Team work and communication. • Where applicable, the safety report provides realistic assessments of the organisation's handling of a range of crisis scenarios post-change, including upsets, escalating incidents and emergencies. • Where required, the safety report describes a competence assurance process to ensure adequate transition arrangements. ♦ Which includes identification of training needs for changed or additional roles in relation to major hazards/process safety. ♦ Adequate planning for competent cover during the training period. ♦ A mechanism for reviewing decisions, and to ensure that all necessary measures are in place before 'go-live'. ♦ A process to monitor performance after change.

13 - GUIDANCE FOR ENVIRONMENTAL ASSESSMENT

Introduction

1 The environmental assessor has a multi-functional role in the assessment process. They complete an initial read of the safety report with the assessment manager to jointly determine whether the minimum information has been provided and assist the assessment manager in determining the make up of the assessment team.

2 Where predictive assessment is required, HSE and Agency assessors should work together to agree:

a. whether or not the major accident scenarios are described adequately;
b. that the key information relating to hazard identification and risk analysis is present;
c. identify the areas where the hazards are either predominantly or solely human safety or environmental;
d. identify the areas where the hazards overlap;
e. agree roles and responsibilities where this overlap exists.

3 Where the major accident hazards on a site are predominantly or solely environmental the agency will lead the assessment process. HSE will provide the Environment Assessors with additional specialist support where required.

General guidance for assessment of environmental criteria

4 The underlying factors of a Major Accident lie in aspects common to “human safety” and the “environment”, be these mechanical, electrical and control, process safety or human factors. In the context of major accidents and their prevention ‘environment’ is not treated as a separate discipline to ‘health and safety’.

5 While the receptor has no bearing on the causes or the prevention of an accident, some events carry a significant, predominant or solely environmental hazard and risk. These must be addressed in the environmental assessment process. Unless there is good reason, only new and / or revised information will be assessed against the new environmental criteria. Further guidance on re-assessment is provided in “Selection of Topics for Inspection” in the Overview Section.

6 The key criteria to be met for environmental risk assessment are stated in the tables below. Three components need to be present before a risk can be manifest, namely:

a) Source (of hazard).
b) Pathway (between source and receptor).
c) Receptor (of the hazard).

7 The criteria and guidance in the following tables overlap in some areas with the requirements for assessment relating to other disciplines detailed in Sections 9 to 12 of the manual. This does not mean that duplicated assessment is proposed, but recognises that much of the information that is needed for assessment of health and safety may also be necessary for assessment of the environment. Attention of assessors is drawn to the guidance contained in Section 8 of this manual - 'How to use the Criteria' under the heading of 'Use of the Criteria' concerning avoidance of duplicated assessment.

8 The assessor should also ensure that other criteria with relevance to the environment are included in the environmental assessment. Appendix 13.2 provides a checklist of the key issues to provide more focus. Where there have been minimal changes that impact on the environmental considerations it should not be necessary to complete re assessment.

9 Some of the information required to assess the impact on the environment may already have been prepared for environmental impact assessment or other authorisation procedures. It is permissible for the operator to refer to this information. However, assessment is made easier and more efficient if it is submitted as part of the COMAH safety report, rather than by reference to authorisations sent separately to the Agencies.

Appendix 13.1 - Environmental Assessment Criteria and Guidance

Environmental Criteria	Guidance
Criterion 13.1 **The safety report should identify all vulnerable environmental receptors and describe the sensitivity of these environmental receptors.** **[Schedule 2 para 4(b);** **Schedule 4 Part 2 para 2]**	These should include: • The presence of Red Book species • Designated Areas (SAC, SPA, SSSI, AONB, Ramsar sites, Local Authority nature classification schemes, etc.) • Surface waters and their classification • Groundwater and aquifers and their classification • Drinking and industrial water abstraction points (ground and surface) • Amenity areas • Sites of architectural and historical importance • Soil and sediment • Agricultural resources (including market gardens and allotments) • Grade 1 listed buildings • Pathways and receptors for any releases include those to air (deposition effects), water and land. • The area over which the receptors should be identified depends on the potential for major accidents. It would be expected that a range of 10 km would be reasonable. • Factors that could affect the behaviour of accidental releases in the environment should be described. These may include hydrology, meteorology, hydrogeology, geography and climate. • Surveys may be needed to determine the nature of local ecosystems. • Activities beyond the site boundary that may interact with the site should be identified. ♦ These may include neighbouring industrial facilities, water treatment plants connected by rivers or sewer systems, and upstream processes. ♦ Examples of interactions which should be considered include spills from the site causing damage to connected facilities, combinations of released substances which may react to produce an

Environmental Criteria	Guidance
	environmental hazard, and upstream processes transferring off-spec material leading to upsets on the installation.
Criterion 13.2 **The safety report should include a description of the aspects of the installation that could be a factor in the potential for releases to the environment** **[Schedule 2 para 4(b); Schedule 4 Part 2 para 3]**	These should include: • Location, inventory and conditions of substances dangerous to environment (including those non COMAH substances which may be released in the event of a major accident) • Secondary containment design, position, capacity, condition • Surface gradients. • Management factors such as operator response, control procedures • Distances between sources and pathways • Site layout and drainage, capacity and condition of drains, etc. • Layout and segregation of entire drainage system, barriers, valves etc. sumps. • Location and capacity of sumps, penstocks, fire-water lagoons and any other barriers to off-site transport of liquids. • Geographical/geological/hydro-geological features that may impede/facilitate pollutant escape • Effect of varying weather conditions (e.g. storm-water) • Treatment plants (on or off-site) • Detection, shutdown • Location of pumps, valves, pipework, penstocks and firewater lagoons. • Suitability, capacity of treatment plant. • The location of discharge points to watercourses/foul sewer/effluent treatment plants; • Maps and plans of the establishment features indicating where runoff of spilled substances and firewater could take place.
Criterion 13.3 **The safety report should include a description of the**	This should include: • Toxicity data (e.g. dose-response

Environmental Criteria	Guidance
dangerous substances which have potential environmental impact **[Schedule 2 para 4(b); Schedule 4 Part 2 para 3]**	relationships). • Environmental harm criteria (e.g. LC50 data, critical loads). • Negligible effect criteria (e.g. No Observed Effect Levels, Suggested No Adverse Response Levels). • If harm criteria are used then the relevant receptors must be clearly identified. • Other potentially harmful properties, for example, BOD/COD, blanketing/smothering or effects on potable water supplies may need to be considered. Other information that may be required includes persistence, bioconcentration factor, bioaccumulation potential, solubility, and density.
Criterion 13.4 **The safety report should identify all Major Accident Scenarios which have potential environmental impact** **[Schedule 2 para 4(b); Schedule 4 Part 2 para 4]**	• The operator should describe the **methodology** used to identify release scenarios. • Three main factors are needed to demonstrate understanding of events: ♦ Behaviour of released substances ♦ Onsite pathway analysis ♦ Domino or escalation effects • Potential **releases** should be identified, which should include a consideration of worst case failures (inventory and process and the sensitivity of the receiving environment (number and types of sensitive sites) • **Pathways** by which the substance reaches the environment should be identified. • Substance behaviour upon release should be identified, e.g. reactions with air/water/other substances, changes of phase, dispersion characteristics (dense or buoyant behaviour), etc. Substance behaviour must be characterised before the types of pathway can be evaluated. • Behaviour under normal conditions and foreseeable abnormal conditions should be considered. • The potential for a release to be associated with firewater should be considered. This could be a direct result of firewater applied to the release or indirectly firewater run-off from another part of the site (i.e. a domino effect).

