Guidance on

'Significant Modifications'

Under the

COMAH Regulations

Table of Contents

Glossary of terms used

ALARP	As Low As Reasonably Practicable
API	Active Pharmaceutical Ingredient
ATM	Additional Technical Measure
BAT	Best Available Techniques
BATC	Best Available Techniques (BAT) Conclusions
BREF	Best Available Techniques (BAT) Reference Documents
CBA	Cost Benefit Analysis
CCA	Central Competent Authority
CDOIF	Chemical and Downstream Oil Industry Forum
COMAH	Control of Major Accident Hazards
CPM	Chance Per Million
EV	Expectation Value
HSA	Health and Safety Authority
IPL	Independent Protection Layer
JRC	Joint Research Centre
LOC	Loss of Containment
LOPA	Layer of Protection Analysis
LUP	Land Use Planning
MAPP	Major Accident Prevention Policy
MATTE	Major Accident to the Environment
PA	Planning Authority
PLL	Potential Loss of Life
SIL	Safety Integrity Level
SRI	Societal Risk Index
TWG	Technical Working Group
VCE	Vapour Cloud Explosion

1. The COMAH Regulations

The *Chemicals Act (Control of Major Accident Hazards Involving Dangerous Substances) Regulations 2015, S.I. 209 of 2015* (the 'COMAH Regulations'), implement the Seveso III Directive (2012/18/EU). The COMAH Regulations lay down the requirements for the prevention of major accidents involving dangerous substances, so as to limit, as far as possible, the consequences of such accidents for human health and the environment: the overall objective is to provide a high level of protection to human health and the environment in a consistent and effective manner.

This is achieved through tiered controls on the operators of COMAH establishments (the larger the quantities of dangerous substances present at an establishment, the more onerous the duties on the operator), controls on developments at those establishments and controls on development in their vicinity.

The COMAH Regulations apply to any establishment with a presence of dangerous substances in quantities that exceed the thresholds specified in the Regulations. The list of dangerous substances and their threshold quantities are specified in Schedule 1 to the COMAH Regulations.

The Health and Safety Authority is the Central Competent Authority ('CCA') for the purpose of the COMAH Regulations.

Detailed Guidance on the COMAH Regulations is available on the HSA website. That Guidance should be consulted for a more detailed examination of the Regulations.

2. Purpose of this Guidance

The purpose of the guidance is to steer operators of COMAH establishments through the 'significant modification' assessment, submission and evaluation processes.

It will help them to determine whether contemplated changes fall into the significant modification category and if so, the information that should be prepared and sent to the CCA well in advance of the modification schedule.

The Guidance also demonstrates how the CCA will assess significant modifications through a number of worked examples.

3. Acknowledgements

The Guidance has been prepared with the assistance of the *COMAH Significant Modifications Technical Working Group* (TWG) set up under the COMAH Cost Review Group.

The HSA thanks the following for their participation and input to the Working Group:

Aisling O'Connor (Pfizer Ireland Ltd.)
Andrew O'Callaghan (Goulding Chemicals Ltd.)
Bob Loade (BOC Gases)
Damien Roche (Roche Freight)
Fergal Leonard (Flogas and LPG Industry Representative)
Finbar Constant (Irish Oxygen Company Ltd.)
Gervase McAleavy (Pernod Ricard)
Iggy Marum (Merck Millipore)

John Craig (Atlantic Fuel Supply Company and Irish Petroleum Industry Association)
Michael Buckley (Novartis Ringaskiddy Ltd.)
Niamh Donohoe (Intel Ireland)
Paschal Byrne (BOC Gases)
Rita O'Sullivan (Eli Lilly Kinsale Ltd.)
Ruth Donohoe (TOP and Irish Petroleum Industry Association)

The TWG set up an expert group to provide assistance on addressing the relevant technical issues. The HSA thanks the following for their participation and input to the Expert Working Group:

Adrian Watson (Managing Director, Project Design Engineers)
Brenda Madden (Senior Process Safety Engineer, PM Group)
Denis Curtin (Consulting Process Safety Engineer, Denis Curtin Ltd)
Maeve McKenna (Principal Risk Consultant, AWN Consulting)
Roger Casey (Senior Consultant, Cantwell, Keogh & Associates)
Sinead Keohane (Lead Process Safety Consultant, PM Group)
Tom Leonard (Partner, Byrne O'Cleirigh)
Tracey Kelly (Professional Process Safety Engineer)

4. What is a Significant Modification?

Article 11 of the Seveso III Directive states:

In the event of the modification of an installation, establishment, storage facility, or process or of the nature or physical form or quantity of dangerous substances which could have significant consequences for major-accident hazards, or could result in a lower-tier establishment becoming an upper-tier establishment or vice versa, Member States shall ensure that the operator reviews, and where necessary updates the notification, the MAPP, the safety management system and the safety report and informs the competent authority of the details of those updates in advance of that modification.

This has been implemented in the COMAH Regulations through Regulations 12 and 24 (the full text of which are in Appendix 1 to this document).

The term 'significant modification' is not used in either the Directive or the COMAH Regulations but is commonly used (and is used here) to describe the modifications encompassed by Regulation 12. The COMAH Regulations are not entirely explicit on the modifications to be controlled or on how the Central Competent Authority (CCA) will assess the significance of a modification, so this guidance document has been produced to provide greater clarity in this area and to make it clear when the CCA will refer a modification to the Planning Authority (PA), in accordance with Regulation 24(5).

5. Deciding if a modification is significant

Appendix 2 sets out the complete approach an operator should take when analysing a potentially significant modification and describes in detail how the CCA will go about making the assessment.

The remainder of this Guidance gives an overview of the system and works through a number of examples to illustrate its operation.

It is essential that operators assess anticipated significant modifications at an early stage, because the COMAH Regulations require plans to be submitted in advance: an early consideration of the modification allows a greater range of options to come under consideration by the operator.

6. Preliminary Analysis

The process begins with the operator performing a preliminary analysis (Appendix 2 and Appendix 6 set out the complete process), using endpoints specified in the Guidance on technical land-use planning advice document[1].

If the accident consequence zone will increase as a result of the modification, or if more receptors will be exposed or will be subject to increased risk, then this indicates a detailed analysis should be undertaken by the operator.

