COMAH COMPETENT AUTHORITY STRATEGY FOR COMAH REGULATION 8-SAFETY REPORT REVIEW AND REVISION

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The Control of Major Hazard Accident Regulations¹ came into force on 1 April 1999. The regulations require those operators of sites having inventories of dangerous substances as defined at above the specified upper threshold to prepare a safety report achieving the purposes set out in, and containing the minimum information listed in, Schedule 4 of the Regulations. Regulation 8 of COMAH details provisions for the review and revision of safety reports. One of the triggers for the review of a safety report is the occurrence of the fifth anniversary of its submission to the Competent Authority. In February 2005 the first significant tranche of safety reports will reach the fifth anniversary of their submission. This paper sets out the Competent Authority's strategy for dealing with those reports which will be subject to review, and, where necessary, revision. It also discusses the other triggers leading to the requirement to review a safety report, and the concept of a 'living' safety report.

KEYWORDS: COMAH; safety reports; review and revision

INTRODUCTION

The Control of Major Accident Hazards Regulations (COMAH) implemented the Seveso II Directive² and came into force on 1 April 1999. Regulation 7 of COMAH requires the operators of top tier establishments to prepare safety reports. Schedule 4 of the Regulations sets out the purpose of safety reports, and specifies the minimum information to be included in them. Regulation 8 of COMAH implements Article 9(5) and Article 10 of the Directive. Article 9(5) requires the periodic review, and where necessary updating, of safety reports, and Article 10 refers to the review, and where necessary, revision, of the safety report where modifications at the establishment could have major repercussions on the major accident hazards presented by the establishment.

Regulation 8 of COMAH sets out when operators of top tier establishments are required to review their safety reports. A review should be carried out:

- At least every five years (Regulation 8(1)(a));
- Because of new facts or to take account of new technical knowledge about safety matters (Regulation 8(1)(b));

- Whenever the operator makes a change to the safety management system (SMS) which could have significant repercussions with respect to the prevention of major accidents or the limitation of consequences of major accidents to persons and the environment (Regulation 8(1)(c)); and,
- In advance of any proposed modification to the establishment or an installation, the process carried on, or the nature or quantity of dangerous substances present and where that modification similarly could have significant repercussions (Regulations 8(4)(a)).

BACKGROUND

Currently the Regulations require that where, following a review of the safety report, it is necessary to revise the report the revision should be carried out forthwith and the Competent Authority* (CA) be informed of the details of the revision. Where a safety report has been reviewed, but not revised as a consequence, the operator should similarly inform the CA of that fact. There is a similar requirement to inform the CA about reviews and revisions to safety reports prior to carrying out the types of modification mentioned previously.

The Seveso II Directive has itself been the subject of an amending Directive³. The amendment to Seveso II will, in turn, result in amendments to COMAH. In order to comply with the amending Directive the amendments to COMAH have to come into force before 1 July 2005. The amending Directive does not of itself require changes to the review and revision provisions contained in Regulation 8 of COMAH. However, the opportunity has been taken to propose, firstly, the reordering of Regulation 8(1), and, secondly, the replacement of 'inform' in Regulations 8(2) and 8(4)(b) by 'notify'.

The reason for proposing the latter is to make clear that the CA should be notified in writing about the revision of a safety report, or the decision that a revision is not necessary. The former proposed change is connected with the concept of the 'living safety report', which is discussed later in this paper. It is intended to change the emphasis in Regulation 8(1) so that the five-year review comes to be seen as a backstop for a system of change management and review, rather than itself being seen as the primary goal of the review process.

The transitional arrangements for the submission of safety reports contained in Regulations 7(8) and 7(9) of COMAH meant that those operators whose CIMAH⁴ safety report update would have been due between 1 April 1999 and 3 February 2000 had until 3 February 2000 to submit their COMAH safety report. As a consequence, the five-year review period for that first group of safety reports submitted expires in February 2005. A larger group will be due for review a year later in February 2006.

