COMAH Competent Authority

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Inspecting Human Factors at COMAH Establishments

(Operational Delivery Guide)

HSE Environment Agency SEPA Cyfoeth Naturiol Cymru Natural Resources Wales ONR Office for Nuclear Regulation

Introduction

1. This Delivery Guide (DG) supports the Competent Authority's (CA) programme of regulating major hazards, by establishing a clear framework to inspect human factors (HF) at COMAH establishments. It builds on the HID Regulatory Model[1] and the principles that determine how HID directs resources to activities that give rise to the greatest risk, or are managed least effectively.

2. The DG will assist Regulatory Inspectors* when they inspect HF aspects of key safety management and risk control systems (e.g. procedures; competence assurance; permit-to-work systems) and provide them with clear guidelines to help decide when specialist HF support may be required. In addition, it aims to target HF specialist resource where it is needed most, by identifying priority topics for inspection by HF Specialist Inspectors.

3. The DG will also enable Regulatory and HF Specialist Inspectors to rate the performance of COMAH operators against success criteria for a number of key HF inspection topics.

4. Although the DG is aimed primarily at Regulatory and HF Specialist Inspectors, it will help COMAH operators prepare for HF inspections and understand the rationale behind those interventions. The key topics and underlying HF principles will also be relevant during HF interventions at other high-hazard sites that are not covered by COMAH.

Justification

5. The COMAH Competent Authority Intelligence Review Group (CAIRG) analysed evidence from loss of containments in the chemical sector across several years up to 2010. As a result of those findings, the 2011 HSE Chemicals Sector Strategy identified 'maintaining competence' as a key priority. This, in turn, led to the launch of the CA's Delivery Guide for inspecting competence management systems[2] and a programme of inspection at COMAH sites running from 2012 to 2015. That programme is now drawing to a close.

6. In a follow-up analysis of dangerous occurrences and loss of containment incidents initiated by human and safety management system failures (up to 2014), CAIRG identified a wide range of HF-related underlying causes. Many of those causes occurred more frequently than failings with competence management systems (e.g. poor operational and maintenance procedures; inadequate risk assessment; poor plant and process design; failings in safety-critical communication, including shift handover and permit-to-work).

7. Consequently, whilst the CA recognises that competence assurance remains an important Performance Influencing Factor[3] (PIF), and acknowledges that the outgoing competence DG continues to secure improvements to competence management systems at COMAH establishments, this new DG aims to establish, and resource, an intervention programme that addresses a broader range of key HF topics. Those topics have been informed by the high-priority HF issues emerging from the 2014 CAIRG analysis.

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* Throughout this DG, the term 'Regulatory Inspector' refers to either an HSE Regulatory Inspector, an ONR Inspector, or an Authorised Person working on behalf of the appropriate agency (EA, SEPA or NRW), acting to fulfil their responsibilities as the Competent Authority.

Background

8. Human factors have been defined as the characteristics of the job, individual and organisation that influence human performance. Further guidance is available in core publications such as HSG48[4] and on the human factors home page of the HSE website.

9. The General Duty under COMAH requires that every operator must take all measures necessary to prevent major accidents and limit their consequences for human health and the environment. Where reliance is placed on people as part of those necessary measures, human factors and human reliability should be addressed with the same rigour as technical and engineering measures. Duty-holders at non-COMAH sites may be required to address HF with a similar degree of rigour under other legislation - including COSHH[5] - if they rely heavily on people to manage high-hazard risks.

10. This DG will help Regulatory and HF Specialist Inspectors decide whether a particular COMAH operator is managing HF with a suitable degree of rigour, in the context of proportionality and relevant good practice.

11. The DG model is based on the Human Factors Roadmap[6], which establishes a practical, framework for managing HF at COMAH establishments. The Roadmap encourages COMAH operators to use HF in risk assessment to establish clear links between site-specific major accident hazards (MAHs) and risk reduction measures that target human reliability (accounting for the normal hierarchy of control).

12. The Roadmap was first published in 2010 and has been widely promoted and circulated since. It has been updated to reflect recent CAIRG findings and to align with the key HF inspection topics defined within this DG. A copy of the updated Roadmap is reproduced in Appendix 3.

Purpose

13. The primary aim of the DG is to support Regulatory and HF Specialist Inspectors when they plan, undertake and rate HF inspections at COMAH establishments (by sampling key HF elements of an operator's systems and arrangements to manage MAHs). It will also help Regulatory Inspectors target HF specialist resource in a proportionate and effective manner.

14. The DG is not intended to be a detailed inspection tool. Rather, it aims to highlight key milestones for HF integration and signpost supporting guidance, such as the Human Factors Inspector's Toolkit[7].

15. The Toolkit was published in 2005 as guidance for Regulatory Inspectors to inspect key HF topics at lower-tier COMAH sites. It will be re-aligned with this DG in due course. In the meantime, Regulatory Inspectors will be provided with additional supporting materials (e.g. updated inspection guides for key interventions).

16. Another aim of the DG is to bring transparency to the CA's programme of HF inspection work. It will help COMAH operators understand why certain HF topics are selected for inspection, how an establishment's performance is judged and rated, and how individual inspections fit into the wider picture of HF integration.

17. The CA believes that HF inspection work is central to ensuring that major hazard risks are properly managed. This DG provides a structured framework for Regulatory and HF Specialist Inspectors to verify that COMAH operators have selected appropriate risk reduction measures, and that those measures are being implemented effectively.

Scope

18. The DG is aimed at upper-tier and lower-tier COMAH establishments. However, many of the key topics and underlying HF principles will be equally relevant at non-COMAH sites that rely heavily on people to manage high-consequence hazards.

