‘All Measures Necessary’ under the EC Seveso II Directive, Demonstration of Safety, Step by Step

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Summary

Gather-Analyse-Demonstrate

This paper will set out in a clear procedural manner the series of individual steps that need to be taken to make a demonstration that ‘all measures necessary to prevent major accidents and to limit their consequences’ have been considered and provided. It will give emphasis to a systematic approach which starts out with a wide analysis at minimum depth and progresses by selecting a representative set of major accidents for more detailed analysis, followed by the identification and analysis of what further measures might be adopted to reduce risk, and finally the process and criteria used to decide which of these further measures (if any) are necessary.

Controls Before Seveso

Regulatory controls in Great Britain before the first Seveso Directive were based on a series of prescriptive Factories Acts and associated Regulations setting out specific requirements for particular safety problems or, sometimes, industry sectors. Such legislation is ill equipped to respond to fast changing industries and the safety issues arising from them. The style of legislation changed following a review by Lord Robens, a well known industrialist. This 'Robens Report'[(1)] set the pattern for future legislation with 'goal setting' requirements rather than 'prescriptive' requirements, largely based on the requirement that operations be 'safe, so far as is reasonably practicable'. Although `reasonably practicable' was not a new concept in GB law, this made it the foundation stone of most subsequent health and safety law. The most relied upon definition of `reasonably practicable' is to be found in the court decision in the case of Edwards -v- National Coal Board[(2)]

The 'Robens Report' led directly to the Health and Safety at Work etc Act 1974 which required both on-site (section 2) and off-site (section 3) risks to be safe 'so far as is reasonably practicable'. It also put the burden of proof on the risk creator rather than the regulator (section 40).

It can be argued that the demonstration required by Seveso II is no more than the computation specified in Edwards -v- National Coal Board. The only difference is that under Seveso II the demonstration must be submitted to the competent authority in advance of operation and that the competent authority must *‘communicate the conclusions of its examination of the report to the operator of the establishment concerned’.*

Seveso I

This directive was implemented in GB as the Control of Industrial Major Accident Hazards Regulations 1984, (CIMAH). CIMAH was an exercise in providing information to the competent authority. That information included stating what is done, and predicting what might happen in a major accident. In the language of Seveso II, it did require a description of 'extent and severity' but did not require a demonstration that went beyond statements on compliance with 'relevant good practice precautions' and describing what those precautions were.

Seveso II

This directive was implemented in GB as the Control of Major Accident Hazards Regulations 1999[3], (COMAH). Seveso II takes the law beyond the requirement for information. Demonstration takes that information and uses it, in further analysis, to show that additional measures are 'not reasonably practicable' (in Seveso terms 'not a necessary measure')

As well as the move from information to demonstration, there is a changed audience for safety reports in GB that now includes a public element. This means that failing to include safety issues, because they can readily shown to be properly controlled, is not acceptable. Previously, information may have been omitted from reports on the basis that the competent authority and the plant operator both know it already, and that such information does not need stating in the report.

Other potential omissions from reports are the failure to carry out a site specific 'so what?', just putting hazard ranges on maps.

The need to keep up to date with developments on all aspects of safety performance, how it can be measured, and whether new approaches are reasonably practicable, is an ongoing requirement on duty holders. In the context of this paper it applies particularly to the predictive modelling which forms part of a safety demonstration. Being aware of the development of new mathematical models, toxicological information, and monitoring changes in nearby off-site populations are all important.

Step 1

> *Identify and list the controlled substances and their inventories and compare them with the controlled quantities.*

This obvious first step still presents some options now that the Seveso II directive includes the generic classes of substances. Substances that come within control due their generic class can be specified by name or class. Specifying by name allows substance specific hazardous properties to be used later in the demonstration. Specifying by class alone means that a generic worst case needs to be assessed, which may appear to be pessimistic but can retain flexibility of operation within a generic class.

There are also the aggregation rules to be applied. The recent amendment to the Seveso II directive (Directive 2003/105/EC of 16 December 2003) has also altered the aggregation rules so that ecotoxics are no longer aggregated with direct human toxics.