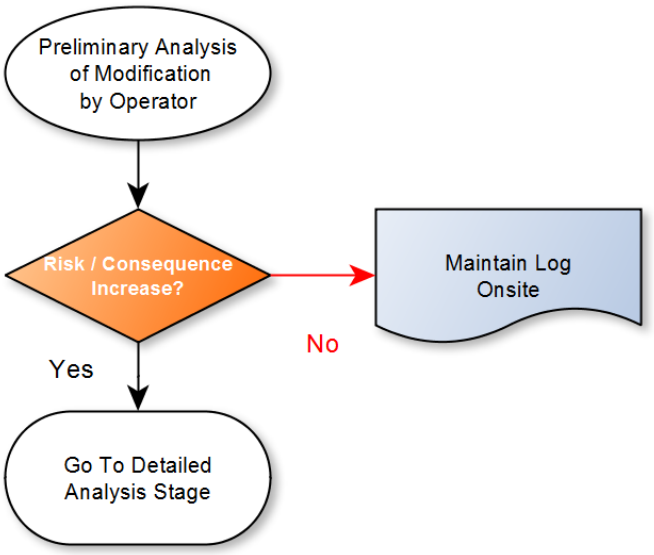


Figure 1: the preliminary analysis

Only if the preliminary analysis indicates the change is potentially significant will a detailed analysis be required. Small changes, such as a new pump installation into an area already containing multiple pumps are unlikely to constitute a 'potentially significant' modification.

Otherwise, the operator maintains a simple log of the modification (such as shown in Appendix 3). The results of the preliminary analysis should be retained for examination during future CCA inspections, for a period of 3 years.

In the process sector, the expectation is that all processes will first be assessed qualitatively through standard process hazard analysis procedures, for example through HAZOP and qualitative risk ranking. Where it is determined that the change is of equal or lesser risk to what had been included

[1] Guidance on technical land-use planning advice

in previous communications to the CCA (that is, if the modification does not change overall risk level significantly), then a log should be kept of the change and be available to the CCA at the next inspection[2].

7. Detailed Analysis

Where it is indicated by the preliminary analysis, the operator must carry out a detailed analysis (Appendix 2 and Appendix 6 set out the complete process).

Figure 2, below, gives an overview of the approach:

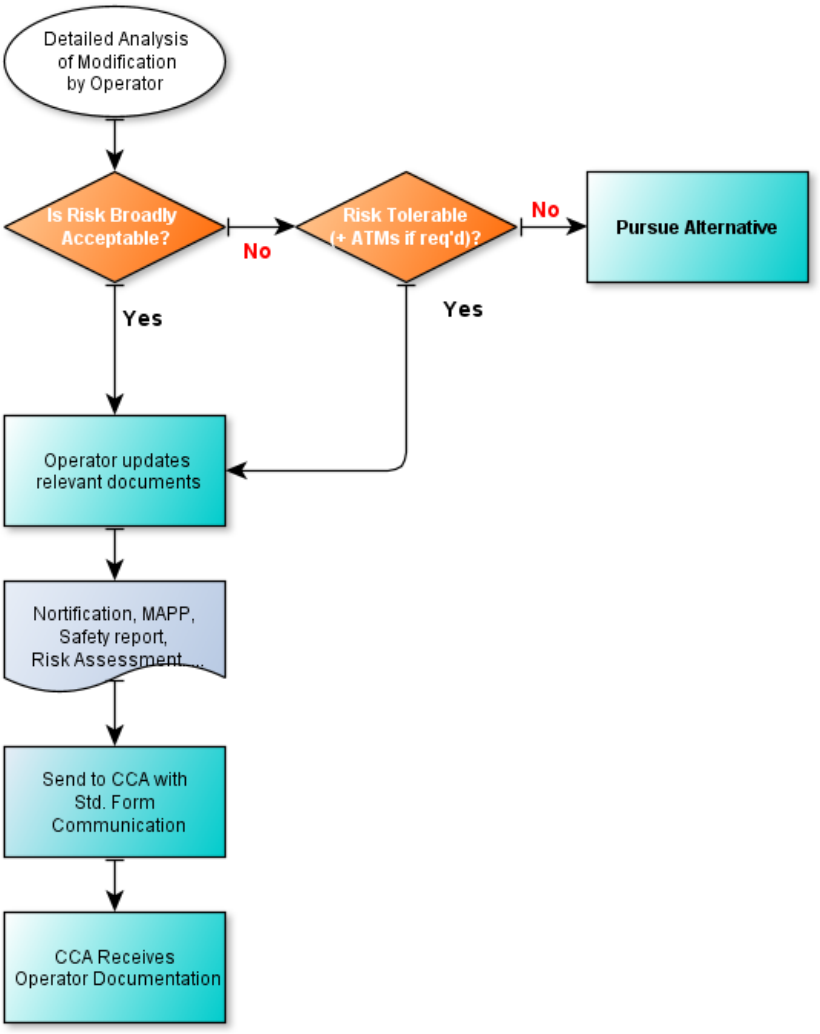


Figure 2: Detailed analysis by operator

In this stage of the analysis, the operator characterises the consequences and risks subsequent to the proposed modification, to the level of detail necessary to enable a determination of its significance.

[2] If it subsequently becomes apparent that the modification poses a significantly greater risk than previously notified to the CCA and it meets the detailed analysis criteria, then the modification should be notified to the CCA and go forward for detailed analysis.

The number of people (or environmental receptors) affected, the extent of that effect and the frequency of occurrence (using figures from the Guidance on technical land use planning advice) are all subjected to analysis, using the methodology set out in Appendix 2.

If the overall risk following the modification is estimated to be broadly acceptable (fatality risk < 1 x 10^{-6} per annum or the equivalent environmental criterion) without the need to implement further technical measures ('additional technical measures' – ATMs), then the operator should update the relevant documents[3] and send them in advance to the CCA. The communication form in Appendix 4 (with Section 1 completed) should accompany the documentation (preferably send to COMAH@hsa.ie).

If the overall risks are not broadly acceptable then the operator should look to apply ATMs that will bring the fatality risk to a tolerable level (in the range 1 x 10^{-4} to 1 x 10^{-6} for people onsite and less than 1 x 10^{-6} at offsite locations). The operator is expected to bring the risk following the modification to a level that is as low as reasonably practicable. Therefore, reasonable ATMs should be implemented: in more complex situations a cost benefit analysis may be required to show that it was not reasonable to implement further additional technical measures.

When the risk has been demonstrated to be as low as reasonably practicable (ALARP), the operator should update the relevant documents and send them in advance to the CCA. The communication form in Appendix 4 (with Section 2 completed) should accompany the documentation (preferably send to COMAH@hsa.ie).

If the overall risks are not as low as reasonably practicable then the operator must look at ATMs that will bring the risk within the ALARP range. If the onsite risks cannot be brought within the ALARP range the modification will not be permitted by the CCA (unless the modification will bring about a reduction in risk). The operator should update the relevant documents and send them in advance to the CCA. The communication form in Appendix 4 (with Section 3 completed) should accompany the documentation (preferably send to COMAH@hsa.ie).

Where the offsite risk criterion is exceeded, the modification will be referred to the planning authority, under Regulation 24(5), with appropriate technical advice. The operator should update the relevant documents and send them in advance to the CCA. The communication form in Appendix 4 (with Section 4 completed) should accompany the documentation (preferably send to COMAH@hsa.ie).