19. Based on findings from the 2014 CAIRG review, the following topics are considered key to managing HF at COMAH establishments (though not all topics will be relevant at every establishment):

    - Managing Human Performance
    - Human Factors in Process Design
    - COMAH-Critical Communications
    - Design and Management of Procedures
    - Competence Management Systems
    - Managing Organisational Factors

20. Further guidance on inspecting each topic – including who would normally conduct the inspection and how performance should be rated – is included in Appendix 1 of the DG.

Targeting HF Specialist Resource in a Proportionate Manner

21. The DG builds on the CA's published methodology for prioritising operational work[8], which is based on intrinsic site hazards and how the COMAH operator is performing against a number of strategic inspection topics. Over time, scores assigned for key HF inspections will inform the on-going cycle of COMAH intervention planning.

22. It is anticipated that Regulatory Inspectors will carry out, and rate, certain topic-based inspections without HF specialist support. These visits will typically involve the inspection of key safety management and risk control systems (procedures; competence assurance; PTW arrangements) at upper- and lower-tier COMAH establishments. The DG will help Regulatory Inspectors identify follow-up work where HF specialist support may be required. Further guidance is provided in Appendices 1 and 2.

23. The DG also provides a framework for Regulatory Inspectors to conduct more general HF inspections at lower-tier establishments, and at certain upper-tier establishments, where there is high reliance on effective procedures, competence and supervision to manage MAHs, and where there is no - or limited - process control (e.g. chemical warehouses; whisky maturation sites; simple bulk storage sites).

24. Establishments that rely heavily on manual intervention for process control (e.g. chemical manufacturers that undertake 'all-in' batch reactions; chemical processing at waste treatment sites) can be especially vulnerable to human failure, even though the processes involved appear relatively simple and the establishments qualify for lower-tier status. At such establishments, where proportionate but effective HF design is an important performance influencing factor, Regulatory Inspectors are strongly advised to seek HF specialist support.

25. Regulatory Inspectors are encouraged to contact the HF Team for guidance if they are in any doubt about allocating HF resource, or if they require support to plan visits and/or discuss key inspection findings.

HF Scoping Visits

26. At COMAH establishments where there have been no previous HF inspections, and/or HF aspects of the safety report have not been assessed in detail, the CA will conduct a preliminary 'scoping visit' to help set the direction of future HF interventions.

27. Scoping visits will generally involve a prima-facie review of the HF topics in Appendix 1 (if relevant). Where appropriate, these visits could be framed around a single, high-priority MAH scenario. By definition, scoping visits will be conducted at a relatively high level and the CA will not rate the COMAH operator's performance against each HF topic.

28. The DG anticipates that either Regulatory Inspectors or HF Specialist Inspectors will carry out scoping visits – those undertaken by HF Specialist Inspectors will be prioritised according to the complexity, hazard score and performance rating of the establishment. An inspection guide is available.

Judging Success and Moving On - Performance Ratings for HF Topics

29. Success criteria for key HF inspection topics are defined in Appendix 1 (with the exception of Managing Organisational Factors – the 'one-off' nature of these interventions means they will not be formally rated). By comparing key findings from the inspection with the relevant success criteria in Appendix 1, the COMAH operator's performance should be rated in line with the descriptions/scores in Appendix 2.

30. Regulatory Inspectors should consider a follow-up inspection with an HF Specialist Inspector whenever they assign a rating score of 40, 50 or 60 to a topic, or if they identify significant shortcomings in a specific, key area.

31. The CA will not apply retrospective performance scores to HF inspections carried out prior to the publication of this DG. However, when preparing for inspections under the DG, Inspectors should refer to key findings from previous HF interventions and, where relevant, use those findings to inform the current topic rating.

32. Ratings achieved under the outgoing competence DG remain valid, but may be revised to reflect findings from follow-up competence inspections under the new DG.

Enforcement Expectations

33. Indicative enforcement expectations are included in Appendix 2. Ultimately, however, Inspectors should use the Enforcement Management Model[9], including assessment of factors that are specific to the COMAH operator, to inform their regulatory decisions.

34. If in doubt, Regulatory Inspectors should approach the Human Factors Team for guidance on HF enforcement matters.

Communicating and Recording Outcomes

35. When the inspection is complete (including review/analysis of any further information requested), performance scores should be communicated to the COMAH operator and recorded in the CA inspection report.

36. Performance scores should also be recorded on the appropriate COIN IRF Tab.

COMAH Operators - Technical Competence in Human Factors

37. Experience suggests that inadequate technical competence in human factors is a significant barrier to HF integration at COMAH establishments. Inspectors should challenge COMAH operators to demonstrate proportionate access to HF expertise.

38. COMAH operators may choose to draw on external, competent support to help inform and direct certain aspects of HF integration (e.g. a Chartered Ergonomist or a Chartered Human Factors Specialist accredited by the Chartered Institute of Ergonomics and Human Factors[10]). This is acceptable, provided the COMAH operator maintains an effective intelligent customer capability[11]. In any event, COMAH establishments should aim to secure local ownership of key HF standards and their implementation. This will usually involve the introduction of measures to develop and maintain a suitable level of 'in-house' HF expertise (either at the establishment, or via a central/corporate HF support function).

Review and Evaluation of the DG

39. The CA will periodically review and evaluate outcomes of the DG and communicate key lessons learned to relevant parties and stakeholders.