^{*}The COMAH Competent Authority is a statutory body established under COMAH to enforce the Regulations and discharge certain statutory functions. In England and Wales the CA is the Health & Safety Executive (HSE) and the Environment Agency (EA). In Scotland, the CA is the HSE and the Scottish Environment Protection Agency (SEPA).

The CA has seen little evidence of 'change' review and revision activity since the first group of safety reports were submitted. Many operators are also unclear as to the minimum requirements of Regulation 8. Some believe that they must fully *resubmit* their safety report every five years. One of the potential consequences of this is that operators and the CA risk expending disproportionate effort on the first cycle of five year review activity, particularly for those reports reaching their first five year anniversary in 2005. The CA strategy seeks to address this.

COMPETENT AUTHORITY STRATEGY

The CA strategy has a number of objectives. It aims to implement the review and revision provisions through a combination of operational policies and procedures to be followed by CA inspectors and through improved guidance for COMAH operators. In particular the strategy aims to:

- Secure operator's compliance with the law in a consistent, proportionate, targeted and transparent manner;
- Minimise the anticipated 'hump' of review and revision activity in February 2005 and avoid any 'humps' in future years;
- Ensure operators and the CA spend proportionate effort on safety report review and revision activity whilst ensuring reports continue to provide the CA with up-to-date information about top tier establishments in a systematic and timely manner to help them, in particular to:
 - Make informed and robust judgements about whether operators' preventive and mitigatory measures are seriously deficient, revise the CA's intervention plans, and inform decisions over developments on or near to establishments; and,
 - Respond proportionately to the impact of new facts and technical knowledge about safety matters leading to revision of safety reports, and significant managerial and physical changes at and around TT COMAH establishments.
- Minimise office-based review and revision assessment activity, maximize verification, and link assessment more closely with intervention plans.
- Reflect recent developments (e.g. ALARP and societal risks), and the CA's and operators' broader experience of implementing COMAH, for example;
 - The introduction of revision plans as part of the safety report assessment outcome aimed at curtailing the assessment process;
 - The longer than expected time taken to complete some assessments; and,
 - Continued lack of common understanding of the purpose of safety reports and the broader role of permissioning in the overall regulation of onshore major hazard industries.
- In the longer term, promote the 'living safety report' concept.

HOW WILL THE OBJECTIVES BE ACHIEVED?

The CA intends that the objectives will be achieved through a package of measures including:

- Clarifying the purpose of safety report review and revision;
- Shifting operators' focus away from five year reviews and towards 'change' review activity throughout the life of the establishment;
- Improved guidance for operators;
- Improved CA assessment procedures; and,
- Effective engagement with operators before, during and after review and revision activity.

Some of these issues are discussed in more detail, below. It is recognised that a number of these measures need to be developed and implemented quickly in order to provide enough time for the CA and operators to develop and implement consequential review and revision arrangements. This has to be done in time for the first five-year anniversary of the submission of safety reports in February 2005, and for the CA to adjust, where necessary, its intervention plans for 2004/05 and beyond.

The next 12 to 18 months also provides an opportunity to test these ideas and to work with operators and other stakeholders so as to move to a position whereby the intended benefits of the COMAH regime are fully realised in the medium to longer term.

As mentioned in the Background section of this paper, the review of the COMAH Regulations is currently underway in order to implement the amendments to the Seveso II Directive. COMAH Amendment Regulations have to be in place by 1 July 2005. HSE is also taking the opportunity to make other minor changes to COMAH in order to clarify the law and assist in compliance. These include changing the Regulation 8 requirement to 'inform' the CA of details of revisions to a safety report to a requirement to 'notify'. It is also proposed that there be a new requirement to record on the public register the confirmation that a safety report has been reviewed at the five-year point, but not revised (Regulation 8(2)). It is likely these proposals will be included in a Consultative Document on the amending regulations to be published during the summer of 2004.

PURPOSE OF SAFETY REPORT REVIEW AND REVISION

There is no requirement in COMAH continuously to maintain a safety report. However, COMAH adopts a proportionate approach to reflect that throughout the life of an establishment or installation an operator's risk control and mitigatory measures will be affected by changes in management arrangements and a range of other issues, both internal and external. Operators will rarely be able to maintain their plant and systems in an 'as built' condition.