Step 2

> *Identify the location of the hazardous installations and specify which substances are held there, in what quantities, and under what conditions.*

It is self evident that the location(s) of the substance(s) is important so that the extent of the hazards, when predicted at a later stage have a source location(s). The conditions are important because the same substance kept under different conditions can present very different hazards. For example, natural gas may be encountered as a cryogenic liquid, a pressurised gas, or as a gas at essentially ambient temperature and pressure. The prediction of extent and severity is greatly affected by the conditions of storage/processing.

Step 3

Specify the local environment including exposed populations (on and off site) and other hazardous installations (including those at designated domino effect sites) that might be affected by major accidents or be initiators of a major accident.

A clear knowledge of the surroundings, both human populations and the natural and built environment, is necessary. It will not only be used when predicting the severity of the identified major accidents for the report but is also a fundamental data need when predicting the risk reducing effects of possible additional safety measures.

Step 4

Identify all major accidents and develop a qualitative view on the significance of each one, having regard to their potential causes, their likelihood and the severity of the anticipated effects.

Annex 2 of the Seveso II directive states that the report must include a *'detailed description of the possible major-accident scenarios and their probability or the conditions under which they occur'* . Describing all the possible major accidents that might occur is, potentially, an infinite task. For this reason the level of detail required at this stage is only so much as is necessary to enable the selection of a representative set for more detailed analysis and subsequent safety demonstration. In other words, breadth of analysis is more important than depth at this step.

Step 5

In the light of this view on the significance of all the identified major accidents, choose a representative subset for detailed consideration.

This step reviews the data collected, and predictions made so far, in order to reduce the breadth of analysis and increase the depth of a well chosen sub-set of major accidents than can represent all the major accidents identified so far. There are no hard and fast rules on how to do this. Some report authors use a risk matrix approach(4). This author prefers a frequency-hazard plot, if expert judgment is insufficient. If a risk matrix or plot is used, care needs to be taken to use frequency and hazard bands that are appropriate to major accident hazard events to give some discrimination between major accidents of varying severity. In either case the objective at this step is the visualisation of the spread of risk to choose a representative set. This approach will be used again at step 8.

Step 6

Refine the prediction of the hazard range(s) (<u>extent</u>) and their likelihood, for each event in the chosen representative subset.

Having narrowed down the number of major accidents for consideration, this is the point at which quantitative mathematical modelling of the releases of the hazardous substances takes place. The details are beyond the scope of this paper but a wide variety of methods/models are available and advice on choosing an appropriate model can be found in the literature(5). It is also necessary to adopt an event frequency for each major accident, perhaps with some estimate of uncertainty. Event frequencies for major accidents are less easy to obtain from the literature although some sources are available(6). The lack of frequency data has been recognised within the EU and technical working group 5 of the 'European Expert Group on Land Use Planning' which has been set up by the European Commission, will be providing specific advice on this topic in due course.

Step 7

Refine the prediction of the consequences (<u>severity</u>), for each event in the chosen subset, including the number of fatalities to man and damage to the environment, and develop a view on the extent of lesser harms such as major and minor injuries to persons.

Having revised the predictions of the hazard ranges, it is then necessary to predict the numbers of people that might be harmed and the type of harm they suffer, in broad terms. Harm to the environment must be considered in a similar way. This information will be required later when the value of potential additional measures, and the harm that might be averted by them, are being considered.

Methods for estimating the consequences of hazardous effects of major accidents are available in the literature(7).

Step 8

> *Show the consequences and the likelihood, for each event in the chosen subset, on an fn matrix or plot (non cumulative) to aid visualisation of the spread of risks and risk ranking.*

One of the most important of the most important principles in health and safety regulation is that of proportionality. In essence this means that the most onerous standard of safety demonstration is reserved for situations that pose the highest risk. In order to take the steps that follow this step provides the 'picture of risk' so that the proportionality can be set for the demonstration that '*major-accident hazards have been identified and that the necessary measures have been taken to prevent such accidents and to limit their consequences for man and the environment;*'

Step 9

> *Divide the area of the matrix (or plot) into 3 bands (broadly acceptable risk, tolerable if ALARP, and intolerable risk) and calibrate these bands against HSE published guidance on tolerability of risk ('R2P2' and 'QRA its input to decision making').*

The GB approach to the regulation of risk is set out in the document 'Reducing Risk, Protecting People'(8). On page 42 it sets out the 3 'region' approach to the regulation/management of risk. Within the Hazardous Installations Directorate this approach has been expanded(9) to '*propose a basic criterion for the limit of tolerability. HID proposes that the risk of an accident causing the death of fifty people or more in a single event should be regarded as intolerable if the frequency is estimated to be more than one in five thousand per annum. This enables criteria for case societal risk to be defined:*

The unacceptable region: the region above the line of slope –1 through this point on the lnF v lnN plot; and
The broadly acceptable region: the region below a line two orders of magnitudes below and parallel to the above line.
The tolerable if ALARP region lies between these two lines.'