Environmental Criteria	Guidance
	• Screening on the basis of a dilute (e.g. through applying firewater) and disperse risk management option is not an acceptable practice. • Consideration should be given to the probability of flooding as a causation or escalation factor.
Criterion 13.5 **The safety report should include an assessment of the extent and severity of the environmental consequences of major accidents** **[Schedule 2 para 4(b); Schedule 4 Part 2 para 4(b)]**	• Source details should be defined for each accident scenario and should include the following: ♦ Substance released, size/release rate/duration of release ♦ Conditions of release (pressure, temperature, phase) ♦ Location, elevation, direction of release ♦ Factors that may determine the extent of environmental impact (e.g. ignition, detection, secondary containment failure, drains, emergency procedures, etc.) • The operator should include the methods used to calculate release rates and the specific values of any variables. It is not necessary that the release rate and resultant environmental concentration of every scenario is considered. It is acceptable if a representative set of releases is chosen to cover the range of releases possible. • The models/methods used to determine the environmental concentration should be detailed. The specific values of any variables should be given. • The resultant environmental concentrations for each member of the set of releases should be given • The effects in the environment should be determined from the predicted environmental concentrations and the toxicity data. The length, area or volume of the environment affected should also be given. The approach used should be described fully. In general the following may be used in combination or separately, for evaluating impacts: ♦ Toxicity relationships (e.g. dose-response relationships). ♦ Environmental harm criteria (e.g. LC50

Environmental Criteria	Guidance
	data, critical loads). ♦ Negligible effect criteria (e.g. No Observed Effect Levels, Suggested No Adverse Response Levels). ♦ Past accident experience. ♦ Population dynamics modelling. • If harm criteria are used then the relevant receptors must be clearly identified. [It should be noted that the LC50 threshold represents an impact of the severest nature. For risk assessment purposes a threshold of LC/2 or LC/3 provides a suitable indicative environmental harm threshold.] Effects may be to individual species, a range of species (biodiversity), the community structure and the overall habitat or ecosystem. Very little information exists on community level responses to damage. In defining the expected level of change, natural variability needs to be considered as this can result in significant changes in receptors. If recovery is assessed then a distinction may need to be drawn between natural unassisted recovery and artificial recovery, particularly if contingency plans include cleanup and restoration that may affect the rate of recovery. • Immediate and delayed effects should be considered in the approach to assessing impacts. • The key uncertainties in the approach should be identified. • The operator should conclude if the effects might constitute a MATTE.
Criterion 13.6 **The safety report should include conclusions on the probability of the major hazards or the conditions under which they occur** **[Schedule 2 para 4(b), Schedule 4 Part 1 para 2]**	• The operator should give an indication of the likelihood of any MATTE identified. This may be by: ♦ Qualitative descriptions (e.g. low/medium/high risk). ♦ Simple relative scoring systems (e.g. 1-5, 1-100). ♦ Quantitative modelling parameters (e.g. Environmental Harm Index). ♦ The operator should explain the method used to determine the likelihood's and any assumptions or principles underlying the method ♦ Risk results may be summed over all events and scenarios to give the total environmental risk and breakdown in terms of the significant risk contributors.

Environmental Criteria	Guidance
	♦ Uncertainties associated with any risk conclusions should also be presented.
Criterion 13.7 **The safety report should include a description of the arrangements to prevent major accidents to environment** **[Schedule 2 para 4(b); Schedule 4 Part 1 para 2]**	• For each scenario that can result in a MATTE the operator should describe the preventative measures in place. • Where a screening approach has been used the operator should use the results of the examination of the representative set of releases to determine which of all of the releases do result in a MATTE and then ensure that for each event the specific precautions are detailed.
Criterion 13.8 **The safety report should provide evidence that suitable and sufficient resources can be mobilised to minimise the consequences of loss of containment of a dangerous substance(s) to ground or water (including Controlled Waters)** **[Schedule 4 Part 2, para 5c)]**	• To meet this criterion the report should consider the following: • measures to stop or reduce a spillage at source; • measures to confine the spillage, the preference being for permanently engineered secondary containment systems fitted with an isolation device but other mobilisable resources may be considered (e.g. sandbags, drain seals etc) • measures to recover and/or treat the spillage (eg pumps, chemicals for neutralising or absorbing the spillage).
Criterion 13.9 **The safety report should provide evidence that suitable and sufficient provisions have been made for the restoration and clean up of the environment following a major accident** **[Schedule 5 Part 1, para 4)]**	To meet this criteria we would expect to see identification of: • the potential need for restoration and clean up measures Other points to consider, where necessary, include: • the envisaged timescale over which temporary containment may be required; • the arrangements made to ensure that such facilities would not pose an unacceptable threat to health and the environment; • suitable disposal arrangements. Examples of measures to be taken may include: • equipment to contain toxic substances; • agents to soak up and/or neutralise contaminants;

Environmental Criteria	Guidance
	• earth moving equipment for the removal of contaminated soil and other material; • booms and skimmers for spillages to water; • temporary storage arrangements e.g. portable storage tanks, for the contaminated material.