Figure 3 (below) summarises the sections of the appendix 4 form to be completed by the operator and to be sent to the CCA:

[3] The relevant documents are: the notification under Regulation 8, the MAPP and safety management system under Regulation 10, the safety report under Regulation 11 and any relevant risk assessment

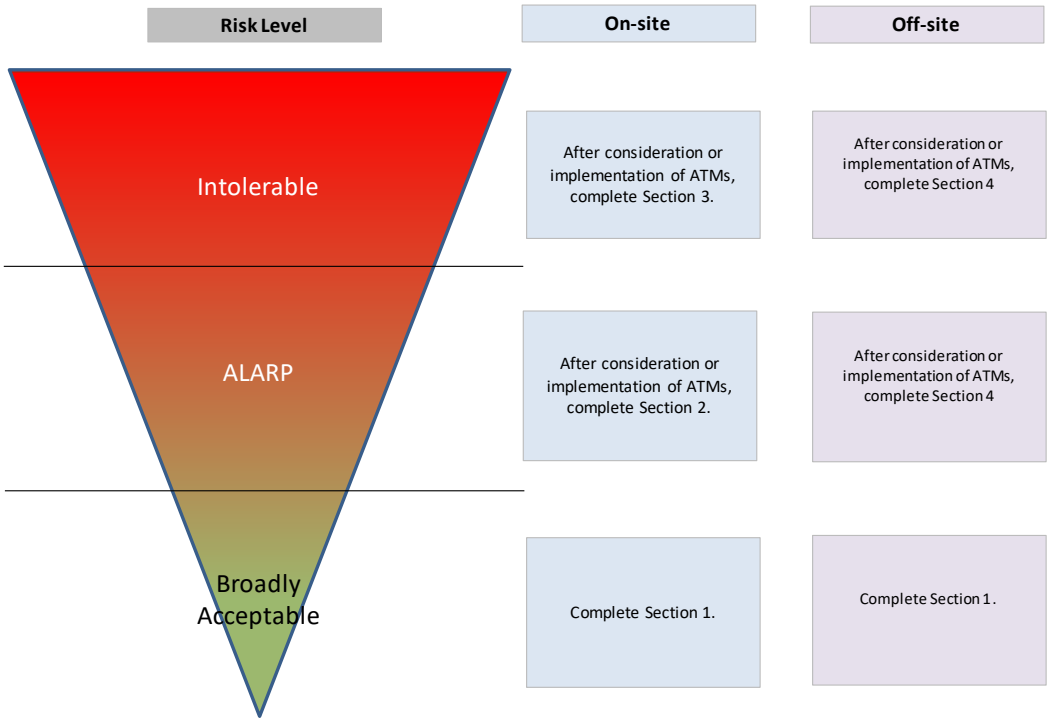
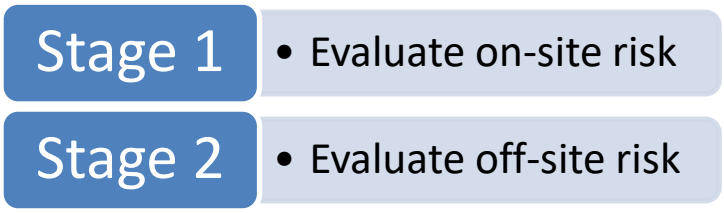


Figure 3: Sections of notification form (Appendix 4) to be completed and sent to CCA

8. The CCA's Assessment Process

The CCA reviews the documentation submitted by an operator in support of a modification in two distinct stages:



8.1 On-site Risk Evaluation

The first decision point for the CCA is whether the on-site human health and environmental risk following the modification will be acceptable, that is, will the risk of fatality to people be below 1 x 10^{-6} per year threshold? If it is (and the societal risk is tolerable) then the CCA will permit the modification.

If the risk is greater than 1 x 10^{-4} per year, the CCA will look for the operator to implement additional technical measures to bring the risk within the tolerable (ALARP) range of 1 x 10^{-4} to 1 x 10^{-6} per year risk of fatality. At risk levels above this threshold, if no ATMs are practicable, then the CCA will reject the modification, unless it actually represents a risk reduction from the existing intolerable situation, for example reducing the risk from 5 x 10^{-4} to 2 x 10^{-4} per year.

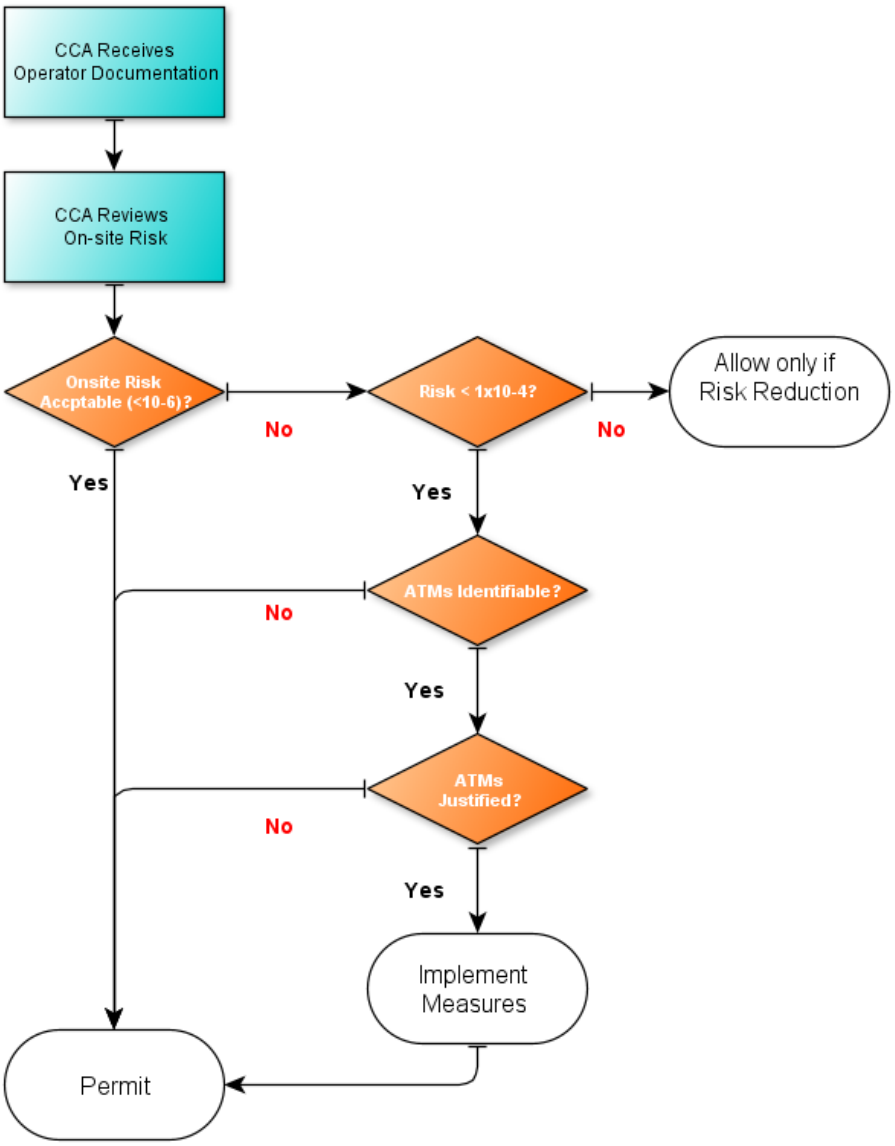


Figure 4: CCA assessment of on-site risk

If the risk is in the (ALARP) range (1 x 10^{-4} to 1 x 10^{-6} per year risk of fatality), the operator will still be required to demonstrate that it is not reasonably practicable to reduce the risk through the further use of technical measures ('additional technical measures').