Appendix 1 – Key Topics for Inspection

Topic 1: Managing Human Performance

1. HF Specialist Inspectors will inspect and rate this topic at most upper-tier establishments.

2. Regulatory Inspectors will normally inspect and rate this topic at lower-tier establishments, and at certain upper-tier establishments, where there is limited or no process control (e.g. chemical warehouses; whisky maturation sites; simple bulk storage sites). Regulatory Inspectors will also find the success criteria useful, during their own scoping visits, in deciding whether HF in risk assessment warrants specialist intervention.

3. Topic 1 comprises the following two elements:

Topic 1.1 Human Factors in MAH Risk Assessment and Accident Investigation

4. HF in risk assessment lies at the heart of managing human factors and underpins the HF Roadmap. The aim is to optimise the performance of people who undertake COMAH-critical tasks[12] in the context of ALARP and the hierarchy of control.[13] Where reasonably practicable, the Roadmap requires COMAH operators to adopt additional risk reduction measures, such as well-designed automated systems and engineered controls, to reduce over-reliance on softer measures, such as procedures and competence. Where there is still reliance on people to manage MAHs, and operators can justify this, the Roadmap seeks to optimise PIFs that may degrade human performance (see Appendix 3 for an overview of these key principles).

5. COMAH operators should use Human Reliability Analysis[14] (HRA), and findings from accident and incident investigations, to gain a clear understanding of where and when they are vulnerable to human failure (COMAH-critical tasks), how those failures are likely to occur (accounting for the different types of human failure), and the factors that make those failures more likely (PIFs).

Topic 1.2 Human Reliability during Maintenance, Inspection and Testing (MIT)

6. Human failure during MIT continues to be cited as an important causal factor in a significant number of major accidents worldwide (most recently, Macondo and Buncefield). The actions and decisions of MIT personnel and contractors can result in immediate loss of containment, or embed unsafe latent conditions deep within a system (which, in turn, may result in the failure on demand of key safety functions, at a time when they are needed most). With these factors in mind, the CA believes that this aspect of managing human performance warrants particular scrutiny.

7. If an establishment claims risk reduction from the activation of safety-critical equipment and safety-instrumented systems, or relies heavily on people during high-consequence MIT activities (e.g. breaking containment; making critical joints; process start-up after shutdown), then human reliability during MIT should be regarded as a high-priority HF inspection topic.

8. Inspection of HF during MIT activities should complement, rather than duplicate, inspection undertaken as part of the CA's Ageing Plant and EC&I DGs, by focusing on issues less likely to be addressed by other discipline specialists. For example, HF inspections could explore the competence of production staff who undertake basic, routine 'first-line' MIT activities (e.g. as part of a multi-skilling initiative), and other PIFs that adversely affect performance, rather than verify the core competencies of dedicated engineering staff.

9. COMAH operators should demonstrate a clear understanding that experienced, competent, well-motivated MIT personnel and contractors are prone to action errors and, under certain circumstances, may not follow procedures. HF inspections should verify that COMAH establishments have undertaken HRA on a representative set of COMAH-critical MIT tasks, in order to evaluate and optimise key PIFs.

10. The relevant Inspector should use the following success criteria to assign a single, overall performance rating score for the topic 'Managing Human Performance'. COMAH operators are unlikely to achieve a rating above 30 until they can demonstrate that MIT is an integral part of their HRA programme, and that meaningful MIT improvement actions are being implemented.

Success Criteria for Topic 1 - the COMAH Operator has:

- developed, and is implementing, a clear, written standard that defines how HF will be integrated into MAH risk assessment and accident/incident investigation processes at the establishment.

- adopted a structured methodology for undertaking HRA on COMAH-critical tasks, in line with relevant good practice. Key elements of the HRA methodology include:
    - structured on-plant task analysis, to gain a thorough understanding of the task and identify key, COMAH-critical steps;
    - systematic identification of the different types of human failure using a recognised approach (e.g. Human-HAZOP guidewords);
    - a framework to identify, evaluate and optimise key PIFs[3] at a job, individual and organisational level – this should be an integral part of the HRA process;
    - the means to implement additional risk reduction measures in line with the normal hierarchy of control, and 'match' them to the failure-types identified;
    - active involvement of front-line personnel who perform the tasks being analysed (with support from facilitators who are competent to undertake HRA).

- identified the full range of COMAH-critical tasks at the establishment. This is a key success criterion and relies on the operator having identified/documented all MAH scenarios - if the operator is still working towards this, and/or is undertaking a full review of MAH risk assessments, the CA may agree to a 'phased' plan to identify critical tasks, provided the operator implements a concurrent programme of HRA as those tasks are identified.

- prioritised COMAH-critical tasks at the establishment, taking account of the nature and level of human involvement/interaction, as well as the consequence of human failure.

- developed, and is actively implementing, a programme of HRA that is suitably representative of the full range of MAH scenarios at the establishment (including high-priority MIT tasks carried out in-house or by contractors).

- used HRA to evaluate and optimise 'MIT-specific' PIFs, such as:
  - maintainability of plant/equipment (simple design; easy access; well-labelled);
  - adequate resources (up-to-date, reliable P&IDs; availability of tools and spares);
  - the work environment (noise; temperature; lighting; weather etc.);
  - usability of MIT procedures, decision-aids and diagnostic tools;
  - COMAH-critical communication;
  - time pressure; workload; fatigue; staffing levels; supervision etc.

- identified additional control measures that target human performance and has developed action plans with realistic timescales for implementation (including priority MIT tasks).

- established measures to develop and maintain the competence of those who facilitate HRA. When a COMAH establishment has engaged competent external support, the operator can demonstrate an effective intelligent customer capability.