Appendix 13.2 - Other criteria to be taken into account for environmental assessment

Section and Criterion	Environment Component and Relevant Environmental Criterion
Descriptive **Criterion 9.5** **The safety report should describe the immediate and delayed harm to man and the environment for each dangerous substance identified**	• The information presented should include the physical, chemical or toxicological characteristics of the dangerous substances that may cause harm and an indication of the hazards posed. The information presented should address both the short and long term effects and may include for example: ♦ effects on the environment, including building damage, the ecosystem and relevant sensitive species, (**Environment criterion 13.3**)
Descriptive **Criterion 9.6** **The safety report should describe the environment of the establishment in sufficient detail to allow the consequences of a major accident to be assessed**	• Land use pattern (i.e. industry, agriculture, urban settlements, environmentally sensitive locations etc.). • Consideration should also be given to allow assessment of the indirect impact of a major accident on the public. For example, as a result of contamination of drinking water. ♦ a description of the underlying and surrounding geology and hydrogeology if it is appropriate to the consideration of a major accident; ♦ a description of the surrounding water courses (under various flow conditions), underlying aquifers and any drinking water extraction points should be given in relation to the dispersion of liquid contaminants or leachate from solids deposited on the surrounding land; ♦ description of surrounding water and land quality; ♦ information on sewerage and rainwater systems if they could be involved in the dispersal of liquid contaminants off-site; ♦ information on tides and currents that might influence dispersion or accumulation if marine or estuarine habitats are at risk; • Information on **the built environment** is expected to include: • each listed building and monument that may be vulnerable to the effects of a major accident. • Information on **the natural environment** is expected to include a description sufficiently detailed to allow the significance of the

Section and Criterion	Environment Component and Relevant Environmental Criterion
	impact of major accidents to be assessed. This should include details of any: ♦ Sites of Special Scientific Interest (SSSI); whether they are Special areas of Conservation (SAC) or Special Protection Areas (SPA); or Ramsar sites; ♦ marine nature reserves; ♦ marine sensitive areas, under English Nature's marine strategy; ♦ and the significance of these features in either a national or international context should be explained, for example the flora or fauna particularly at risk. (**Environment Criterion 13.1**)
Descriptive **Criterion 9. 7** **The safety report should describe the environment of the establishment in sufficient detail to allow the contribution of external factors to major accidents at the establishment to be assessed**	• The contribution of the external factor to the major accident could be as an initiating or exacerbating event. Factors for consideration under this criteria include: ♦ historical evidence of other external events that might act as accident initiators such as flooding; (**Environment Criterion 13.4**)
Descriptive **Criterion 9.11** **The safety report should provide focused information about each installation, in sufficient detail to support the demonstration that major accident hazards will be prevented or the effects mitigated**	• The safety report should contain plan(s), map(s) or diagram(s) plus descriptions, which clearly set out information about the installations with major accident potential. The description should allow determination of the purpose, location and function of equipment within the installation that has a bearing on major accident prevention and control. In particular, information about items of plant such as: • drainage (e.g. routes, purpose [e.g. foul water, fire fighting run-off water]) including details relating to; • safety (or environment) critical valves, instruments, control loops and detection systems; • monitoring equipment, e.g. for toxic products in air, sewers, discharges to water; for fires or explosive atmospheres; (**Environment Criterion 13.2**)
Predictive **Criterion 10.1** **This criterion summarises the description in the safety**	• Description of the role that risk assessment has in the demonstration that the risks are ALARP for on-site personnel, people off-site and the environment.

Section and Criterion	Environment Component and Relevant Environmental Criterion
report of the company's general approach to the use of risk assessment in the process of identifying necessary measures.	(**Environment criterion 13.6**)
Predictive **Criterion 10.1.2** **Any criteria for eliminating possible hazardous events from further consideration should be clearly justified**	The intent of this criterion is to ensure no important hazardous events go unconsidered. • Periodic review considers known or foreseeable changes to the sensitivity of the surrounding environment. (**Environment Criterion 13.1**)
Predictive **Criterion 10.2** **The safety report should demonstrate that the operator has used information and data that are suitable and sufficient for risk analysis**	• Consideration of a range of suitably applied harm levels (e.g. toxic, thermal, pressure effects) to people and the environment. • Use of current maps, off-site population data and surrounding environmental features. (**Environment Assessment criterion 13.6**)
Predictive **Criterion 10.3.1** **A systematic hazard identification process has been used to identify all major accident scenarios, including worst case and lesser events.**	• **External events** where relevant may include: ♦ Extreme environmental conditions (e.g. abnormal rain, snow, temperature, wind, floods (both as a causation or escalation factor), lightning). • The range of MA scenarios affecting people and the environment is sufficient for identifying necessary measures and includes: ♦ The scenarios include events where planned or installed measures fail. **(Environment Criterion 13.4)**
Predictive **Criterion 10.5** **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**	The intent of this criterion is to ensure valid and appropriate consequence assessment and should include a range of potential harms to the environment **(Environment Criterion 13.5)**
Predictive **Criterion 10.5.4** **The harm criteria or vulnerability models used to assess the impact of each MAH on people and the environment should be**	• The safety report shows, where the scale and nature of the hazard and risks is significant: ♦ Justification for the approach to environmental impact assessment and data used. (**Environment Criterion 13.3**)

Section and Criterion	Environment Component and Relevant Environmental Criterion
appropriate and have been used correctly for each relevant major accident	
Predictive **Criterion 10.5.6** **Estimates of the severity and extent of each major accident consequence are realistic**	Extent and severity is concerned with who (people) or what (environment) might be harmed, how badly, and how many (people) or how much (environment) are affected by major accidents. (**Environment Assessment criterion 13.5**)
Technical	Relevant criteria affecting assessment of environmental aspects is dependant upon allocated responsibilities within the Assessment team.
Emergency Response **Criterion 14.2** **The safety report should describe the organisation of the alert and intervention in the event of a major accident to provide evidence that the necessary measures have been taken on-site**	• Arrangements for intervention in an emergency situation ♦ the nature and location of any pollution control devices and materials, and the arrangements for subsequent environmental clean up and restoration; • Where relevant, or where more rigorous or detailed demonstrations are required, consideration of the following: ♦ the effects of emergency response actions, including fire fighting activities, in order to minimise the overall impact on people and the environment (for example, due to contaminated firewater); this should include short term and long term effects and alternative options for disposal or discharge together with the least damage solutions and the circumstances in which they apply.
Emergency Response **Criterion 14.3** **The safety report should describe the on-site and off-site resources which can be mobilised by the operator to provide evidence that the necessary measures have been taken to limit the consequences of a major accident to people and the environment**	Of relevance but nothing specific described
Emergency Response **Criterion 14.3.2** **The safety report should provide evidence that suitable and sufficient**	Of relevance but nothing specific described.