Where ATMs are possible within the ALARP region, the CCA assesses whether the risk can be brought within the tolerable range through the use of those additional technical measures and whether all the reasonably practicable technical measures have been applied to bring the risk to as low a level as practicable.

It may be relatively straightforward to demonstrate that further risk reduction is not reasonably practicable (or not justifiable) where there are no identifiable technical measures that could be implemented or where the identified measures are clearly disproportionate to the benefit to be gained. But in more complex situations, where this is not immediately obvious and where measures

are identifiable but not proposed to be implemented on cost grounds, a formal Cost Benefit Analysis will be required to justify non-implementation.

If the risks are ALARP or can be made ALARP (and the societal risk increase is tolerable) then the CCA will permit the modification.

The CCA will advise the operator within 4 weeks of receiving the appropriate documentation.

Assessment of modifications is a chargeable activity under the COMAH Regulations (*Significant change under Regulation 12*. The minimum charge of €1,800 covers the first 3 days of assessment time; the maximum charge is €6,000).

8.2 Off-site Risk Evaluation

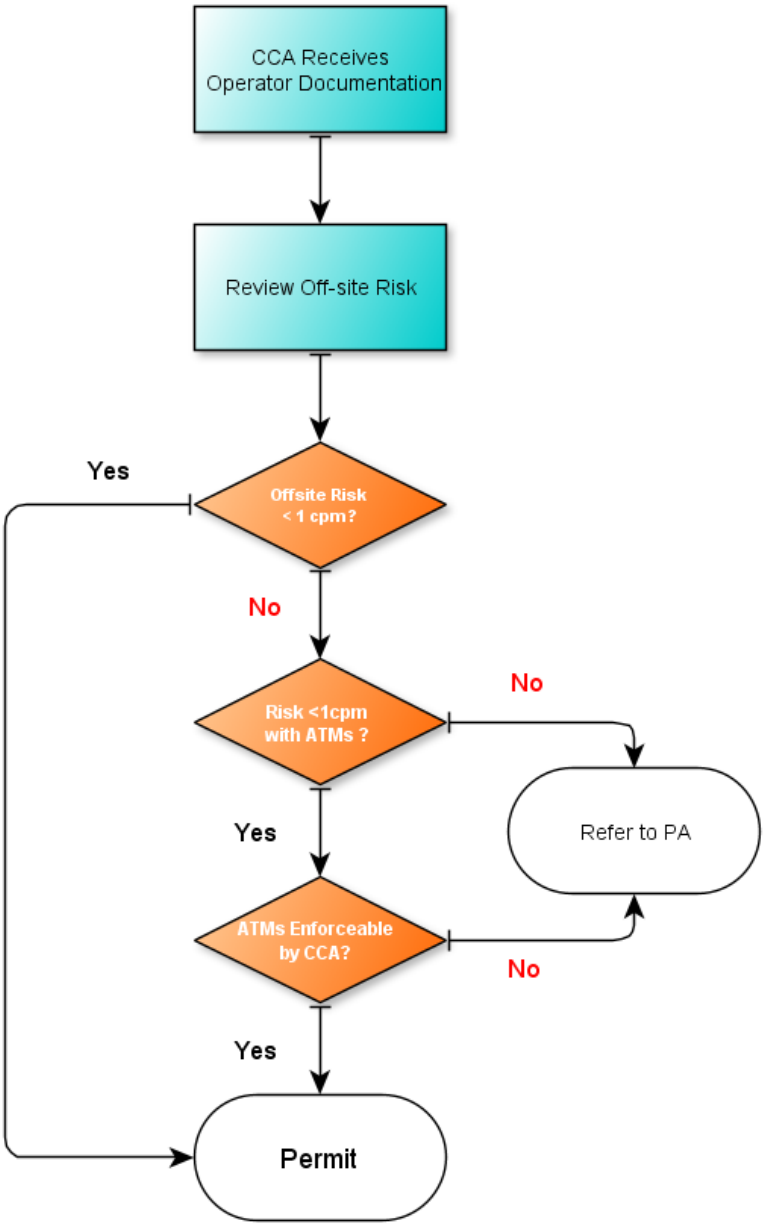


Figure 5: CCA assessment of the off-site risks

The first decision point for the CCA, in this evaluation stage, is whether the off-site 'location' risk, following the modification, will be acceptable: that is, will the risk be below 1 x 10^{-6} per year[4] fatality level? A separate environmental risk evaluation determines if it will be broadly acceptable according to the CDOIF[5] methodology. If it is (and societal risk increase is tolerable) then the CCA will permit the modification without referral to the planning body.

If the risk is greater than this value, the CCA will expect the operator to explore what, if any, additional technical measures would bring the risk below this level.

If the risk can be brought below the target value through the use of additional technical measures, and these technical measures are within the control of the operator, then the CCA will permit the modification without referral to the planning body.

If the risks can only be brought below the target value through the use of additional technical measures, and these technical measures are not within the control of the operator, then the CCA will refer to the planning authority, with technical advice in accordance with the *Guidance on technical land use planning advice* document.

If the operator can robustly demonstrate that no ATMs can be identified, or if identified ATMs cannot be justified to implement, then the CCA will refer it to the planning authority with technical advice, in accordance with the *Guidance on technical land use planning advice* document.