Regulation 8 is silent on the *purpose* of reviewing and revising safety reports. The CA's view is that the overall purpose reflects that for the preparation of the original safety

report. Review and revision is therefore to ensure that the safety report:

- Continues to provide an accurate description of conditions on site and demonstrates that the purposes of COMAH Schedule 4 continue to be met;
- Presents information in a way that shows the operator has:
 - New or revised measures in place to prevent major accidents and limit their consequences to people and the environment that fully reflect any new facts or new knowledge about safety matters, SMS changes, or planned modifications and/or;
 - Arrangements in place to put right any shortcomings and implement any further measures identified; and,
- Demonstrates that the measures on site have been arrived at as a result of a systematic process.

Review and revision also:

- Alerts the CA so that they can respond in a timely and proportionate manner to new facts and technical knowledge about safety matters and significant managerial and physical changes at or around top tier COMAH establishments; and,
- Provides the CA with a comprehensive, up-to-date description of the detail and impact of changes on an establishment so the CA can, in particular:
 - Judge whether operators' new or revised preventive and mitigatory measures are seriously deficient;
 - Assess any improvement plans proposed by the operator;
 - Review, and, where necessary, revise, the CA's intervention plans; and
 - Make informed decisions about developments at or near to establishments.

THE FIVE-YEAR REVIEW

There are widely held misconceptions about the 'five-year review' provisions. Many operators believe that they must re-submit their safety reports every five years. In fact, what Regulation 8 requires currently is that operators '*review*' their safety report '*at least every five years*... and where in consequence of that review it is necessary to revise the report, the operator shall do so forthwith and inform the competent authority of the details of such revision.' The duty on the operator is therefore to review the safety report and to revise it as necessary, notifying the competent authority of the details of the revision. That is not the same as resubmitting the report in every case.

Operators are also free to conduct a full review at any time before the five-year time limit expires, for example, as part of a programme of SMS audit and/or review. An interim 'change' review would also count as a full review provided it involved a review of the whole of the report. The five-year 'clock' would then be reset.

The 'change' review provisions (discussed below) should capture any significant issues impacting on the accuracy of the safety report in the interim. The five-year review provides a 'back-stop'. It provides an opportunity to reflect on those minor changes in the intervening five-year period which did not trigger reviews at the time, but which cumulatively may be significant with respect to the prevention of, or limiting the consequences of, major accidents. They may also impact on the quality of the safety report. Revision plans agreed at the closure of the original submission assessment process may also help in some cases to reduce the extent of the five-year review.

The five-year review will include not only the original submission, but also any supplementary material, or further information provided to the CA in response to the assessment or inspection process, where such material forms part of the safety report. The five-year review may also be an opportunity, where practicable, to consolidate this supplementary material when carrying out any consequential revisions.

Where appropriate 'change' reviews have been carried out in the interim the CA expects that the five-year review should be a relatively 'light-touch' process for operators. Under those circumstances the five-year review should result in little new information being revealed in safety report revisions sent to the CA. And although wide-ranging, the review should be proportionate and ultimately limited in its scope. The depth of the review should be sufficient to confirm that the report continues to meet the purposes in COMAH Schedule 4 Part 1 and contains the minimum information in Part 2.

However, if, as evidence available to the CA suggests, 'change' review activity since COMAH was introduced has been limited, operators may find that the effort required to complete the review of those reports reaching their fifth anniversary in February 2005 is greater than suggested here. The CA hopes that by encouraging more 'change' review activity in the interim, five-year reviews from 2006 onwards will better reflect the expectations set out in this paper.

Nevertheless, for the first batch of reports the CA wants to ensure that operators expend proportionate effort on the review and revision process. This will mean that, if they have not done so already, all operators must begin to plan now for their five-year reviews. They should ensure they have robust mechanisms for collating information and intelligence on new facts and new knowledge and for tracking modifications and changes to their SMS in order to inform the full review process.