Section and Criterion	Environment Component and Relevant Environmental Criterion
arrangements are in place to ensure that the equipment to be mobilised for mitigating the consequences of reasonably foreseeable major accidents will be fit for purpose when called upon for use	
Emergency Response Criterion 14.3.4 **The safety report should provide evidence that suitable and sufficient on-site fire fighting and fire protection provisions can be mobilised in the event of a major accident, taking account of resources available from local and other fire brigades**	That adequate consideration has been given to the possible environmental impact of contaminated firewater on watercourses and groundwater.
Emergency Response Criterion 14.3.8 **The safety report should provide evidence that suitable and sufficient provisions have been made for the restoration and clean up of the environment following a major accident**	To meet this criterion the report should include identification of: • the potential need for restoration and clean up measures. • Other points to consider, where necessary, include: ♦ the envisaged timescale over which temporary containment may be required; ♦ the arrangements made to ensure that such facilities would not pose an unacceptable threat to health and the environment; ♦ suitable disposal arrangements. • Examples of measures to be taken may include: ♦ equipment to contain toxic substances; ♦ agents to soak up and/or neutralise contaminants; ♦ earth moving equipment for the removal of contaminated soil and other material; ♦ booms and skimmers for spillages to water; ♦ temporary storage arrangements e.g. portable storage tanks, for the contaminated material.
Emergency Response Criterion 14.5 **The safety report should**	• The training should include where relevant: ♦ the nature of major accidents posing a threat to the environment and the

Section and Criterion	Environment Component and Relevant Environmental Criterion
provide evidence that suitable arrangements have been made in the safety management system for training of individuals on-site in the emergency response	particular steps to take in the event of such accidents;
Emergency Response Criterion 14.7 **The safety report should supply information to enable the off-site emergency plan to be drawn up**	• The minimum information to be included in the safety report includes: ♦ Details of the off-site area likely to be affected by a major accident e.g. maps with sectors and environmentally sensitive areas and a drainage map to help determine where spillages could leave the site. ♦ Details of the dangerous substances on-site covered by the COMAH Regulations and similar information for other hazardous materials held on site, including: quantities; hazardous properties and the nature of their effects on people and the environment.

14. EMERGENCY RESPONSE ARRANGEMENTS

Introduction

Scope

1 This set of criteria is concerned with the on-site arrangements to respond to a major accident, the interface of these arrangements with the off-site emergency plan, and the resources that can be mobilised by the operator to take mitigatory action to minimise the consequences of a major accident.

Relevant requirements of the COMAH Regulations

2 Schedule 4 Part 1, para 2 requires that one of the purposes of a safety report is to demonstrate that the necessary measures have been taken to limit the consequences of major accident hazards to people and the environment. Additional purposes are set down in Schedule 4 Part 1, para 4 which requires the safety report to demonstrate that on-site emergency plans have been drawn up and to supply information to enable the off-site plan to be drawn up.

3 Schedule 4 Part 2, paras 5(a-d) set down the minimum data to be considered in the safety report with respect to emergency response: para 5(a) requires a description of equipment installed for limiting the consequences of major accidents, 5(b) is concerned with the organisation of the alert and intervention, 5(c) requires a description of the mobilisable resources, 5(d) requires a summary of information from sections 5(a) to 5(c) necessary for drawing up the on-site emergency plan. The emergency response criteria cover paras 5(b-d) with para 5(a) addressed by the Technical Aspects criteria presented in Section 12.

4 Aspects of the Safety Management System directly relevant to emergency response arrangements are specified in the following sections of Schedule 2: 4(a) which addresses training needs; 4(c) which covers arrangements for maintenance of plant and equipment; 4(e) which requires the safety management system to address the adoption and implementation of procedures to test and review emergency plans. General assessment criteria for Safety Management Systems are presented in Section 11.

5 Regulation 10(7) recognises that situations may apply where the CA deems it appropriate to exempt a local authority from the requirement to produce an off-site emergency plan in respect of an establishment. This is further addressed in this section.

6 The layout of the criteria is intended to reflect the layout of the Regulations.

General guidance for the assessment of the emergency response elements

7 The assessment criteria listed below, together with their explanatory text, are representative of the type of necessary measures that the Competent Authority would expect the operator to take to limit the consequences of major accident hazards to people and the environment. It is recognised that the assessment criteria may not all be relevant to a particular establishment, however the onus is on the operator to demonstrate that the necessary measures which have been made are adequate in the context of the major accident hazards that could occur at the site concerned. They should be related (and preferably cross referenced) to the major accident scenarios described elsewhere in the safety report.

8 Where the term evidence is used in the criteria then a statement of confirming that specific measures have been taken may be sufficient to satisfy the requirement. For example, a statement confirming that equipment is included in plant maintenance schedules, maintenance records, maintenance procedures and instructions etc. It is not expected that examples of these documents are included in the safety report. Such documents may be subject to post assessment inspection.

Pre-construction and pre-operation safety reports

9 For Pre-Construction Safety Reports (PCSRs) and Pre-Operational Safety Reports (POSRs) the organisation of alert and intervention arrangements should be described to the extent that information is available and in relation to the hazards that apply. For PCSRs, relevant information may include:

- Control and limitation of escalation of major accidents, including isolation and removal of inventories.
- Communication during emergency response.
- Emergency control centres.
- Access routes
- Design and construction of mobilisable resources, particularly nearer pre-operation stage.
- Arrangements during phased commissioning of plant.

10 Training in emergency response, testing of emergency plans, information for the offsite emergency plan has principal relevance to POSRs.

Exemption from producing an off-site emergency plan

11 Regulation 10(7) deals with exempting a local authority from the need to produce an off-site emergency plan. Where this is deemed appropriate, the CA is required to notify the local authority in writing of the exemption and the reasons for granting it. Members of the assessment team will need to agree the basis of such an exemption and record it as an outcome of the assessment conclusions meeting.

12 In reaching a decision that an exemption to producing an off-site emergency plan in respect of an establishment is appropriate, the assessment team should be in agreement that, based on the evidence in the safety report, the consequences of a major accident affecting health and safety or the environment will not extend beyond the establishment boundary. Where team agreement cannot clearly be reached, an exemption should not be granted (i.e. a cautious approach should be adopted).

13 Consideration of consequences extending beyond the establishment boundary for matters relating to health and safety will be based primarily on the consequence ranges provided in the report and will also need to take account of the proximity and extent of populations beyond the site boundary. Assessors need to consider if uncertainty in the consequence analyses and assumptions is such that a clear exemption decision cannot be reached,

14 Consequences to the environment may be more difficult to determine if uncertainty over pathways beyond the establishment boundary exist (e.g. underground pathways to water supplies, streams, etc.).

15 The AM will be responsible, in the first instance, for identifying whether a possible exemption situation exists as an outcome of the initial read. Attention to this possibility should be raised in the Stage 1 Assessment Plan. The predictive assessor (for health and safety consequences) and the environmental assessor (for environmental consequences) should consider the possibility of an exemption during their initial read prior to the assessment planning meeting. It the assessment planning meeting reaches the view that an exemption remains possible, this should be identified as an assessment scope item for further consideration during the assessment. The assessment should seek to establish that sufficient evidence exists in the report to conclude that an exemption is appropriate.