The overall assessment is summarised by Figure 6:

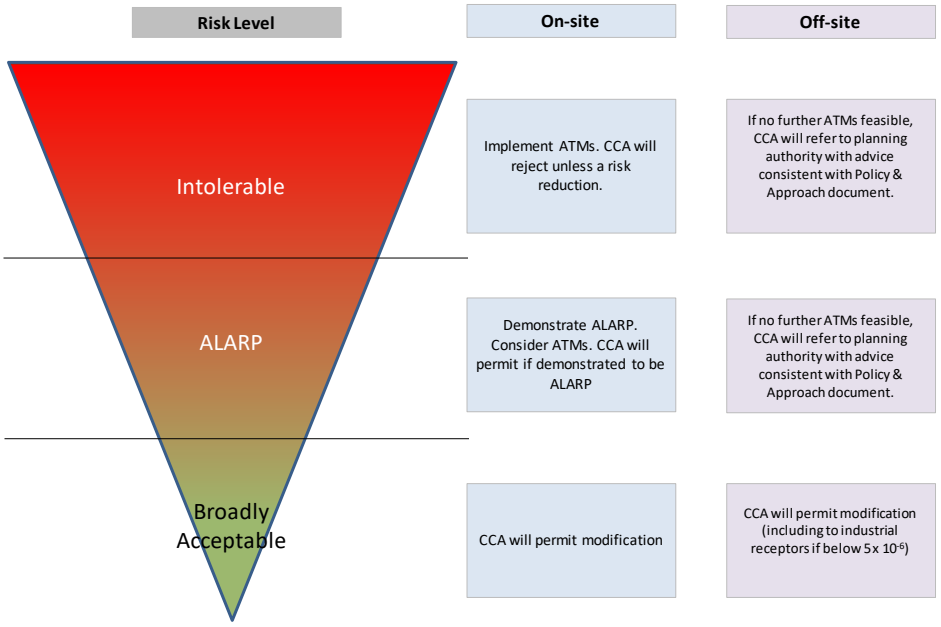


Figure 6: CCA actions following assessment

[4] This is relaxed to 5 x 10^{-6} per year if all relevant neighbours are considered to be industrial in nature
[5] Chemical and Downstream Oil Industries Forum publication : *Guideline on Environmental Tolerability for COMAH Establishments*, v2.0

8.3 Change of tier

Tier change is specifically identified in Regulation 12 as a significant modification.

8.4 Permission

Significant modifications must be notified in advance to the CCA and, under Regulation 24(6), the operator may proceed only if the specified ATMs are put in place and if formal permission is given to the operator by the CCA.

Where a modification is referred to a planning authority (PA), the modification may not proceed until permission has been received from the planning authority, or, if the referral has been declined by the PA, the CCA.

9. Examples

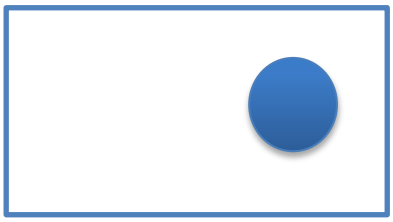
All the examples included in this section are fictitious and while the figures used draw on those in the Guidance on technical land use planning advice document, they are not to be interpreted as the figures to be used in a particular situation. Advice should always be sought from a competent person.

9.1 Example 1: Changed contents of a storage tank containing toxic liquid

Modification

An establishment storing toxic liquid in bulk intends to change the contents of a storage tank from substance X to substance Y. How significant is this modification?

Analysis



The relevant major accident scenario is determined to be a loss of containment (LOC) from the tank into the bund. It is assumed all of the tank contents will be held within the bund (dimensions 10m x 5m).

Therefore there will be no significant change in the volume of dangerous substance spilled.

There are no other risk sources in the immediate area.

Three routes to a major loss of inventory to the bund have been identified by the operator:

- loss of containment through a hole in the tank;
- a piping failure;
- a catastrophic failure of the tank.

LOC frequencies, given in the *Guidance on technical land use planning advice* document, are used to estimate the risk levels.

In this way, the overall annual frequency of this accident is determined by the operator to be 1.1 x 10^{-4}.

Modelling in ALOHA suggests, for the pre-modification scenario, that the concentration of the existing substance (X) at distance 10 metres from the bund would be ~2,000 ppm which equates to a 3% fatality rate.

This puts the existing annual fatality risk (R_{af}) at the location 10 metres outside the bund as:

$$R_{af} = 1.1 \times 10^{-4} \times 0.03 = 3.3 \times 10^{-6}\ per\ year \quad (1)$$

Similar modelling for the post-modification scenario suggests a concentration of 1,200 ppm of the new substance(Y), leading to an estimate of 8.5% fatality (using a relevant Probit equation, such as those listed in the *Guidance on technical land use planning advice* document).

As there is an increase in the consequences, a detailed assessment is required.

The new annual fatality risk at the location 10 metres outside the bund is:

$$R_{af} = 1.1 \times 10^{-4} \times 0.085 = 9.35 \times 10^{-6}\ per\ year \quad (2)$$

The increase in risk is:

$$9.35 \times 10^{-6}\ per\ year - \ 3.3 \times 10^{-6}\ per\ year = 6.05 \times 10^{-6}\ per\ year \quad (3)$$

The requirement is to determine the overall risk, not the increase, so the figure in equation (2) is used.

The analysis predicts an increase in the location-based on-site risk and the risk level following the modification would lie towards the middle of the 10^{-6} to 10^{-4} ('ALARP') range.

The operator then analyses whether any persons would be exposed to this risk.

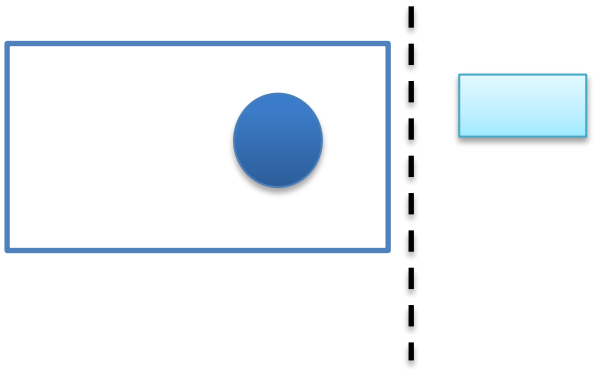
It is found that the maximum time a person could be present was 25% of the time. Therefore the annual on-site individual fatality risk was calculated to be:

$$R_{af} = 9.35 \times 10^{-6} \times 0.25 = 2.33 \times 10^{-6}\ per\ year \quad (4)$$

While the on-site fatality risk is lower than originally calculated, it still falls within the ALARP range and the operator must consider the identification and application of additional technical measures and, if it is not intended to apply them, the operator must provide a solid justification for this in the appendix 4 communications to the CCA (the operator could also try to refine the risk calculation by allowing for other variables, such as wind direction).

There are no sensitive environmental receptors offsite and no pathway for a spillage to go offsite, so no further environmental assessment is required.

Alternative Scenario



All the conditions in the example above apply, but, in addition, because one end of the bund is adjacent to the site external boundary, there are off-site risks to be considered.

So, as well as completing the on-site analysis described above, the operator must also carry out an off-site risk analysis.

As shown above, the new annual off-site risk figure is 9.35 x 10^{-6}. As the off-site criterion is location-based and does not depend on the presence of people, the acceptable individual risk criterion will be exceeded.