CHANGE REVIEWS

The CA has received a small number of safety report revisions, the majority in advance of installation or process modifications. However, the number of revisions received has been much lower than expected. The CA will not necessarily be informed of safety reports that have been reviewed, but not revised. Operators are only required to inform the CA that a report has been reviewed but not revised following a five-year review. Feedback from industry suggests that there has been little activity in this area as operators have been heavily committed to the initial submission and assessment process.

Operators' management arrangements have a key role to play in identifying when a review and, where necessary, a revision are required. In particular, operators' safety management systems and change management arrangements should support the review/ revision process. Change management systems already play a key role under the Health

and Safety at Work etc. Act 1974, other relevant statutory provisions and IPC/IPPC, and the modification of these where necessary to better address the review and revision requirements of COMAH should be straightforward.

There are three triggers for 'change' reviews in Regulation 8 of COMAH. These are:

- Because of new facts or to take account of new technical knowledge about safety matters;
- Whenever the operator makes a change to the safety management system which could have significant repercussions with respect to the prevention of major accidents or the limitation of consequences of major accidents to persons and the environment; and,
- Where modifications to the establishment, an installation in it, the process carried on there or the nature or quantity of dangerous substances present there are proposed, and those modifications could have significant repercussions with respect to the prevention of major accidents or the limitation of consequences of major accidents to persons and the environment.

In the first two examples operators are required to review the safety report, revise it forthwith as necessary and inform the CA of the details of the revision. The situation is somewhat different in the case of modifications in that operators are required, in *advance* of any modification, to review and, where necessary, revise the safety report and inform the CA of the details of such revision. The requirements for 'change' reviews are discussed further below.

NEW FACTS OR TECHNICAL KNOWLEDGE ABOUT SAFETY MATTERS (REGULATION 8(1)(b))

On the face of it the very broad nature of this provision imposes a wide-ranging review requirement on operators, as the nature of the triggering new information is not qualified by, for example, 'significant repercussions'.

The CA expects operators to have robust and proportionate management systems to identify and assess the impact of all changes within and outside of their establishment on their control and mitigation of major accidents. This will include mechanisms for ensuring operators obtain intelligence on, for example, changes in legislation, developments in technical standards and information about incidents occurring elsewhere. These information flows need to be brought together so that the operator can use the information to decide whether a review of the safety report should be carried out.

As a matter of policy the CA adopts a proportionate approach, and the COMAH guide⁵ advises that only changes relevant to the hazards identified, the prevention and control measures required, or mitigatory arrangements necessary, are likely to justify review and revision of the safety report. Trivial changes are unlikely to justify a review unless the cumulative effect of many such changes is significant.

Operators should not have to rely solely on their own intelligence gathering mechanism to identify the need for change reviews. The CA has a part to play in ensuring that operators are informed of changes to legislation or the outcomes of incident investigations. The CA will also have a role in enforcing the provisions of Regulation 8(1) and ensuring operators are conducting reviews where appropriate and revising their reports where necessary.

SAFETY MANAGEMENT SYSTEM CHANGES AND MODIFICATIONS (REGULATIONS 8(1)(c) AND 8(4))

Both SMS change and modification reviews are qualified by changes 'which could have *significant repercussions* with respect to the prevention of major accidents or the limitation of consequences of major accidents'. Existing guidance in the COMAH guide focuses on broad, establishment-wide SMS changes, whereas these can occur at many different levels. The guidance is more extensive in relation to modification reviews. However, the small number of revisions received suggests that operators may have difficulty understanding what the trigger thresholds should be.

Further guidance and criteria are therefore needed, building on the guidance in the COMAH guide, to help operators judge whether such reviews are required, and encourage more change review activity in the interim. Criteria could include, for example, when the nature of the new facts or new knowledge means that the safety report no longer meets the purposes in COMAH Schedule 4 Part 2. Guidance is also required on what may be considered to be 'significant repercussions'.