16 Historically, few exemptions from producing an offsite emergency plan have been granted. Procedure 4.2 will normally apply for prompt notification to the local authority when it is determined that the minimum information required by the regulations exists to prepare a plan. The framework letter 6 in Appendix 4.6 informs the local authority that the report has been read, but not fully assessed. This letter, prepared early in the assessment process, allows progress to be made by the local authority in preparing a plan. Exemption from producing a plan, however, places an increased obligation on the CA to be as sure it is reasonable to be so that no plan is necessary. It is for this reason that the decision to grant an exemption is left until a complete assessment of the safety report has been made and conclusions reached (see Procedure 6.1).

Appendix 14.1 Emergency response assessment criteria and guidance

Emergency Response Criteria	Guidance
Consultation	
Criterion 14.1 **The safety report should confirm that the operator has consulted the following in the preparation of the on site emergency plan: those working in the establishment; the Agency; the emergency services; the health authority; the local authority** **[Regulation 9(3) and (4)]**	Simple confirmation of the compliance with the regulation should be sufficient to meet this criterion. However, it would be preferable for the report to give details of the means and nature of the consultation, and any impact that this has had on the emergency planning arrangements.
Organisation of Alert and Intervention	
Criterion 14.2 **The safety report should describe the organisation of the alert and intervention in the event of a major accident to provide evidence that the necessary measures have been taken on-site** **(Schedule 4 Part 2, para 5b)**	To meet this criterion, the safety report should describe: • Basic organisational issues necessary for emergency response: ♦ identification of key posts, and groups, with duties in the emergency response (and the arrangements for deputies); ♦ description of the functions of key posts with duties in emergency response; ♦ description of provisions for establishing and maintaining communications during the emergency response; ♦ the nature and location of: emergency control centres; first aid centres; emergency refuges; muster points; pre-defined forward control points, etc; • Arrangements for raising the alert to the hazardous situation: ♦ to cover individuals on site, the general public and, where relevant, neighbouring establishments and downstream water abstractors ♦ description of the nature of the alarms and the plant conditions required to activate them; ♦ the roll call and search and rescue arrangements;

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	• Arrangements for intervention in an emergency situation: ♦ the initial actions required both on-site and off-site in response to alarms/warnings; ♦ the arrangements for controlling and limiting the escalation of accidents on-site, including: the isolation of hazardous inventories and the removal of inventories (where appropriate); the use of fire fighting and other mitigatory measures; and the prevention of domino effects; ♦ the nature and location of any pollution control devices and materials, and the arrangements for subsequent environmental clean up and restoration; ♦ provision has been made for monitoring wind speed and direction, and other environmental conditions, in the event of a major accident. • Where relevant, or where more rigorous or detailed demonstrations are required, the report should include consideration of the following: ♦ the effects of emergency response actions, including fire fighting activities, in order to minimise the overall impact on people and the environment (for example, due to contaminated firewater); this should include short term and long term effects and alternative options for disposal or discharge together with the least damage solutions and the circumstances in which they apply; ♦ the nature of, and arrangements for maintaining, any mutual aid agreements with nearby establishments ♦ the nature and location of any installations which may require special protection, or rescue intervention; ♦ the location of: access routes for emergency services; rescue routes; escape routes; and any restricted areas; ♦ the arrangements for unmanned sites and sites that are not continuously manned, and sites with varying manning levels at different times; ♦ the arrangements and conditions for alerting and mobilising: individuals or groups with defined responsibilities under the emergency plans including essential personnel on-site and off-site; the emergency services (including arrangements for briefing the

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	emergency services of the nature of the incident and of any special problems they might face); neighbouring establishments (where mutual aid agreements exist); and off-site agencies; ♦ the evacuation arrangements and any transport requirements.
Description of Mobilisable Resources	
Criterion 14.3 **The safety report should describe the on-site and off-site resources which can be mobilised by the operator to provide evidence that the necessary measures have been taken to limit the consequences of a major accident to people and the environment** **(Schedule 4 Part 2, para 5c)**	This criterion is used to make a conclusive comment on the emergency response aspects which come below it. However, when considering the sub criteria below, the following issues should be considered: • The descriptions should be referenced to the major hazard scenarios described elsewhere in the report and it should cover both human resources and hardware • There is no requirement to present extensive technical details about these resources in the safety report, however the evidence presented should be sufficient to give confidence that the necessary measures have been taken in relation to the type and magnitude of the foreseeable consequences, and that the equipment provided is fit for its intended use. • The assessment criteria presented below are deliberately in non-prescriptive terms in recognition of the fact that on-site "necessary measures" will depend upon: the type and magnitude of the foreseeable major accidents which will vary widely according to the nature of the establishment involved. However, the onus is on the operator to demonstrate in the safety report that the necessary measures have been taken, in the context of the specific circumstances at the site concerned, hence the need for reference to the identified major accident scenarios.
Criterion 14.3.1 **The safety report should provide evidence that sufficient personnel can be made available within appropriate timescales to carry out the mitigatory actions required by the on-site emergency plans**	The safety report should be able to give confidence that the following factors have been taken into account: • the various functions required to implement the on site emergency plan have been identified; • the numbers of personnel, with appropriate skills or competencies, required to implement the on site emergency plan have been determined;

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(Schedule 4 Part 2, para 5c)	• these numbers of staff can be assembled in the required response time; • the mitigatory actions can be achieved in practice; • the potential for incapacity of key operators has been taken into account.
Criterion 14.3.2 **The safety report should provide evidence that suitable and sufficient arrangements are in place to ensure that the equipment to be mobilised for mitigating the consequences of reasonably foreseeable major accidents will be fit for purpose when called upon for use** **(Schedule 4 Part 2, para 5c)**	To be fit for purpose the equipment should be: • appropriately specified to meet the needs of the identified major accident scenarios; • able to operate in the ambient conditions (eg weather/frost protection); • able to operate in the local environmental conditions expected in an emergency; • able to sustain the mitigatory action for the necessary length of time; • suitably protected for the foreseeable environmental conditions so as not to introduce additional hazards (eg electrical equipment). To ensure that the equipment can be mobilised consideration needs to be given to: • determination of the required quantities of equipment; • timescales in which both the equipment will be needed, and in which it can be made available for use; • storage of the equipment, to ensure it is both accessible, and protected from the consequences of a major accident. Other factors to be considered include: • the possibility of loss of essential services (such as power, water, and communications) and other facilities has been taken into account and alternatives provided where necessary; • the compatibility, where necessary, of the emergency equipment with that of the emergency services and that provided by organisations with which a mutual aid agreement exists.
Criterion 14.3.3 **The safety report should provide evidence that**	Could include equipment such as, but not restricted to:

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suitable and sufficient personal protective equipment will be available in the event of a major accident **(Schedule 4 Part 2, para 5c)**	• respirators and/or breathing air sets; • protective clothing for radiant heat, water, or specific chemical hazards. To ensure availability of the equipment consideration should be given to: • identification of the specification of PPE appropriate to the mitigatory actions required; • identification of those individuals, or groups, who may require use of PPE; • determination of the supplies required to meet the potential demand; • storage of the equipment, to ensure it is both accessible, and protected from the consequences of a major accident. Groups which may require PPE may include: • members of the emergency response team • those with duties under the emergency plan • other individuals who may be required to wear it e.g. emergency escape respirators for site personnel in the event of a toxic gas release.
Criterion 14.3.4 **The safety report should provide evidence that suitable and sufficient on-site fire fighting and fire protection provisions can be mobilised in the event of a major accident, taking account of resources available from local and other fire brigades** **(Schedule 4 Part 2, para 5c)**	The safety report should provide sufficient evidence to show that the quantity and specifications of the on-site fire fighting provisions that can be mobilised, with due consideration of off-site resources available from local and other fire brigades, are adequate for the major accident scenarios that are identified elsewhere in the safety report. Where circumstances are foreseeable that make the use of fire fighting or other mitigatory measures impracticable or unsafe (for example, it may be unsafe to fight certain fires involving explosives), the arrangements should identify such circumstances and the additional arrangements necessary to limit the consequences of a major accident. The evidence may include some or all of the following: • that the fire fighting roles of the on-site personnel (e.g. full time on-site fire brigade, auxiliary fire fighters, other site personnel) during an emergency have been defined and are appropriate;

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	• that the fire fighting roles of the on-site personnel are complementary to the role of the off-site emergency services; • that the quantity and specification of on-site fire fighting equipment is sufficient; • that the water requirements for fire fighting and fire protection (e.g. cooling) have been pre-determined and that the capacity and reliability of the water supply are adequate taking into account the various sources which may be available, and the time required to establish back up supplies; • that suitable and sufficient portable and mobile fire fighting equipment (such as mobile monitors, mobile pumps, hand/portable extinguishers, foam generation equipment, hoses), and hydrants have been located at appropriate points throughout the installation according to the hazard; • that suitable and sufficient stocks of foam compound are available when and where necessary; • that adequate consideration has been given in the design (e.g. the positioning of walls, fire screens), to assist the positioning and protection of fire fighting equipment and personnel, and that the reach of fire protection and extinguishing equipment is appropriate; • that adequate consideration has been given to flammable substances being carried with fire water and spreading the fire to other areas; • that adequate consideration has been given to the possible environmental impact of contaminated firewater on watercourses and groundwater.
Criterion 14.3.5 **The safety report should provide evidence that suitable and sufficient provisions can be mobilised to minimise the release of, and mitigate the consequences of, airborne toxic and/or flammable substances in the event of a major accident**	To meet this criterion the report should consider the following: • measures to terminate or reduce the leak at source (e.g. patching or plugging of leaks, or isolation by valve closure or other means); • measures to reduce the evolution of fumes where hazardous materials have already been spilt (e.g. foam cover or cooling); • measures to reduce the effects of airborne substances (e.g water sprays)

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(Schedule 4 Part 2, para 5c)	The safety report should also show how consideration has been given to: • the practicability of carrying out these tasks in foreseeable accident conditions; • the equipment, tools and PPE that will be required to carry out these tasks.
Criterion 14.3.6 **The safety report should provide evidence that suitable and sufficient resources can be mobilised to minimise the consequences of loss of containment of a dangerous substance(s) to ground or water (including Controlled Waters)** **(Schedule 4 Part 2, para 5c)**	To meet this criterion the report should consider: • measures to stop or reduce a spillage at source; • measures to confine the spillage, the preference being for permanently engineered secondary containment systems fitted with an isolation device but other mobilisable resources may be considered (e.g. sandbags, drain seals etc)) • measures to recover and/or treat the spillage (eg pumps, chemicals for neutralising or absorbing the spillage)
Criterion 14.3.7 **The safety report should provide evidence that suitable and sufficient provisions for monitoring and/or sampling can be mobilised in the event of a major accident** **(Schedule 4 Part 2, para 5c)**	To meet this criterion the report should include: • consideration of the benefits of monitoring/sampling during emergency response (this may be based on the hazardous substance involved, the rate at which it disperses to safe levels and the speed at which the results may be obtained); • explanation of how the results of monitoring/sampling might influence decisions made during emergency response; • identification of any sampling/monitoring measures to be carried out, and the equipment, methods and specialist expertise that may be required.
Criterion 14.3.8 **The safety report should provide evidence that suitable and sufficient provisions have been made for the restoration and clean up of the environment following a major accident**	To meet this criterion the report should identify: • the potential need for restoration and clean up measures. Other points to consider, where necessary, include: • the envisaged timescale over which temporary containment may be required;

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(Schedule 5 Part 1, para 4)	• the arrangements made to ensure that such facilities would not pose an unacceptable threat to health and the environment; • suitable disposal arrangements. Examples of measures to be taken may include: • equipment to contain toxic substances; • agents to soak up and/or neutralise contaminants; • earth moving equipment for the removal of contaminated soil and other material; • booms and skimmers for spillages to water; • temporary storage arrangements e.g. portable storage tanks, for the contaminated material.
Criterion 14.3.9 **The safety report should provide evidence that suitable and sufficient provisions have been made to mobilise first aid/medical treatment during the emergency response** **(Schedule 4 Part 2, para 5c)**	The safety report should demonstrate that suitable consideration has been given to the first aid/medical provisions required in the event of a major accident and show how the on-site provisions dovetail with the provisions in the off-site emergency plan.
Criterion 14.3.10 **The safety report should provide evidence that suitable and sufficient provisions have been made to mobilise any ancillary equipment which may be required during the emergency response** **(Schedule 4 Part 2, para 5c)**	Ancillary equipment is defined in this context as those miscellaneous provisions that may be required to enable the emergency response to be carried out. Such equipment could include vehicles to transport emergency equipment to and from the site of the accident, heavy lifting gear, earth moving equipment, emergency lighting, and special tools, parts etc. required to carry out emergency repairs and actions.
Maintenance, etc. of Emergency Response Equipment	
Criterion 14.4 **The safety report should provide evidence that suitable arrangements have been made for the maintenance, inspection,**	The safety report should provide evidence that suitable arrangements have been made for the: • maintenance (planned and breakdown), • inspection, examination and