The operator now has to consider additional technical measures and, if not intending to apply them, provide a strong justification in the appendix 4 communication to the CCA.

In this situation the operator should also consider societal risk. If it is assumed that 10 people are present within the risk contour, the Expectation Value (EV_A) would be:

$$EV_A = \Delta R_{cpm} \times N = 6.05 \times 10 = 60.5 \text{ (5)}$$

(Increased frequency of accident in chances per million x number of fatalities)

As this is below the action level of 450 for a detailed societal risk assessment, no further societal risk evaluation is required.

In these circumstances, the CCA would refer to the planning authority, with appropriate technical advice, in accordance with the *Guidance on technical land use planning advice* document ('Not Against').

9.2 Example 2: Introduction of a new process in the Pharmachem sector

Modification

The operator of a COMAH establishment intends to introduce a new process and must decide if the modification is significant and the extent of the information that should be supplied to the CCA.

Analysis

The establishment has a number of process buildings on a large rural site. In the relevant process building there could be up to a maximum of 4 different processes in progress at any one time.

Until now, the operator has not performed a formal quantified risk assessment, on the risk to the operatives present in the building.

The operator carries out a preliminary assessment and this indicates that the consequences from the worst case accident for the new process are somewhat worse than for any of the existing 4 processes. As there is an increase in the consequences, a detailed assessment will be required.

In establishing the necessary major accident preventative controls, the establishment already uses numerical risk assessment techniques. The target value set by the establishment is a risk of operative fatality of less than 1 x 10^{-5} per year (once per hundred thousand years) per scenario and a total risk of operative fatality of less than 1 x 10^{-4} per year (once per ten thousand years) from all scenarios. To achieve this, the operator applies good practice to the design of the process and the equipment used, which will comply with the relevant standards and guidelines and generally with 'good practice'. In addition IPL's (independent protective layers) consisting of hardwired interlocks and with a SIL 2 (EN 61511) rating will be installed for the various scenarios. As a result, when all the relevant scenarios from the process capable of causing a fatality to the operative are taken into account, the risk calculations indicates the target risk value of 1 x 10^{-4} per year will be comfortably met.

The process building operates continuously for 50 weeks per year, staffed by a maximum of eight operatives at any one time. In the new situation, with a maximum 5 processes running simultaneously in the process building, an individual operative's fatality risk for the processes meeting the in-house target criterion is:

$$R_{af} = (1 \times 10^{-5}) \times 5 = 5 \times 10^{-5}\ per\ year \quad (1)$$

Allowing for the max maximum time a particular operator is present gives:

$$R_{af} = 5 \times 10^{-5} \times 0.23^{6} = 1.15 \times 10^{-5}\ per\ year \quad (2)$$

Therefore the overall individual risk level in the new situation will put it in the middle of the ALARP zone.

[6] 48 Weeks for 40 hours, whereas processes operate 50 weeks continuously)

Societal risk

There are a maximum of 8 operatives present at any one time in the hazard areas of the process building.

The initial societal risk calculation looks only at the increased level of risk. As the new process meets the company's target risk threshold, the *increased* risk of fatality is taken as:

$$\Delta R_{af} = 1 \times 10^{-5}\ per\ year = 10 cpm \quad (3)$$

The fatality proportion in an explosion in this situation is assumed as 0.75 (using the Probit equation from the *Guidance on technical land use planning advice* document and a modelled overpressure of 179 kPa), which means for 8 operators, N= 6.

The Expectation Value is therefore:

$$EV_A = \Delta R_{cpm} \times N = 10 \times 6 = 60 \quad (4)$$

This is below the threshold value of 450 and so there is no requirement for a full societal risk assessment in relation to the proposed modification.

Conclusion

The risk is in the ALARP zone. The operator complies with all relevant good practice and exceeds it by using additional technical measures where required by LOPA. The operator forwards a case to the CCA that the risk is ALARP and that no further measures are necessary, with an updated notification and safety report and awaits a decision.

Given the human risk level and that environmental risks are not relevant, the absence of possible further technical measures and the quality of the case presented, the CCA would consider the risk to be ALARP and allow the modification.

9.3 Example 3: Warehouse change in inventory

Modification

The operator of a lower-tier establishment has bid for a contract to store material for an API manufacturer and is considering whether to notify the HSA of a significant modification.

Analysis

The operator follows good practice in the warehousing of dangerous substances and ensures incompatible substances are always segregated. The warehouse is appropriately zoned under the Hazard Area Classification standard [EN 60079].

The worst case major accident has been identified as a warehouse fire.

The new contract will involve storage of up to 10 tonnes of a dangerous substance with the hazard category H 203 (risk of explosion by shock, friction, fire or other sources of ignition), Seveso category P1a. The substance is a solid. None of the existing dangerous substances in the warehouse have this hazard classification.

The material will be in 50 kg drums, stored four per pallet.

Storage of the substance will not bring the operator into the upper-tier classification.

As a new type of hazard is being introduced, a detailed analysis will be required.

The detailed assessment identifies that, generally, an explosion can be ruled out, except in the situation of a fire in the warehouse.

The warehouse does not have sprinkler system and will, essentially, rely on a response from the local fire service to extinguish a fire. The fire brigade response time is confirmed by the emergency responders to be 15 minutes.

The frequency of a major fire in the warehouse is estimated at 1 x 10^{-4} per year and a minor fire at 1 x 10^{-3} per year (refer to *Guidance on technical land use planning advice* document).

A minor fire in the vicinity is postulated to have a low probability of leading to an explosive event, while, for a major fire, the likelihood of a fire engulfing this material and causing an explosion is higher. Therefore it is assumed that 10% of minor fires and 50% of major fires could result in an explosion.

This puts the explosion frequency at:

$$R_{af} = (1 \times 10^{-3} \times 0.1) + (1 \times 10^{-4} \times 0.5) = 1.5 \times 10^{-4}\ per\ year \quad (1)$$

Fatal overpressures from such an explosion would be experienced within a 50 m radius. Emergency responders as well as site personnel would be at risk.

The explosion frequencies are per year, but the site operates for 60 hours (five 12 hour days) per week only. Site personnel will therefore be present for a maximum of:

$$60 \div (7 \times 24) = 0.36 \quad (2)$$

of the time.

The maximum risk to any employee from the explosion is put at:

$$R_{af} = 1.5 \times 10^{-4} \times 0.36 = 5.4 \times 10^{-5}\ per\ year \ (3)$$

The operator presents a case to the CCA that the risks are ALARP.

The CCA notes the risk is close to the intolerable line (10^{-4}) of the ALARP zone and that only the risk related to the explosion has been presented and not the total major hazard risk to the most exposed employee. It also notes that ATMs have not been identified, even though some obvious measures (installing a sprinkler system, putting the material in a separate building) are worthy of consideration. Further assessment of the risk and the application of additional technical measures to reduce that risk will be required.