GUIDANCE ON CHANGE REVIEW

As already mentioned, the CA has seen little evidence of the revision of safety reports arising from 'change' review activity. It is unlikely that the review of underlying risk assessments has not been taking place, but this work does not appear to have been feeding through to the review and revision of safety reports. This may be because, as mentioned earlier, operators have been heavily committed to the initial submission and assessment process.

The CA would like to see operators' performance in this area improve in the short term. One of the CA's aims is to minimize the anticipated 'hump' of review and revision activity in February 2005 and avoid any 'humps' in future years. Increased 'change' review activity is key to minimizing five-year review and revision activity. There may be limited scope for achieving this with respect to the February 2005 'hump', but a change in emphasis now should assist in reducing the workload for both operators and the CA in the future. The CA plans to publish guidance for operators and CA inspectors by the autumn that:

- Describes how operators' safety management systems and change management arrangements should support the review and revision process;
- Helps operators judge whether 'change' reviews are required and encourage more 'change' review activity in the interim. Criteria could include, for example, when the nature of the new facts/new knowledge means that the safety report no longer meets the purposes in COMAH Schedule 4 Part 2;

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- Advises on the scope, depth and breadth of 'change' reviews;
- Helps operators provide revision information in a systematic way to assist the assessment process and avoid unnecessary work (and costs) for the CA and operator; and,
- Describes enforcement benchmarks to help CA inspectors respond proportionately to breaches of the law.

Robust change management systems should mean that the assessment of proposed changes already includes an assessment of the effect that they might have on the major accident hazards associated with the establishment. The process should also include an assessment of whether a review, and subsequently a revision, of the safety report are necessary. The change management process is key here. What the CA is seeking to encourage is that what should already be good practice so far as change management is concerned feeds through into the management of the safety report. This also has implications for the living safety report concept.

It follows that in order to encourage more of the activity mentioned in the previous paragraph additional guidance on whether and when 'change' reviews are required is necessary. The example above mentions the requirements of Part 2 of Schedule 4 of COMAH. Clearly those requirements must be met in order to comply with the law.

Merely indicating that compliance with the law is required is not particularly helpful. The CA will aim to provide guidance that will clarify what Regulation 8 of COMAH requires. It will deal with the question of what constitutes a *significant repercussion* with respect to the prevention of major accidents or the limitation of consequences of major accidents to persons and the environment. This is a key qualifying-factor in Regulation 8(1)(c), changes to the SMS, and Regulation 8(4), modifications. This same qualification does not appear in Regulation 8(1)(b), new facts or new technical knowledge about safety matters. The guidance will aim to assist in deciding when a review is *necessary*, perhaps defined in terms similar to those concerning significant repercussions. It will similarly aim to assist in defining what constitutes new facts or new technical knowledge about safety matters.

The COMAH guide advises that reviews triggered by new facts or knowledge or SMS changes need not cover the whole report but need only to examine those parts which are relevant (paragraph 174 in the COMAH guide). This, so far as the scope of the review is concerned, needs to be clarified. Interim 'change' reviews should consider the *implications* of the changes for the *whole* of the safety report. The operator should then decide to which parts, of the report the change is relevant and review those parts as appropriate. The depth and breadth of the review will depend on the nature and extent of the change. The review will need to include not only the original submission but also any supplementary information, for example, supplied at the request of the CA, that is deemed to form part of the report.

Information provided in a systematic way will help to minimise the resources expended on (and the costs of) the assessment process. With that end in mind, and recognising that COMAH is silent on the format for revisions, the CA would like to encourage operators to support safety report revisions (or a decision not to revise a safety report following review) with information that:

- Describes the initiator for the review (e.g. modification; SMS change);
- Describes their mechanism for judging that a review was required;
- Describes how they conducted the review; and,
- Justifies their conclusions.

In the case of a five-year review the following information would also be useful, and may help to reduce the resources expended in assessment by the CA:

- Reference to interim 'change' reviews/revisions conducted previously;
- A description of changes or other issues that did not merit interim 'change' reviews since the initial submission or last full review; and,
- A description of how the information was collated;
- A reference to issues identified in improvement plans following previous assessment or interventions, together with details of progress made, issues completed or expected dates of completion; and,
- Where revisions are incorporated into the report rather than submitted as an appendix or supplement to the original, a brief covering document signposting the changes. This will enable the assessment team to focus effort on the new information without having to re-assess the entire report.