- used accident, incident or near-miss investigations to identify immediate human failures and underlying causes (including relevant human and organisational factors). Specific examples are available. The COMAH operator understands why human failures occurred in accidents/incidents and is implementing appropriate, site-wide improvement actions.

11. Further guidance is available on the Managing Human Failures and MIT pages of the HSE website, and in relevant sections of the HF Toolkit. A new inspection guide is also available.

Topic 2: Human Factors in Process Design

12. HF Specialist Inspectors will normally inspect and rate this topic.

13. The design of plant and process control systems can have a significant impact on human performance. Poor plant and process design was identified as an important underlying cause of incidents in the 2014 CAIRG review, and has been cited as a contributory factor in many major accidents (e.g. Texas City; Texaco Milford Haven). Topic 2 aims to verify that COMAH operators have established proportionate arrangements to integrate HF into the design of COMAH-critical process control systems, including processes that require a high degree of manual intervention.

14. Topic 2 comprises the following three elements (other aspects of design for operability and maintainability will be addressed under Topic 1, Managing Human Performance):

Topic 2.1 Design of Process Control Systems

15. Process control systems at COMAH establishments range from modern, purpose-built control rooms with Distributed Control Systems (DCS), to simpler on-plant control panels, displays and instruments.

16. COMAH operators should demonstrate a user-centred approach when designing the human-machine interfaces (HMI) and human-computer interfaces (HCI) that make up their process control systems, taking account of relevant HF design standards. They should use task analysis, link analysis, HRA etc. to inform local design and optimise PIFs (e.g. environmental factors in the control room or in the immediate vicinity of plant-based HMI/HCI).

Topic 2.2 Managing Process Upsets and Abnormal Situations

17. Good HF design is essential to support personnel who manage process upsets. COMAH operators should demonstrate that process control systems are designed and managed to account for limitations in human performance, so that detection, diagnosis and recovery to a safe state can be achieved in a reliable and timely manner (e.g. HMI/HCI and alarm systems that enhance situational awareness and support decision-making under pressure).

18. EC&I specialists will inspect certain aspects of alarm systems under the functional safety element of the EC&I DG, including human intervention in safety instrumented systems.[15] Joint EC&I/HF visits should be undertaken when appropriate. In any event, CA specialists should discuss and agree the content of their respective DG interventions. HF inspections will routinely explore how system design impacts on human reliability during process upsets (and verify that other, relevant environmental and organisational PIFs are being optimised).

Topic 2.3 Human Factors Integration - New Projects and Major Modifications

19. COMAH operators should demonstrate a structured approach to integrating HF into the design of new projects and major modifications. The earlier that human factors are considered in the design process, the better the results will be in terms of human performance. For larger, complex projects, this will generally mean the development of a Human Factors Integration Plan (HFIP). For smaller modifications, COMAH establishments should establish a framework for proportionate HF integration (e.g. targeted HRA triggered by local Management of Change arrangements or Hazard Studies/HAZOPs).

20. Key principles of HF integration are detailed in HSE Research Report 001[16]. The CA will verify progress at COMAH establishments during assessment of pre-construction safety reports, as well as inspection under this DG.

21. The HF Specialist Inspector should use the following success criteria to assign a single, overall rating score for the topic 'HF in Process Design'. COMAH operators are unlikely to achieve a rating above 30 if systems are not designed to manage process upsets, or if they have failed to establish a clear framework to integrate HF into new projects and major modifications.

Success Criteria for Topic 2 - the COMAH Operator has:

- established local policies for HF design, based on relevant good practice (e.g. site-specific standards for the design and management of process alarms in line with EEMUA 191[17]).

- benchmarked the design of local process control systems against relevant HF standards, for example: BS EN 9421[18] (human/system interaction); EEMUA 201[19] (HCI); EEMUA 191 (alarm systems); BS EN 11064[20] (control rooms). Improvement actions have been prioritised and are being implemented in a timely manner.

- used task analysis/HRA, and involved users, to understand task demands and further inform the design process (especially during process upsets). The operator can justify the allocation of function (degree of automation) for key ESD systems. Where there is reliance on people to respond to high-priority alarms, analyses have explored sub-tasks associated with alarm handling (detection; diagnosis; planning; action) in the context of time available to respond.

- designed plant and process control systems to support personnel who manage process upsets and abnormal situations. There is evidence that other relevant PIFs are optimised:

    - key personnel are available to respond; they can see/hear high-priority alarms;
    - alarms are well-justified and suitably-prioritised; nuisance alarms are addressed;
    - written alarm response procedures are usable and readily available at points-of-use;
    - the system enhances situational awareness (e.g. permanently displayed process overviews; well-designed alarm lists, alarm status graphics and annunciator panels);
    - effective arrangements exist to develop and maintain the competence of personnel who deal with process upsets (including simulation and non-technical skills);
    - personnel have time to respond and carry-out follow-up actions.

- accounted for environmental factors in the control room or the vicinity of plant-based HMI/HCI (lighting; thermal comfort; noise and acoustics; distractions etc.) and relevant organisational factors (staffing levels; supervision; leadership; willingness to shut-down).

- defined, and is monitoring, key performance indicators (e.g. alarm metrics; user feedback about HCI; findings from investigations). The operator reacts to outcomes and can give specific examples of design improvements arising from local monitoring, audit and review.

- developed a structured framework to integrate HF into the design of new projects and major modifications (including, where appropriate, arrangements to initiate a formal HFIP). To achieve an overall score of 10 for Topic 2, an operator would need to demonstrate that it had developed, and then successfully implemented, an HFIP - or proportionate equivalent - for a real-world project/modification (as well as meeting all other success criteria).