Step 10

> *Split the "Tolerable if ALARP band" into, say, 3 sub bands to enable proportionate demonstration.*

The identified major accidents in the representative subset that fall within the '*tolerable if ALARP band*' are all to be analysed to determine '*what more might be done*' by way of additional measures and what further measures are necessary, if any. Options to split the band include using 'maximum potential fatalities', F x N, F x N^2, F x $N^{1.4}$, where F is the frequency of the major accident and N the number of fatalities predicted. F x $N^{1.4}$ has been advocated recently by authors working in this topic area at HSE(10). The number of sub-bands chosen depends on the number of distinct types of demonstration that are to be adopted. Two bands might be adopted if the only distinct types of demonstration are qualitative and quantitative. The authors view is that no more that 3 types of demonstration are sufficiently distinctive. They are:-

- Derivation of possible measures, estimated costs and benefits of implementation and cost/benefit comparison are all qualitative.
- Derivation of possible measures structured from HAZOPs etc, estimated costs quantified in monetary terms and benefits of implementation and cost/benefit comparison remain qualitative.
- Derivation of possible measures highly structured from an analysis of bow-tie diagrams etc., estimated costs quantified in monetary terms and benefits of implementation and cost/benefit comparison all quantitative in monetary terms.

Step 11

Consider individually all the major accidents in the tolerable if ALARP band with, say, a MPF of less than 10, and provide a 'standards plus' demonstration that the qualitatively assessed costs, of a qualitatively determined range of additional risk reduction measures, show that nothing more is reasonably practicable.

At this lower level of proportionality the process of demonstration may consist of showing compliance with relevant good practice precautions followed by a qualitative analysis by an expert group of possible additional measures and whether the costs greatly outweigh the benefits.

Step 12

Consider individually all the major accidents in the tolerable if ALARP band with, say, a MPF of 10 to 100, and provide a 'qualitative' justification that the identified costs, of a qualitatively determined range of additional risk reduction measures, show that nothing more is reasonably practicable.

At the middle level the analysis is more structured throughout and actual monetary costs of possible additional measures are used. Generally speaking quantification of the monetary costs of additional measures is much easier than quantification of the monetary value of harms averted by those measures.

Step 13

Consider individually all the major accidents in the tolerable if ALARP band with, say, a MPF of greater than 100, and provide a 'quantitative' cost benefit analysis, on a range of systematically determined additional risk reduction measures, to show that nothing more is reasonably practicable.

At the highest level the analysis is highly structured throughout and predictions need to be made of the monetary value of harms averted to people and the environment. The cost benefit comparison is carried out explicitly in monetary terms with a clear description of how the conclusion in respect of costs outweighing benefits has been made, if a measure is demonstrated to be not necessary.

Step 14

Check that the most exposed individual on and off site is not at intolerable individual risk.

When considering major accidents, the focus is quite naturally on those that, if they occur, are predicted to have high severity. There may however be some situations where the predicted severity is low, perhaps due to an isolated single dwelling near an installation, but the likelihood for the occupier of that isolated dwelling is high. The analysis above may fail to highlight such cases which need separate analysis in an analogous way.

Policy Issues arising from this Approach

The preceding description does not state how the issues of uncertainty of predictions, and sensitivity of conclusions to assumptions, and other factors in the risk assessment, must be dealt with. There are a wide range of factors that have a bearing on making a demonstration and only a few can be briefly considered here.

Depth of Analysis

The depth of the analysis necessary in a demonstration is relative to the scale and nature of the hazards and risk being revealed by the analysis, and its significance. This is not easy and is, largely, an iterative process. However it is the key to a good COMAH safety report, and needs to be properly covered in the approaches adopted by report authors.