The documentation presented to the CCA does not address the societal risk level. In the event of fire, the fire brigade personnel would almost certainly be present and fighting the fire at the time an explosion could occur.

The explosion frequency is:

$$R_{af} = 1.5 \times 10^{-4}\ per\ year \ (4)$$

(see above – it is assumed a fire could break out at any time, not just when site is normally occupied.)

If 6 fire personnel were present (and assuming no operatives present), the number of fatalities, given a fatal fraction of 0.83 (using the Probit equation from the *Guidance on technical land use planning advice* document and a modelled overpressure of 193 kPa) would be expected to be 5.

Since the Expectation Value (EV) -

$$EV_A = \Delta R_{cpm} \times N = 150 \times 5 = 750 \ (5)$$

exceeds the threshold of 450 (see appendix 2), there are also societal risk concerns.

Therefore the operator will be required by the CCA to have a competent person carry out a cost benefit analysis to establish if additional technical measures are reasonably practicable and to provide a more detailed societal risk assessment that includes an FN curve.

Environmental Risk

The CCA would also be concerned that the site lacks the retention capability for contaminated firewater runoff. The frequency of a major fire event is estimated at 1 x 10^{-4} per year and a substantial quantity of contaminated firewater would be generated. Therefore a MATTE source

exists. A stream runs near the plant and sensitive receptors are considered likely to be present. It is considered likely that in a fire event, a significant amount of firewater would reach the important receptors.

Based on CDOIF methodology, this would be considered to be a MATTE of consequence type C. This is the only scenario at the establishment that could give rise to a MATTE of this severity). According to the table (Box 7 in appendix 2 of this document), the frequency (per receptor per year) of this event is deemed intolerable if it exceeds 1 $x10^{-4}$ per year, which is uncomfortably close to the major fire risk for this site. The CCA therefore would also require the operator to provide a fuller environmental risk assessment and consideration of additional technical measures.

The risk levels do not extend offsite in this case, but if they did a referral to the planning authority under Regulation 24(5) would also be necessary.

9.4 Example 4: Inventory increase at a fuel terminal

Modification

A fuel storage terminal stores 12,000 m^3 Class I Petroleum, 13,000 m^3 Class III and 56,000 m^3 Class II petroleum. It intends to double its Class I storage. This will also result in a doubling of the daily throughput of road tankers, from 100 to 200.

Analysis

The operator had previously notified the CCA of the storage of 12,000 m^3 Class I Petroleum in a tank of nominal capacity 24,000 m^3. Filling above the 12,000m^3 level was reliably prevented through the implementation of a safety instrumented function complying with EN 61511.

The operator carried out a preliminary analysis and decided the change wasn't significant.

During a subsequent routine COMAH inspection, the inspector queried the change log (appendix 3) that recorded the change as 'not significant'.

As the relevant loss of containment frequencies in the *Guidance on technical land use planning advice* document are per tank, and there has been no increase in the number of tanks, the risk of a loss of containment from a tank has not increased.

However, in the event of a catastrophic loss of containment, a much greater quantity of Class I Petroleum would now overtop the bund.

Therefore the operator should have carried out a detailed assessment.

The operator was advised by a technical consultant that the risk of a VCE related to the storage tank remained unchanged. However the risk in the tanker loading bay had doubled, because the number of Class I truck movements had doubled.

Also, a much larger pool fire outside the bund would now be possible. The fatal consequence zone would increase.

Therefore a detailed analysis should have been undertaken and the risk to onsite personnel calculated.

There would also be a possibility of a significant proportion of the overtopping fraction leaving the establishment and affecting the sensitive estuarine environment - this should have been considered.

The inspector prohibits the storage above the original notified quantity and requires the operator to notify a significant modification and supply the necessary documents for assessment.

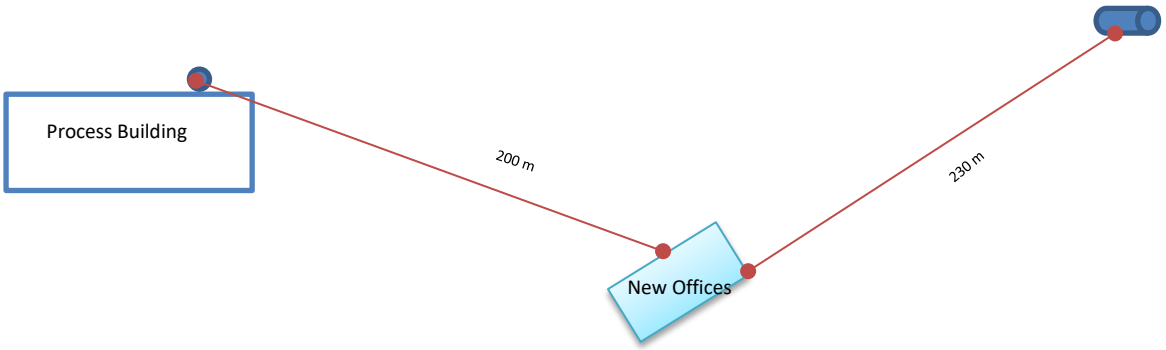
9.5 Example 5: New office building

Modification

A pharmachem site intends to construct a new office building within the establishment. The new building will be in the vicinity of a process building and a pressurised flammable gas storage location.

Analysis

The proposed office building is intended to accommodate 70 employees and its location in relation to major accident sources is shown in the diagram below (NTS).



On the face of it, placing 70 people in this area increases the consequences of a major accident (more people affected).

Two relevant major accident sources were identified from previous HAZOP and LOPA studies – the release of the toxic gas Chlorine (while feeding a chemical reaction in the process building) and a BLEVE from a vessel containing 20 tonnes of a pressurised flammable gas (process hazard upsets originating in the process building were found not to exceed the specified thresholds at the proposed location).

Toxic gas exposure scenarios

The new office building is proposed to be 200m from the potential release point. The endpoint of interest is 1% fatality (as per appendix 2 of this document). The TNO 1999 Probit (from the *Guidance on technical land use planning advice*) is used. This suggests a 30 minute exposure to 71 ppm will lead to 1% fatalities.

In the detailed analysis, the frequencies of these 'loss of containment' events are determined. For the gas release, the operator refers to the *Guidance on technical land use planning advice*. This gives a series of release scenarios with appropriate associated release rates, tied to the number of drum movements. The number of drum movements is uncertain. As that section also allows the use of loss of containment frequencies from the Purple Book, the operator decides to follow that approach.

The Purple Book events to be modelled include instantaneous, 10 minute and 10mm releases from the pressurised drum and a full-bore and 10% leak from the 75mm connecting pipe to the process building.

