

## 10 PREDICTIVE ASPECTS OF SAFETY REPORT ASSESSMENT

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### 1. INTRODUCTION

- 1.1** This guidance is for assessors completing the predictive assessment and is relevant to all types of safety report.
- 1.2** All predictive assessment must use the criteria and guidance set out in Appendix: 10.1 '*Predictive Assessment Criteria and Guidance*'.

Predictive Assessment must be recorded on the following forms:

SRAM 08 – RECEIPT – Early Predictive Screen Record; and  
SRAM 17 - '*Predictive Assessment Record*'

- 1.4** The criteria are designed to follow in sequence the specific requirements set down in Schedule 3 of the 2015 COMAH regulations and to reflect relevant purposes set out in Regulation 8 of the same regulations. These are minimum legal requirements and are clear and enforceable (Regulation 9).
- 1.5** Experience has shown that it is essential for operators to identify all major accident hazards, their likelihood, and consequences before going on to perform a sufficient and suitable risk assessment and identify risk reduction measures.
- 1.6** Any subsequent 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.
- 1.7** Demonstrations should be proportionate to the hazard and risks of identified major accident hazards. This aspect can only be decided by an operator when all the elements of Schedule 3 have been determined. The determination of proportionality is an iterative process both for an operator and an assessor

**1.8** An assessor will then have to decide if a safety report adequately satisfies the requirements of demonstrating that the necessary measures have been taken to prevent the identified major accident hazards and to limit their consequences (Regulation 8b).

### **1.9 Use of Assessment Criteria**

The criteria will be applied by a competent assessor against the content of the safety report. In this context, a competent assessor will have a good understanding of the safety report assessment process, its place within the HID Regulatory Model and of any stated benchmarks.

- a. Criteria will be **“met”** when all relevant items are included in descriptions and the necessary supporting information has been provided;
- b. Criteria will be **“not met”** when all relevant items are not included in descriptions or the necessary supporting information has not been provided;
- c. Criteria will be **“not relevant”** when they are not relevant to the establishment;
- d. Criteria will be **“previously met”** when the previous assessor recorded the criterion as “met”.

## **2. RELEVANT REQUIREMENTS OF THE COMAH REGULATIONS**

**2.1** Regulation 5(1) of COMAH 2015 places a general obligation upon all COMAH operators to take all measures necessary to prevent major accidents and to limit their consequences for human health and the environment. The work undertaken and measures implemented by an operator to meet the requirements of Regulation 5(1) must, when requested by the Competent Authority, be demonstrated per Regulation 5(2). The Competent Authority’s programme of inspections is designed to check this.

**2.2** Specifically in relation to safety reports the operator must show that they have assessed the risks and implemented the necessary controls because of Part (b) Regulation 8 of the COMAH Regulations 2015, which requires the operator to prepare a safety report for the purposes of demonstrating that *“major accident hazards and possible major accident scenarios, in relation to the establishment, have been identified and that the necessary measures have been taken to prevent such accidents and to limit their consequences for human health and the environment”*.

**2.3** The operator can usually show this by providing sufficient information to satisfy the requirements of Schedule 3 part 5 ‘Identification and accidental risks analysis and prevention methods’.

## **3. ‘ALL MEASURES NECESSARY’ AND THE ASSESSMENT OF PREDICTIVE ASPECTS**

**3.1** HSE policy is that taking all measures necessary equates to reducing risks as low as is reasonably practicable at the COMAH establishment. Operators are required to take measures to reduce the likelihood of hazards and to mitigate their consequences until the associated risks are As Low As Reasonably Practicable (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.

- 3.2** In general the Tolerability of Risk (TOR) framework is applied so that 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. However if the hazard is very high then less account should be taken of risk.
- 3.3** In practice 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.
- 3.4** The issue with COMAH safety reports is whether any necessary measures to reduce risks to ALARP have been excluded by the COMAH operator. 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.
- 3.5** The key is to be able to decide when any possible further measures are reasonably practicable (i.e. necessary), and when any possible further measures are not reasonably practicable.
- 3.6** A good demonstration in a safety report will provide an amount of evidence and a depth of argument that is proportionate to the risk posed by the establishment.
- 3.7** In particular the assessor needs to assess the analysis of possible further risk reduction measures. The information needed to determine if the necessary measures for risk reduction have been implemented must either be available or referenced and summarised, where appropriate in the safety report.

## **4. RISK ASSESSMENT**

- 4.1** 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 remaining hazards, 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 in sufficient detail to demonstrate that the necessary measures have been taken to prevent and mitigate major accidents.

**4.2** 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.

**4.3** 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.

**4.4** 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 by evidence that can be made available on request;
- Risk reduction cannot be looked at without first doing a risk analysis.