Valuing Costs and Benefits

Deciding which costs and benefits are within scope of this type of safety demonstration can be difficult. Clearly direct costs of a measure are in scope, as are direct benefits of harms averted. Other monetary costs averted such as loss of production during plant down time are less clear. Some costs averted may be out of scope although very substantial. An example of this, from another area, is the costs of public disruption caused by accidents which could have be averted by additional measures. This has been a particular issue in GB in connection with the possible adoption of ‘automatic train protection’ subsequent to several well publicised railway accidents. Published analyses that only take account of the direct value of averting fatalities lead to the conclusion that ‘automatic train protection’ is far too costly for the safety gains that would accrue. The author of this paper wonders how the judgement might change should the full costs to the economic life of the country of such accidents were taken into account as well. Some further guidance on valuing costs and benefits is given in guidance by HM Treasury(11).

Gross Disproportion

When comparing costs and benefits, the ratio of monetary costs to monetary benefits is called the proportion factor. In GB measures must be adopted unless there is a gross disproportion between the costs and benefits, or put another way, the proportion factor is numerically large. But how large is large? Despite the passage of 50 years since the court decision, it is only recently that some benchmarks have been published. See paragraph 51 of the reference(11).

Author’s Note

The views expressed in this paper are those of the author; and, except where the context indicates, not necessarily those of the Health and Safety Executive.

Other related documents in this topic area have been published(13)(14)(15)(16).

References

(1) Lord Robens, Safety and Health at Work. Report of the Committee 1970-72. HMSO Cmnd 5034, 1972

(2) Edwards v National Coal Board [1949]1 ALL ER 743 *‘Reasonably practicable’ as traditionally interpreted, is a narrower term that ‘physically possible’ and implies that a computation must be made in which the quantum of risk is placed in one scale and the sacrifice, whether in money, time or trouble, involved in the measures necessary to avert the risk is placed in the other; and that if it be shown that there is a gross disproportion between them, the risk being insignificant in relation to the sacrifice, the person upon whom the duty is laid discharges the burden of proving that compliance was not reasonably practicable. This computation falls to be made at a point of time anterior to the happening of the incident complained of.* At 747 per Asquith LJ.

(3) The Control of Major Accident Hazards Regulations 1999, SI 1999 No 743, The Stationary Office Ltd. ISBN 0-11-082192-0

(4) Mark Middleton and Andrew Franks, ‘Using Risk Matrices’, The Chemical Engineer, September 2001

(5) TNO Yellow Book-Methods for the calculation of the physical effects due to releases of hazardous materials (liquids and gases), Committee for the Prevention of Disasters, CPR-14E, The Hague, The Netherlands, Third edition, 1997.

(6) TNO Purple Book-Guidelines for Quantitative Risk Assessment (CPR 18E), 1999

(7) TNO Green Book-Methods for Determining the Possible Damage to People and Subjects resulting from Release of Hazardous Materials

(8) Reducing Risks, Protecting People, HSE's Decision-Making Process, HSE Books, 2001, ISBN 0-7176-2151-0 (http://www.hse.gov.uk/dst/r2p2.pdf)

(9) HID's Approach to 'As Low As Reasonably Practicable' (ALARP) Decisions (http://www.hse.gov.uk/comah/circular/perm09.htm)

(10) I.L. Hirst and D.A. Carter, A "worst case" methodology for obtaining a rough but rapid indication of the societal risk from a major accident hazard installation, Journal of Hazardous Materials, Volume 92, Issue 3, 10th June 2002, pages 223-237

(11) Appraisal and Evaluation in Central Government, The Green Book, HM Treasury, 1997, ISBN 0115601074

(12) Guidance on 'as low as reasonably practicable' (ALARP) Decisions in Control Of Major Accident Hazards (COMAH) (http://www.hse.gov.uk/comah/circular/perm12.htm)

(13) Quantified Risk Assessment: Its Input to Decision Making, HSE Books, 1989, ISBN 0-7176-0520-5

(14) Principles and Guidelines to Assist HSE in its Judgements that Duty-Holders have Reduced Risk As Low As Reasonably Practicable (http://www.hse.gov.uk/dst/alarp1.htm)

(15) Assessing Compliance with the Law in Individual Cases and the Use of Good Practice (http://www.hse.gov.uk/dst/alarp2.htm)

(16) Policy and Guidance on reducing risks as low as reasonably practicable in Design (http://www.hse.gov.uk/dst/alarp3.htm)