22. Further guidance is available on the Human Factors in Design page of the HSE website, and in the 'specific topics' sections of the HF Toolkit.

Topic 3: COMAH-Critical Communications

23. Either Regulatory or HF Specialist Inspectors will inspect and rate this topic.

24. Failings in shift handover and permit-to-work (PTW) systems were identified as common underlying causes of incidents in the 2014 CAIRG analysis, and have been cited as key contributory factors in a range of major accidents (Texas City; the Sellafield Beach Incident; Piper Alpha). Topic 3 will typically focus on these two aspects of COMAH-critical communication (though the CA may decide to inspect the sub-topics separately).

Topic 3.1 Shift Handover

25. Effective shift handovers incorporate the following elements:

- meaningful preparation by out-going personnel;
- an exchange of key information between out-going and in-coming personnel;
- a cross-check of information by in-coming personnel, as they assume responsibility.

26. COMAH operators should develop and implement arrangements to ensure accurate, reliable communication of COMAH-critical information during shift handovers.

Topic 3.2 Permit-to-Work Systems

27. As well as enhancing COMAH-critical communication between relevant parties (including the display of active permits in control rooms and on plant), PTW systems can bring other HF benefits. For example, the permit issuer should always conduct site visits to check that the conditions of the permit are being complied with (as a minimum, at the start and end of the job, with interim checks depending on hazard, complexity and duration). These site visits represent a good opportunity to identify and prevent human failures (e.g. inadvertent isolation of the wrong plant, or 'cutting corners' and non-compliance with key control measures). Permit issuers can also satisfy themselves that workers and contractors accepting the permit understand the hazards, consequences and key control measures. This aspect of PTW systems can help bring underlying risk assessment to life.

28. However, careful planning and resourcing is essential to prevent PTW overload and ensure that issuing authorities have time to carry out plant visits. In this context, organisational factors such as work scheduling, and the provision of sufficient, competent personnel to issue and supervise permits, can be as important as the design of PTW documentation.

29. COMAH operators should develop and implement PTW systems in line with relevant good practice (e.g. HSG 250 Guidance on PTW Systems) and take action to manage relevant PIFs.

30. Major accidents involving shift handover and PTW systems often occur during planned maintenance and shut-down activities. In such circumstances, the actions and decisions of contractors may warrant particular consideration. With these factors in mind, there may be some overlap between DG Topic 3 and MIT inspections conducted under DG Topic 1.2.

31. Topic 3 may cover other aspects of COMAH-critical communication, for example: two-way radio communication between control rooms, field operators and MIT personnel; ship-to-shore communication, where language barriers may be a factor; verbal communication between control room staff (that latter should be considered at an early stage in control room design – see Topic 2).

32. Communication equipment should be readily available, usable and reliable. COMAH operators should take action to address known transmission black-spots.

33. The relevant Inspector should use the following success criteria to assign a performance rating score for either 'COMAH-Critical Communications Shift Handover' or 'COMAH-Critical Communications PTW', depending on the sub-topic inspected (there are two, separate performance rating topic categories available on the COIN IRF tab).

Success Criteria for Topic 3 - the COMAH Operator has:

- used risk assessment to identify and evaluate aspects of communication that are critical to managing MAHs (e.g. who needs to communicate and what their needs are).

- developed local policies and procedures for shift handover and PTW, which define minimum standards for effective communication (including what needs to be communicated and how).

- implemented arrangements for shift handover and/or PTW that meet relevant good practice and adhere to key principles of effective communication. For example:

  Shift Handover

  - the operator plans for work to be completed in a single shift whenever possible;
  - allows sufficient time for handover (preparation, checking and consolidation);
  - minimises distractions during handovers;
  - facilitates face-to-face communication;
  - provides structured, written logs, to support verbal communication (with mandatory sections to record COMAH-critical information);
  - identifies, and controls, higher risk handovers e.g. if maintenance work on critical plant crosses a shift; when safety-systems are overridden; following an individual's lengthy absence from work (holiday, shift-break, illness etc.); between experienced and inexperienced personnel.

PTW

- the operator uses PTWs for the right activities (e.g. non-routine, high consequence MIT tasks);
- ensures that all permits are underpinned by meaningful risk assessment;
- has developed simple, usable PTW documentation, with end-user involvement;
- displays active permits in control rooms and on-plant;
- plans work and manages resources to avoid PTW overload;
- always conducts on-site visits when permits are issued and the work is complete;
- has established workable hand-back arrangements, which verify that plant is returned to a safe state and control is passed back to operations personnel.

- established arrangements to develop and maintain staff competence in safety-critical communication. Key personnel are trained and assessed in relevant procedures (i.e. how to conduct shift handovers and issue/manage PTWs). The operator also develops the communication and non-technical skills of relevant staff (active listening; two-way communication with repetition and feedback; radio protocols; Crew Resource Management etc.) – these skills are defined in competence standards.

- established arrangements to monitor, audit and review implementation of PTW and shift handover procedures, and other aspects of safety-critical communication. The operator can give specific examples of improvements to underlying management systems for PTW and shift handover, which have arisen from the review process.

34. Further guidance is available on the Safety Critical Communications page of the HSE website, and in the 'common topics' section of the HF Toolkit.

Topic 4: Design and Management of Procedures

35. Regulatory Inspectors will normally inspect and rate this topic, calling on specialist HF support when required.

36. Poor operating procedures were the most common underlying cause of incidents initiated by human and safety management failures in the 2014 CAIRG review. The related topic of supervision was also a prominent, causal factor.