ASSESSING SAFETY REPORT REVISIONS

The CA plans to assess all safety report revisions received where those revisions are considered necessary in order to comply with Regulation 8. The CA will:

- Adopt a proportionate and targeted approach. For example, where revisions are minimal or insignificant to the control or mitigation of major accidents then the CA will spend relatively little time on assessment;
- Look to minimise office-based assessment and evaluate revisions as part of planned on-site verification activity as far as possible;
- Review and revise the 'modifications' assessment procedure in the CA Safety Report Assessment Manual (SRAM) to provide sufficient flexibility to reflect the broad variation in modifications and allow more on-site activity;
- Develop structured, fit for purpose assessment procedures for interim 'change' reviews and the five-year review; and,
- Determine an approach for handling notifications that the operator has conducted a 5-year review but has decided not to revise the report.

The CA will also develop new assessment procedures that will, for example:

• Include an 'initial read' stage to judge the significance of the revisions, and determine the appropriate depth and breadth of assessment;

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- Focus on key objectives of the assessment process and what the CA wants to achieve;
- Ensure any requests for further information are justified and capable of support through formal enforcement mechanisms, with the operator given a clear view of what is needed;
- Deliver clear and robust conclusions supported by evidence; and,
- Be informed by the outcomes of any previous revision assessments and earlier discussions between the operator and CA.

INTERVENTION/INSPECTION STRATEGIES

One of the aims of the CA's strategy is to minimise office-based review and revision assessment activity, maximise verification, and link assessment more closely with intervention plans. The CA proposes intervention/inspection strategies that:

- Focus on inspection of the design and implementation of operators' change management arrangements, including consideration of operators' decision making on whether safety report reviews are required;
- Examine operator's arrangements and plans for conducting five-year reviews, focusing initially on those operators whose safety reports are five years old in February 2005; and
- Seek to agree with operators how revisions can be best presented to the CA to facilitate the assessment process.

The CA also wants to engage with industry and employee representative organisations to develop mechanisms within the onshore major hazards sector for obtaining intelligence and disseminating more effectively information on, for example, changes in legislation, developments in technical standards, and information about incidents occurring elsewhere, and for alerting operators of top tier establishments of new facts and knowledge that are likely mean that a review of safety reports will be necessary.

LIVING SAFETY REPORTS

In the longer term the CA is also keen to promote the 'living safety report' concept and improve the overall usefulness of safety reports for industry, the public, and other stake-holders. Currently, the CA's experience is that few safety reports are truly embedded within the operators' SMS. Their primary purpose is often viewed as meeting the assessment 'hurdle' imposed by the legislation.

The 'living safety report' concept has become common terminology following the Cullen Inquiries into Rail Safety after the Ladbroke Grove accident. It requires revisions to the safety report at the time of the change. However, this risks continuous or regular revision becoming over-bureaucratic and without proportionate benefit in health, safety and environmental protection. To guard against this the CA needs to work with industry to establish a common shared understanding of the demonstration requirement and move to ensuring that only necessary information is contained in safety reports.

The concept of the living safety report is closely allied to the existence of a robust change management system. As part of the change management system risk assessment is a key prerequisite in ensuring health and safety and the protection of the environment. In this respect COMAH merely reflects what operators should, in any case, be doing so far as the identification and control of risks are concerned. The difference is that COMAH deals specifically with major accident hazards. Operators should be reviewing their risk assessments as appropriate. This may take place for a number of reasons, for example as part of a process review, or under circumstances of change as identified in Regulation 8 of COMAH.

When the relevant risk assessments are reviewed that review should include potential major accident hazards and the implications for them. At that point a decision needs to be made about the status of the safety report and whether it needs to be revised. The potential triggers for this process have been discussed earlier, but if a decision about the review of the safety report is built into the change management process, that is a step towards a 'living safety report'. This is the theme that the CA hopes to develop over the longer term.

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