## **5. PROPORTIONALITY**

**5.1** 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 within SRAM.

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

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

## **6 FITNESS FOR PURPOSE**

**6.1** 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.

## 7. EARLY PREDICTIVE SCREENING

- 7.1** 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 3 of the 2015 COMAH regulations 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 their place within the establishment's overall requirement to ensure that risks have been reduced to ALARP.
- 7.2** 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.
- 7.3** In advance of a safety report submission the Assessment Manager and Predictive Assessor will decide if an Early Predictive Screening (EPS) should be undertaken before the report is sent to other members of the Assessment Team. The decision should be guided as follows:
- a. For a 'New / Other' Establishment safety report an EPS would normally be undertaken;
  - b. Where a review of an Existing Establishment's safety report has been submitted, it would normally be unnecessary to carry out an EPA.
  - c. When an Early Predictive Screening is to be carried out it should be finalised within the completeness check timeframe.
- 7.4** All Early Predictive Screening should use the template in Appendix 10.3 '*Early Predictive Screening Record*'
- 7.5** Where undertaken, the completed Early Predictive Screening record should be forwarded to the Assessment Manager in advance of the draft Assessment Plan being finalised.

## Appendix 10.1 'Predictive Assessment Criteria and Guidance'

TECHNICAL CRITERION	REFS	GUIDANCE
<p><b>10.1</b> The safety report should identify and describe in detail all potential major accident scenarios</p> <p><b>Reg 8(b)</b> <b>Schedule 3 Para 5(a)</b></p>	<p>SRAG SPC 11</p>	<p>All possible MAs should be identified and described. For complex sites, for the purposes of a demonstration, the company may define a representative and sufficient set.</p> <p>In this case MAs may be put into example groups to make a demonstration less voluminous.</p>
<p><b>10.1.1 Proportionality</b></p> <p>An initial view on the degree of rigour required in a demonstration should be made.</p> <p><b>Reg 8(b)</b></p>	<p>SRAG</p>	<p>An initial view on the required proportionality should be made (i.e. the depth of analysis required for the demonstration). Where relevant, this should take into account the findings of an Early Predictive Screening (EPS).</p> <p>This process is iterative and informs a later decision (See 10.4) on the degree of rigour which should be undertaken when making ALARP decisions.</p>
<p><b>10.1.2</b> 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</p> <p><b>Schedule 3</b> <b>Paras 5(a) (i),(ii),(iii)</b></p>		<p>A comprehensive process should have considered loss of containment derived from all reasonably foreseeable:</p> <ul style="list-style-type: none"> <li><b>(i)</b> On-site operational causes including Human Factor related initiators.</li> <li><b>(ii)</b> External causes. E.g. domino effects or any offsite initiating events that may impact upon site operations.</li> <li><b>(iii)</b> Natural causes.</li> </ul> <p>The report should outline how major accident hazards are identified and show that a suitable range of events has been identified for further assessment.</p> <p><u>On-site Events, where relevant, may include:</u></p> <ul style="list-style-type: none"> <li><b>(i)</b> Loss of containment accidents due to equipment, vessel, pipe work and pipeline failures and those initiated by human error.</li> <li><b>(ii)</b> Explosions.</li> <li><b>(iii)</b> Condensed Phase Explosions relating to explosives.</li> <li><b>(iv)</b> Large fires (Warehouses, pool fires, jet fires, etc.).</li> </ul>

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		<p>(v) Events influenced by emergency action or adverse operating conditions etc.</p> <p>(vi) Loss or interruption of utilities</p> <p>(vii) Other types of major accident hazard or abnormal discharge.</p> <p><u>External Events where relevant may include:</u></p> <p>(i) Aircraft impact.</p> <p>(ii) Seismic event; land slips, subsidence.</p> <p>(iii) Extreme environmental conditions (e.g. abnormal rain, snow, temperature, wind, floods, ightning). Vehicle/train impact or other external missiles</p> <p>• Human error can play a significant role in major accident and their causes.</p> <p>• The Predictive assessor should discuss relevant issues with the Human Factors assessor as appropriate.</p>