37. As well as being an important PIF in their own right, procedures help bridge the gap between major hazards and competence management systems. COMAH operators should demonstrate that they have implemented effective arrangements to develop and manage procedures that are reliable, usable and clearly linked to local MAHs.

38. The Regulatory Inspector should use the following success criteria to assign a rating score for the topic 'Design and Management of Procedures', accounting for relevant aspects of supervision.

Success Criteria for Topic 4 - the COMAH Operator has:

- established, and is implementing, a clear written standard for developing and managing COMAH-critical procedures (based on relevant good practice).

- established clear links between procedures and local MAH scenarios. Written procedures are available for the full range of COMAH-critical tasks. The operator has used HRA to demonstrate that the establishment does not place too much reliance on procedures to manage MAHs. Where reasonably practicable, the operator has introduced additional risk reduction measures – including engineered controls – to reduce the potential for human failure.

- used on-plant task analysis to inform the step-by-step content of COMAH-critical procedures - they define the agreed way of carrying out relevant tasks in a safe manner. Critical steps are clearly identified and appropriate warning information is given, helping define a 'human basis of safety' for tasks where reliance is placed on people as part of the necessary measures. Technical content is validated during the approvals process.

- established a framework to optimise usability. COMAH-critical procedures are up-to-date and readily available at points-of-use. The level of detail is appropriate to the task, user and consequence of failure. Style, language and layout are consistent and reflect good practice[21]. Users are actively involved in the development and review process, and are given time to do so. Overall, there is clear evidence of front-line ownership of COMAH-critical procedures.

- developed arrangements to ensure day-to-day compliance with COMAH-critical procedures, including effective supervision (e.g. there are enough supervisors, with sufficient time, to carry out their supervisory responsibilities; those responsibilities are clearly defined; supervisors display a good understanding of local MAHs and control measures). Procedural controls are reviewed following evidence of non-compliance and other incidents where procedural failings or weaknesses have been identified.

- established a structured framework to train and assess personnel in new or updated procedures. The COMAH operator recognises that the ability to follow a procedure does not equate to competence.

39. Further guidance is available on the Procedures and Supervision pages of the HSE website, and in the 'core topics' section of the HF Toolkit. A new inspection guide is also available.

Topic 5: Competence Management Systems (CMS)

40. Regulatory Inspectors will normally inspect and rate this topic, calling on specialist HF support when required. HF Specialist Inspectors may address certain aspects of CMS implementation during related inspections (e.g. verifying competence to manage process upsets under Topic 2.2, including access to proportionate simulation and the development of non-technical skills).

41. Topic 5 builds on findings from the CA's outgoing competence DG. In particular, inspections under the new DG will verify that the inter-relationships between competence, procedures and HRA of COMAH-critical tasks are being used to define competence standards that link the CMS to local MAHs.

42. The 5-Phase CMS Cycle described in the competence DG (originally defined in ORR guidance[22]) remains a valid and proven benchmark for designing and implementing effective competence management systems at COMAH sites. Key principles in that model, as well as lessons learned from the outgoing DG, underpin the success criteria below.

43. The Regulatory Inspector should use the following success criteria to assign a performance rating score for the topic 'Competence Management Systems'.

Success Criteria for Topic 5 - the COMAH Operator has:

- established a CMS to develop and maintain the competence of personnel - from front-line to board level - who are responsible for preventing or mitigating the consequences of major accidents at the establishment. The CMS is aligned with relevant good practice.

- taken steps to ensure that the CMS is clearly linked to local MAHs (e.g. the register of COMAH-critical tasks sets the scope and rigour of the CMS; relevant competence standards take account of HRA outcomes; training and assessment targets key steps in COMAH-critical procedures; generic vocational qualifications are tailored to reflect local plant, processes and MAHs).

- developed a structured framework for on-the-job training and assessment (including task observation, where appropriate). This is supported by structured training and assessment for non-routine and infrequent activities (e.g. process start-up/shut-down; managing a process upset).

- developed arrangements to allow for consolidation of training, evidenced by extra support and supervision.

- defined a system to periodically monitor and re-assess the performance of COMAH-critical personnel. Arrangements are in place to manage sub-standard performance.

- actively implemented the CMS. Records show that personnel meet relevant competence standards. Those interviewed (including managers and supervisors) fully understand the role they play in preventing and mitigating the consequences of local MAHs - especially non-routine and infrequent COMAH-critical activities. There is evidence to demonstrate that performance is being monitored and re-assessed.

- established a framework to audit and review CMS implementation. The COMAH operator can give specific examples of improvements to the underlying CMS arising from the audit/review process.

44. Further guidance is available on the Training and Competence page of the HSE website, and in the 'core topics' section of the HF Toolkit. A new inspection guide is also available.

Topic 6: Managing Organisational Factors

45. HF Specialist Inspectors will normally inspect the key organisational factors that comprise this topic. These factors will not be routinely inspected in their own right, but should be prioritised in the event of significant change, or if the CA finds evidence for concern during related interventions.

46. The 'one-off' nature of these inspections means they will not be formally rated using success criteria or the performance scores in Appendix 2. However, the CA will judge a COMAH operator's performance against relevant good practice and take enforcement action in line with the EMM.

47. Topic 6 comprises three organisational factors that can have a significant impact on human reliability. The sub-topics may be inspected independently, though are often interrelated.

Topic 6.1 Managing Organisational Change

48. Organisational change at COMAH establishments should be managed with the same rigour as physical changes to plant and equipment. Relevant good practice is available in CHIS7[23].