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examination and testing of the mobilisable resources and other equipment to be used during the emergency response. (This criterion only applies to mobilisable resources and other equipment for which the operator has responsibility) **(Schedule 2, para 4c)**	• testing, of emergency response equipment and provisions. The arrangements should cover: • equipment with a direct mitigatory function such as fire fighting equipment; • other equipment with a key function, such as alarms to warn personnel of the accident. The evidence may take the form of statement of confirmation that specific equipment is included in plant maintenance schedules, maintenance records, maintenance procedures and instructions etc.
Training In The Emergency Response	
Criterion 14.5 **The safety report should provide evidence that suitable arrangements have been made in the safety management system for training of individuals on-site in the emergency response** **(Schedule 2, para 4a & e)**	The safety report should provide evidence to give confidence that the safety management system has taken account of the need to train individuals in the emergency response, and to ensure that the training is kept up to date (e.g. by refresher training). The training should cover: • those members of staff with a specific role in the event of a major accident; • as well as the training/information needs of other employees, • contractors and visitors to the site. The training should include where relevant: • information on the major accident scenarios which may trigger the on-site and off-site emergency plans; • the nature of major accidents posing a threat to the environment and the particular steps to take in the event of such accidents; • knowledge of the alarm systems and the required response to each alarm; • the procedures for reporting/responding to incidents on site which have the potential to escalate into a major accident; • the use of the resources which may be mobilised in the event of a major accident e.g. fire fighting equipment, special chemicals, etc; • the use of protective equipment (e.g. respirators, breathing air, clothing etc.), and any limitations

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	on their use; • the evacuation and mustering procedures; • the actions required by staff with key roles in the implementation of the on-site emergency plans e.g. the site main controller or site incident controller; • the training of individuals from organisations with which a mutual aid agreement exists.
Testing of Emergency Plans	
Criterion 14.6 **The safety report should provide evidence that procedures have been made and adopted to test and review emergency plans, and to revise the emergency arrangements in the light of the lessons learned** **(Schedule 2, para 4e)**	The safety report should provide sufficient evidence to give confidence that a suitable programme of emergency exercises has been drawn up, and has been implemented, to test the emergency arrangements at all levels (i.e. the local plant response the site-wide response, and the interface with the off-site response) and that a procedure exists to ensure that the lessons learned from these exercises are reviewed and the emergency arrangements revised where necessary.
Information Required for the Offsite Emergency Plan	
Criterion 14.7 **The safety report should supply information to enable the off-site emergency plan to be drawn up** **(Schedule 4, part 1 para 4)**	The minimum information to be included in the safety report is listed below: • details of the site including its location, nearby roads, and site access. (This topic is considered in more detail in Section 9)*;* • site plan showing location of key facilities such as control centres, medical centres, location of main process plant and stores. Details of staffing levels. (This topic is considered in more detail in Section 9)*;* • details of the off-site area likely to be affected by a major accident e.g. maps with sectors and environmentally sensitive areas (e.g. Sites of Special Scientific Interest (SSSI's), Special Areas of Conservation (SAC's), Special Protected Areas (SPA's)) indicated, information on the types of building, the population density, roads, sensitive buildings (e.g. schools, hospitals), and a drainage map to help determine where spillages could leave the site. (This topic is considered in more detail in Section 9); • details of the dangerous substances on-site covered by the COMAH Regulations and similar

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	information for other hazardous materials held on site, including: quantities; hazardous properties and the nature of their effects on people and the environment; an outline of the use and storage of the materials on site; and an outline of the major accident hazards. (These topics are covered in more detail in Sections 9 and 10); • details of the technical advice that company can provide to assist the emergency response (criterion 14.2 refers); • relevant technical details of the equipment (and other resources such as chemicals) which may be normally available on site and which may be available to assist the off-site emergency services during an emergency response, including resources supplied from other establishments with which a mutual aid agreement may exist (criterion 14.3 refers); • the functions of key posts with duties in the emergency response, their location and how they can be identified: e.g. the posts authorised to set the emergency procedures in motion and the conditions for doing so; the post responsible for the co-ordination of the on-site mitigatory action; the post responsible for liaising with the off-site emergency services (criterion 14.2 refers); • outline of the initial actions, and procedures in the on-site emergency plans, to be taken by on-site staff once the emergency has been declared e.g. the warning of the public and adjacent sites, the setting up of emergency facilities such as the emergency control room, and the response expected from on-site personnel (e.g. sheltering) (criterion 14.8 refers).
Elements in the Safety Report Necessary to Draw Up the On-site Emergency Plans	
Criterion 14.8 **The safety report should summarise those measures of protection and intervention which have been used as the basis for drawing up the on-site emergency plans** **(Schedule 4 Part 2, para 5d)**	The information that has been used as the basis for drawing up the on-site emergency plans should be brought together in the form of a summary in the safety report and should cover: • the equipment installed in the plant to limit the consequences of a major accident; • the organisation of the alert and intervention; • the on-site and off-site resources that may be

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	mobilised.
Criterion 14.9 **The operator should confirm the arrangements that have been made to give information to the public, and every hospital, school or other establishment serving the public, in the area around the site, so designated by the competent authority** **(Regulation 14)**	Operators should explain the arrangements that they have made and when the details were sent out. This information should be sent out at intervals not exceeding 5 years or where changes are required as a result of the reviews discussed below. They should also confirm that the information required by Schedule 6 has been included. This criterion will not be applicable until the local authority has prepared an off-site plan required by COMAH. Updated reports should include confirmation of the review arrangements for the information provided required by Regulation 14(6) every 3 years or where there are changes on site requiring a review.

15. GLOSSARY

Terms defined in COMAH Regulation 2(1) and elsewhere in the regulations carry the same definition within SRAM where used. These definitions are not repeated below.