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<p><b>10.2</b> The safety report should contain estimates of the probability (qualitative or quantitative) of each major accident scenario or the conditions under which they occur.</p> <p>This should include a summary of the initiating events and event sequences (internal or external), which may play a role in initiating each scenario</p> <p><b>Schedule 3 Para 5(a)</b></p>	<p>SRAG SPC 11 HSE Website</p>	<p>The likely frequency or probability of major accidents should be considered.</p> <p>The depth of the analysis of event likelihood should be proportionate to the scale and nature of the hazard</p> <p><u>For failure rates the safety report should :</u></p> <ul style="list-style-type: none"> <li>(i) Justify the failure rate values used</li> <li>(ii) Include references and methods of derivation (where appropriate).</li> </ul> <p>When quantitative human reliability assessment (QHRA) is used to determine human error probabilities (HEPs) (e.g. for initiating events and layers of protection in SIL assessments) the report should demonstrate that:</p> <ul style="list-style-type: none"> <li>(i) The process has been carried out by a competent human factors assessor (competent in both human factors and the methodology used);</li> <li>(ii) All assumptions are grounded on a thorough and systematic qualitative assessment.</li> </ul> <p><b>Use of generic HEP data is unacceptable unless it has been qualified to reflect local circumstances or is more than or equal to an HEP of 0.1.</b></p>
<p><b>10.2.1</b> There should be a suitable review of past accidents and incidents relevant to the site</p> <p><b>Schedule 3 Para 5(c)</b></p>	<p>e.g.Review of high cost accidents (Hirst et al) COMAH Intelligence system-annual reports</p>	<p><b>COMAH 2015 REQUIREMENT</b></p> <p>A review of past accidents and incidents with the same substances and processes used, consideration of lessons learned from these and explicit reference to specific measures taken to prevent such accidents is required by Schedule 3 and is a minimum requirement. Clearly, this should look beyond the site to the wider industry relevant to the site.</p>
<p><b>10.3</b> The safety report should contain the results of calculations showing suitable estimates of the severity and extent of the consequences of each major accident</p>	<p>SPC 35 Consequence assessment guidance CD</p>	<p><b>This the most important predictive part of a safety report and must be included. Without it is impossible to come to an appropriate view on proportionality and where a company should put effort into risk reduction measures</b></p> <p>Extent and severity is concerned with who (people) might be harmed, how badly, and how many (people) are affected by major accidents. The safety report should provide details to demonstrate that suitable</p>

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<p><b>Schedule 3 Para 5(b)</b></p>		<p>and sufficient consequence assessment for each major accident scenario has been carried out with respect to people</p> <p><u>The safety report should:</u></p> <ul style="list-style-type: none"> <li>(i) Combine harm criteria, predicted hazard ranges, specific data for on/off site populations.</li> <li>(ii) Present extent Information               <ul style="list-style-type: none"> <li>○ Effects distances on maps and /or images of the site and surrounding area showing areas likely to be affected by major accidents(with identified estimations of numbers, centres and types of populations both on and off site).</li> </ul> </li> <li>(iii) Presents severity information in a suitable form, e.g.:               <ul style="list-style-type: none"> <li>○ Numbers of fatalities, serious injuries, hospitalisations.</li> <li>○ Banding in terms of consequence to people (e.g. 1-5, 5-20 20-100, etc).</li> <li>○ Where major accidents have been put into example groups, then it is acceptable to present extent and severity for each group.</li> </ul> </li> </ul>
<p><b>10.4 Proportionality - The risk assessment should be suitable and sufficient and proportionate to the level of hazard and risk.</b></p> <p><b>Reg 8(b)</b></p>	<p>SRAG</p>	<p>Where necessary, pre-receipt discussions will provide an expectation of the level of rigour which should be utilised in the risk assessment used to assess the risk levels and which further risk reduction measures to employ. The assessment of the safety report content will take into account those expectations.</p>
<p><b>10.4.1</b> 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.</p> <p><b>Reg 8 (b)(c)</b></p>	<p>SRAG SPC 37 SPC 9 ALARP Suite SPC 11 CIA guidance on Occupied Buildings</p>	<p><b>The applied risk assessment methodology should be proportionate to the scale and nature of the hazards and the estimated risks.</b></p> <p>The safety reports should pull together the information from the risk assessment such that it:</p> <ul style="list-style-type: none"> <li>• Draws together the likelihood and consequence assessments in an appropriate way to make estimates of the risks. Where major accidents have been put into example groups, it is essential that the frequency of all the major accidents within the group is taken into account (i.e. frequencies must be added together for all similar types of major accident).</li> <li>• Identifies Safety Critical Events (See SPC 11)</li> </ul>

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		<ul style="list-style-type: none"> <li>● Recognises that high consequence events warrant attention for further risk reduction on a case by case basis.</li> <li>● Considers both individual and (where appropriate) societal risk.</li> <li>● Compares the risks against suitable criteria and takes account of aversion to large scale serious events where necessary, in the selection of necessary measures.</li> <li>● Draws conclusions about the tolerability of risks from the site.</li> <li>● Considers sensitivity and uncertainty in the risk assessment.</li> <li>● Shows that risk assessment has been used in an appropriate way as part of the process to reduce risks on the establishment to ALARP.</li> <li>● Includes a suitable and sufficient consideration of risk reduction options and describes the decision making process.</li> <li>● Comes to conclusions about what further risk reduction options are reasonably practicable</li> <li>● Puts in place a programme of implementing further risk reduction options with timescales</li> </ul> <p>Where the further measures include automation (to remove the human contribution to failure) the automation should be well-justified, well-designed, and selected for the right reasons.</p> <p>Training and procedures should not be viewed as the sole defence against human failure; they should form an integral part of a broader range of measures to reduce the potential for human failure.</p>