49. Regulatory Inspectors should bid for HF specialist support if they become aware that a COMAH establishment is planning key organisational changes, for example:

- downsizing with a reduction in staffing levels;
- a move to multi-skilling;
- de-layering and changes in supervision, such as introducing self-managed teams;
- outsourcing of key functions to contractors; centralisation or dispersal of functions;
- mergers/acquisitions;
- changes to key personnel.

Topic 6.2 Managing Shift Work and Fatigue

50. Fatigue can arise from poorly designed shift patterns, or well-designed shift patterns that are poorly managed (e.g. a failure to set, monitor and enforce clear standards and limits for working hours, overtime, shift-swapping and on-call work).

51. Regulatory Inspectors should bid for HF specialist support if a COMAH site is planning changes to working hours and shift patterns, or if there is evidence for concern with existing shift work arrangements, for example:

- staff who carry out important 'vigilance' tasks are unable to take rest breaks because competent cover is not available;
- evidence of excessive overtime, especially during a major project or turnaround (contractors and sub-contractors can be particularly susceptible to excessive working hours, on-call working and overtime during such projects);
- personnel routinely swap shifts on an informal basis.

Topic 6.3 Managing Resources – Staffing Levels and Workload

52. COMAH operators should demonstrate that they have adequate numbers of competent people to prevent or mitigate the consequences of local MAHs, and that workloads are not too high (or too low).

53. Regulatory Inspectors should bid for HF specialist support if there is evidence for concern with staffing levels or workloads, for example:

- an establishment fails to conduct a structured staffing/scenario assessment following organisational change in a control room;
- an establishment takes on additional short-term contracts, which are prolonged indefinitely, without employing more personnel;
- personnel are unable to take meal or rest breaks;
- evidence of excessive overtime or shift-swapping;
- deteriorating MIT backlogs;
- increased absence and ill-health;
- high staff turnover;
- evidence of excessive workloads during/after organisational change and temporary peaks in demand such as MIT campaigns, process start-up and major turnarounds;
- work under-load on a night shift.

54. Further guidance is available on the Organisational Change, Fatigue and Staffing pages of the HSE website, and in the 'specific topics' section of the HF Toolkit.

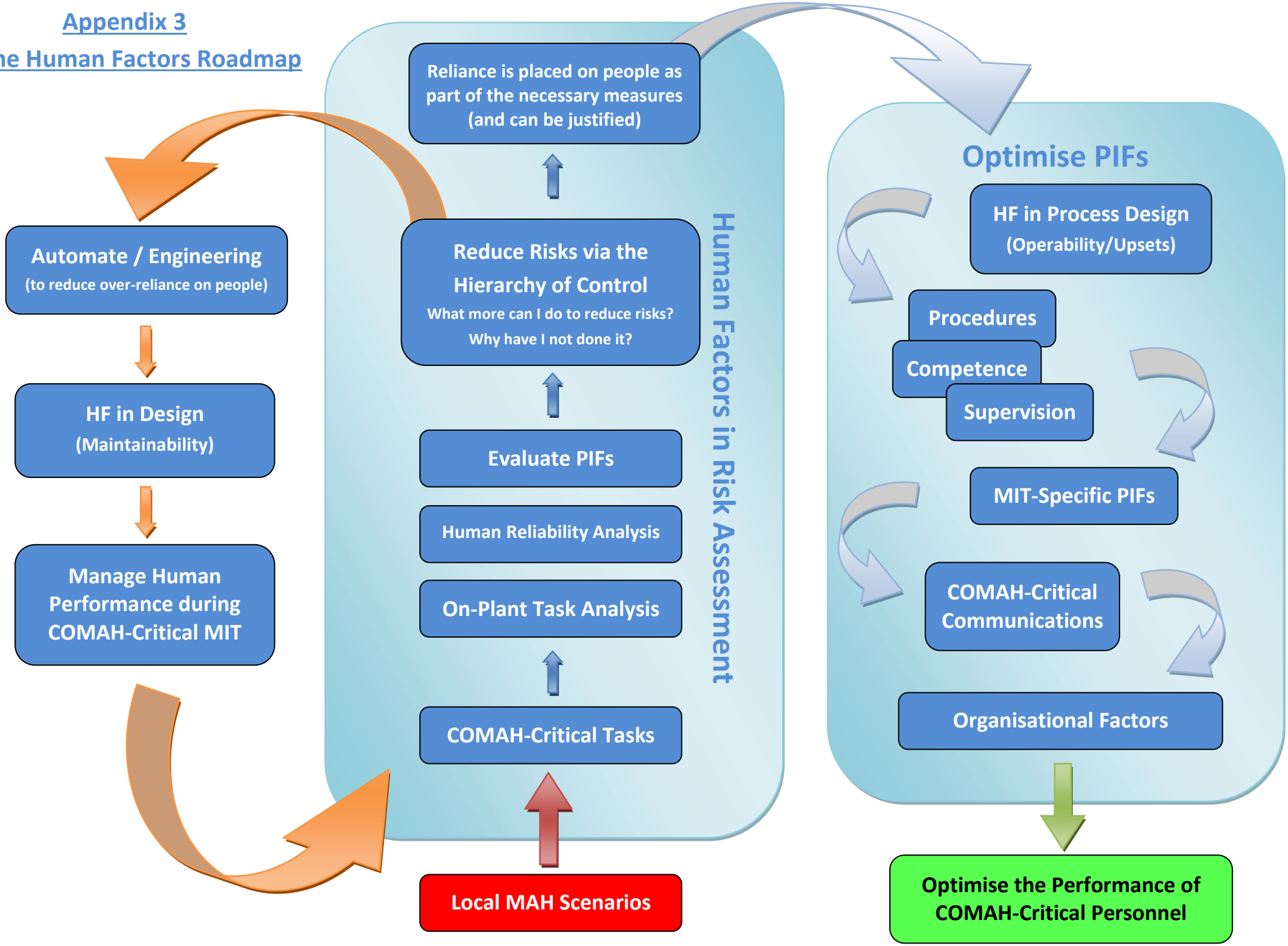
Appendix 2 – Performance Rating Against Success Criteria