Activities	Events in the establishment under the control of the occupier but not necessarily directly involved with the installations where dangerous substances are located. These will include vehicle movements, transport and transfer operations.
ALARP	Stands for `as low as reasonably practicable'. The concept implies that ultimately there is a trade-off between the costs of risk reduction and the benefits obtained. Most decisions on whether risks are ALARP should be made by exercising professional judgement on whether the risks are reasonable when set subjectively against the cost of further risk reduction. In some cases, a formal cost-benefit analysis can be used which can be seen to give a more objective analysis of costs against the benefits of risk reduction. The ALARP concept is sometimes referred to as BATNEEC (best available technology not entailing excessive cost), which is often applied in environmental contexts.
Appropriate	Fit-for-purpose in the particular context.
Assessment	In this context, the process of reading a safety report and reaching a conclusion as to the adequacy of the **demonstration** that all necessary measures have been taken to prevent major accidents or minimise their effects.
Assessment Manager (AM)	The field inspector responsible for co-ordinating the various **assessment** tasks and ensuring that the **conclusions** are communicated to the operator.
Assessors	The various people who will be completing the **assessment** process to the satisfaction of the **assessment manager.** These will include representatives from the various disciplines within HSE and the Environment Agencies.
CAS Number	A unique numbering system used to identify chemicals according to the Chemical Abstracts System scheme.
Competent Authority (CA)	In relation to an establishment in England and Wales, the Health and Safety Executive and Environment Agency acting jointly. In relationship to an establishment in Scotland, the Health and Safety Executive and Scottish Environment Protection Agency acting jointly (Regulation 2(1) refers).
Conclusions	The judgemental view reached by assessors on the adequacy of the arguments and demonstrations made in the safety report based on prima facie assessment of a safety report. The written conclusions of the assessment team are sent to the operator in accordance with COMAH regulation 17. Conclusions may include an agreed plan for additional action by the operator.
Control measures	The means for controlling the realisation of **hazards** (i.e. limiting their occurrence probability / likelihood) and for mitigating the associated consequences (e.g. a water spray system for mitigating releases of anhydrous hydrogen fluoride).
Controlled Waters	As defined in paragraph 104 of Part III of the Water Resources Act 1991.
Criteria	Defined standards of performance against which actual or predicted performance can be assessed.

Demonstration of safety	The process by which the operator provides information to show that all necessary measures to prevent major accidents, or **mitigate** their effects have been taken.
Enforcement	The range of tools available to the regulator from advice and guidance through to legal action.
Environment	The surroundings around, over and under an establishment including the flora, fauna, buildings and infrastructure.
Harm	The severity of the consequences of any potential major accident for people or the environment.
Harm criteria	Essentially dose-response relationships for converting hazardous phenomena (spatial and temporal variations in contamination concentration, overpressure, thermal radiation) into **harm** for people and the **environment**.
Hazard	A physical situation with the potential for human injury, damage to property, damage to the environment or some combination of these.
Hazard analysis	The process of identifying undesired events that lead to a **hazard** being realised, the analysis of the mechanisms by which these undesired events could occur and the estimation of their likelihood and the magnitude of any harmful effects.
Individual risk	The frequency at which an individual may be expected to sustain a given level of **harm** from the realisation of specified **hazards**.
Inherent safety	The principle whereby a **hazard** is avoided at source rather than by employing measures to prevent its realisation or reduce the consequences of that realisation after the event.
Key Risk Control Systems	Those **risk control systems** which are of key importance for the prevention and mitigation of major accidents.
Management arrangements	In the context of health and safety at work in general, the term applies to an employer's arrangements for health and safety management and covers the elements of "policy", "organising", "planning and implementing", "measuring performance" and "audit and review". The concept is explained in HS(G)65 and the HID Inspection Manual. In the context of major hazards, the term applies to the operator's arrangements for managing major hazards and covers the same elements but as they relate to the prevention and mitigation of major accident i.e. "Major Accident Prevention Policy", "organising.... etc".
Mitigation	The process of reducing the scale of the consequences of a major accident.
Process	Any operation by which dangerous substances are stored, transferred, handled, or changed in some way.
Protective system	An active or passive means of protecting plant from dangerous conditions either from within (e.g. overpressure) or without (e.g. fire).
Prevention	The means for eliminating hazards or reducing their likelihood and for mitigating the associated consequences. This includes approaches to **inherent safety** and identification of suitable **control measures**.
Qualifying inventory or quantity	The quantity of a dangerous substance as defined in Schedule 1 of the Regulations and used to determine the application of the various provisions of COMAH.
Residual risk	The risk remaining after all proposed **control measures** for the establishment have been properly implemented.
Risk	The likelihood of a specified undesired event occurring within a specified period or in specified circumstances.

Risk analysis	The process of **hazard analysis**, and the estimation of associated levels of risk to people, property, the environment or a combination of these.
Risk assessment	The process of **risk analysis** and the evaluation of the significance of the results.
Risk Control System (RCS)	A part of the overall safety management arrangements that sets out how the SMS is applied to a specific task or activity.
Risk reduction	The process of **risk assessment** coupled to a systematic consideration of possible **control measures** and a judgement on whether they are reasonably practicable to implement. Essentially the process for demonstrating that the adopted controls make the risk to people and the environment **ALARP**.
Safety-critical	An item of plant or human action is safety-critical if either its failure could cause or contribute substantially to a major accident, or its purpose is to prevent or limit the effect of, a major accident. An event is safety critical if its occurrence could lead to a significant release of a dangerous substance with major consequences to people or the environment.
Safety-integrity	The probability of a safety related system satisfactorily performing the required safety functions under the stated condition within a stated period of time.
Safety-related control system	A system which is intended to implement the required safety functions needed to maintain a safe state, and achieve, in conjunction with other risk reduction measures, the necessary **safety integrity**.
Safety Management System (SMS)	In the context of major **hazards**, the term applies to the operator's management arrangements and **key risk control systems** required for the prevention and **mitigation** of major accidents, and in scope encompasses the issues described in Schedule 2 of the Regulations.
Scale of the hazard	The severity of the worst-case scenario associated with a **hazard**. Usually determined by the loss of containment of the maximum inventory of the substance presenting the **hazard**.
Serious deficiency	When the measures for prevention and mitigation of a major accident are sufficiently lacking to require prohibition of the use of an establishment, installation or part thereof, as described in Regulation 18.
Societal risk	The relationship between frequency and the number of people suffering from a specified level of harm in a given population from the realisation of the specified **hazards**.
Trip system	A means of actively ensuring that conditions within plant remain within safe limits. Trip systems work in association with **alarm** systems and operate by detecting excursions beyond **alarm** conditions and controlling the process or equipment to a defined (safe) state.
Used correctly	Suitable procedures or models have been applied without mistakes, including validity checks e.g. the derived estimates of event likelihood, consequences etc. (whether qualitative semi-quantitative, or quantitative) are realistic and compatible with company or other recognised benchmarks.
Verification	Used in SRAM in the context of testing the accuracy of any aspect of the safety report. This will be part of the inspection process after the desk top **assessment** of the safety report is complete.
Worst case scenario	Usually associated with the loss of containment of the maximum inventory of the hazardous substance and the subsequent scenario that produces the worst outcome for people or the environment.