Rating	Description	Indicative CA Action	Score
Exemplary	• All success criteria are fully met. • Evidence of best practice. • A high standard of HF technical competence. • *HF integration into new projects is demonstrated.*†	No further action.	**10**
Fully Compliant (Good)	• Most success criteria are fully met. • Achieving good practice in most respects. • An acceptable standard of HF technical competence. • *A framework exists for HF integration into new projects, but has not yet been implemented locally.*	Advice only. No follow-up required in the short-term. Consider recommendation in inspection report to achieve best practice.	**20**
Broadly Compliant	• A number of success criteria are not fully met. • 'Key' criteria are not met (e.g. no HRA of MIT tasks; process control design does not support upsets); • Falling short of good practice in some key areas. • HF technical competence is under development. • *No framework exists to integrate HF into projects.*	Consider Action Legal to achieve relevant good practice. Consider follow-up inspection in due course (specialist HF input not necessarily required).	**30**
Poor	• At least half of the success criteria are not met, or are only partly met. • Falling short of good practice in many areas. • Plans to develop HF competence, but not resourced. • *No framework exists to integrate HF into projects*	Action Legal to secure good practice. Consult HF specialist and consider COMAH IN. Consider follow-up inspection with HF Specialist.	**40**
Very Poor	• Most success criteria are not fully met. • Very few, if any, examples of good practice. • No plans to develop HF technical competence. • *No framework exists to integrate HF into projects.*	COMAH IN very likely. Contact HF Specialist for advice. Consider follow-up inspection with HF Specialist.	**50**
Unacceptable	• No success criteria are met. • No attempt to achieve relevant good practice. • No attempt to develop HF technical competence. • Operator displays a poor attitude to HF integration – managing HF is viewed as 'common sense'.	COMAH IN. Consider COMAH PN and prosecution if evidence of significant failings with other layers of protection. Urgent follow-up inspection with HF Specialist.	**60**

† Descriptions in italics, referring to HF integration into projects, only relate to DG 'Topic 2' inspections.

Appendix 3

The Human Factors Roadmap



Appendix 4 – References and Supporting Information

[1] The HID Regulatory Model http://intranet/hid/hid-regulatory-model.pdf

[2] Operational DG: Inspection of Competence Management Systems at COMAH Establishments

[3] Performance Influencing Factors (PIFs) http://www.hse.gov.uk/humanfactors/topics/pifs.pdf

[4] Reducing Error and Influencing Behaviour, HSG48, Second Edition, 1999

[5] The Control of Substances Hazardous to Health Regulations 2002.

[6] The Human Factors Roadmap http://www.hse.gov.uk/humanfactors/resources/hf-roadmap.pdf

[7] The Human Factors Inspector's Toolkit http://www.hse.gov.uk/humanfactors/toolkit.htm

[8] COMAH CA Site Prioritisation Methodology: Intrinsic Hazard (Safety and Environment) and Performance http://www.hse.gov.uk/comah/guidance/site-prioritisation-methodology.pdf

[9] Enforcement Management Model (EMM) http://www.hse.gov.uk/enforce/emm.pdf

[10] Chartered Institute of Ergonomics and Human Factors http://www.ergonomics.org.uk/

[11] Intelligent Customer Capability http://www.hse.gov.uk/humanfactors/topics/customers.htm

[12] Though accepted terminology defines such tasks as 'safety'-critical, the definition includes all tasks where human failure could result in a MATTE. Throughout this DG they are referred to as COMAH-critical tasks.

[13] See paras 79-91, The Control of Major Accident Hazards Regulations 2015, Guidance on Regulations, L111

[14] Also known as Human Failure Analysis (HFA), Human Error Analysis (HEA), Safety-Critical Task Analysis (SCTA)

[15] SPC/Technical/General/50: Operator Response within Safety Instrumented Systems

[16] HSE Research Report 001, 2002, Human factors integration: implementation in the onshore and offshore industries http://www.hse.gov.uk/research/rrhtm/rr001.htm

[17] Alarm Systems. A Guide to Design, Management and Procurement: Engineering Equipment and Materials Users Association Publication 191 (Third Edition, 2013)

[18] BS EN ISO 9421-210: 2010 Ergonomics of Human-System Interaction. Human Centred Design for Interactive Systems (Replaces BS EN ISO 13407:1999)

[19] Process Plant Control Desks Utilising Human-Computer Interface: Engineering Equipment and Materials Users' Association Publication No. 201 (Second Edition, 2010)

[20] BS EN ISO 11064: 2001 Ergonomic Design of Control Centres

[21] Procedures Audit Tool http://www.hse.gov.uk/humanfactors/topics/procedures-audit-tool.pdf

[22] Office for Rail Regulation, Developing and Maintaining Staff Competence, 2nd Edition, 2007 http://orr.gov.uk/__data/assets/pdf_file/0016/4264/sf-dev-staff.pdf

[23] Organisational Change and Major Accident Hazards http://www.hse.gov.uk/pubns/chis7.pdf