D5 weather/Stability is considered to be 80%, while F2 is 20%. The results are summarised in the table:

Event	LOC freq/yr	Exposure duration	D5 ppm	F2 ppm	D5 %Fat	F2 %Fat	Risk
G2 Instantaneous	5×10^{-7}	2 min	2,200	4,000	81	96	0.083×10^{-6}
G2 Continuos	5×10^{-7}	6 min	700	1400	50	83	0.0566×10^{-6}
G3 10mm hole	1×10^{-5}	30 min	5	20	0	0	0
Pipe (3m, 75mm) 100% D	3×10^{-6}	30 min	105	200	3	18	0.06×10^{-6}
Pipe (3m, 75mm) 10% D	1.5×10^{-5}	30 min	0	10	0	0	0

The risk at the proposed office block from this hazard is therefore 0.199×10^{-6}.

Thermal radiation exposure scenario

For the pressurised flammable gas, the thermal radiation from a BLEVE is short-lived (12 seconds). The predicted thermal radiation of 15.4 Kw/m^2 exceeds the threshold of 6.8 Kw/m^2 (see Box 2 of Appendix 2) and therefore the operator correctly decides that a more detailed analysis is necessary.

For a vessel containing 20 tonne of a pressurised flammable gas, a BLEVE frequency (refer to *Guidance on technical land use planning advice*) of 1×10^{-5} per vessel per year is advised.

However, the exposure to 15.4 Kw/m^2 for the fireball duration of 12 seconds (using the Eisenberg Probit from the *Guidance on technical land use planning advice*), which would only follow a prolonged fire, will not result in > 1% fatality at a distance of 230m. The risk of fatality is therefore estimated to be below 1×10^{-7} per year.

Conclusion

From the above, the operator establishes that the risk at the proposed office block location is in the 'broadly acceptable' region.

The operator completes section 1 of the form (appendix 2) and sends it to the CCA.

Comment

At the projected level of thermal radiation, the building will not catch fire and therefore those within would not be materially affected.

The predicted thermal radiation level is below the threshold for ignition of wood (refer to *Guidance on technical land use planning advice*). However, it is above the heat flux for piloted ignition of wood and also exceeds the technical specification for standard cladding under the building regulations. The operator should consider increasing the specification for cladding on the side facing to withstand 18KW/m^2.

The operator should assess the overpressure effects of a BLEVE. Calculations show this to be ~3.15 kPa. From the *Guidance on technical land use planning advice*, this can be expected to lead to window damage, with potential for consequences to those within. The operator should review the level of fenestration on the side of the building facing the tank, to reduce this risk.

Appendix 1 – COMAH Regulations 12 and 24

Regulation 12 Modification of an installation, establishment or storage facility

12. (1) An operator shall review and where necessary update—

(a) the notification under Regulation 8;

(b) the MAPP and safety management system under Regulation 10; and

(c) the safety report under Regulation 11;

prior to the modification of an installation, establishment, storage facility, or process or of the nature or physical form or quantity of dangerous substances which could have significant consequences for major accident hazards, or could result in a lower-tier establishment becoming an upper-tier establishment or vice versa.

(2) Whenever an operator carries out a review referred to in paragraph (1), the operator shall inform the Central Competent Authority of the details of any update arising thereunder in advance of any such modification and in sufficient time to allow the Central Competent Authority to carry out its functions under Regulation 24.

Regulation 24 Technical advice on land-use planning

24. (1) The Central Competent Authority shall, on receiving a notification under Regulation 8, advise a planning authority of a consultation distance for that establishment, if it is within the planning authority's functional area or could affect its functional area, and the Central Competent Authority shall periodically review this advice and update it as necessary.

(2) The Central Competent Authority shall provide technical advice in response to a notice sent by a planning authority under Part 11 of the Planning and Development Regulations 2001 (S.I. No. 600 of 2001), requesting technical advice on the effects of a proposed development on the risk or consequences of a major accident in relation to the following types of developments within the consultation distance notified in paragraph (1)—

(a) the siting and development of new establishments;

(b) modifications to establishments of the type described in Regulation 12(1);

(c) new developments including transport routes, locations of public use and residential areas in the vicinity of establishments, where the siting, modifications or developments may be the source of, or increase the risk or consequences of, a major accident.

(3) The technical advice provided by the Central Competent Authority to a planning authority pursuant to paragraph (2) may be generic or case specific in nature and shall be so formulated that it will assist the planning authority to take into account the need, in the long term—

(a) to maintain appropriate safety distances between establishments covered by these Regulations and residential areas, buildings and areas of public use, recreational areas, and, as far as possible, major transport routes;

(b) to protect areas of particular natural sensitivity or interest in the vicinity of establishments, where appropriate through appropriate safety distances or other relevant measures; and

(c) for the operator to take additional technical measures, in the case of existing establishments, in accordance with Regulation 7, so as not to increase the risks to human health and the environment.

(4) In the case of existing establishments, the Central Competent Authority shall review proposed modifications of the type described in Regulation 12(1), which do not constitute development as defined in section 3 of the Planning and Development Act, to determine whether additional technical measures consistent with the operator's duties under Regulation 7 should be taken, so that such modifications will not increase the risks to human health and the environment.

(5) If, in the opinion of the Central Competent Authority, a proposed modification reviewed under paragraph (4) is considered to be a significant change it shall be referred by the Central Competent Authority, with relevant technical advice, to the relevant planning authority under section 5(1) or section 5(4) of the Planning and Development Act, for a declaration as to whether the proposed modification is or is not development or is or is not exempted development within the meaning of that Act.

(6) Where the Central Competent Authority informs the operator pursuant to paragraph (4) that the proposed modification shall not proceed until the specified additional technical measures are taken by the operator, the operator shall not carry out the modification unless the said specified measures are put in place.

(7) Where the Central Competent Authority informs the operator pursuant to paragraph (5) that the proposed modification shall be referred to the relevant planning authority, the operator shall not carry out the modification unless either a declaration is obtained that the proposed modification is not development, or is exempted development in which case paragraph (8) applies, or planning permission is obtained in respect of the proposed modification.

(8) Where the planning authority issues a declaration under section 5 of the Planning and Development Act that a proposed modification referred to it under paragraph (5) is not development, or is exempted development, then it shall be dealt with by the Central Competent Authority under paragraph (4).

(9) The Central Competent Authority shall provide the technical advice referred to in paragraph (2) within four weeks of receiving a request from a planning authority.

(10) Without prejudice to paragraph (9), where the Central Competent Authority requires additional information in order to provide the requested technical advice to the planning authority under paragraph (2), the following shall apply—

(a) the Central Competent Authority shall request the information from the planning authority within two weeks of the receipt of the request for technical advice;

(b) the planning authority shall provide the additional information requested by the Central Competent Authority, if necessary after requesting it from the applicant;

(c) the Central Competent Authority shall provide technical advice to the planning authority within four weeks of receiving the requested information.

(11) Operators of establishments shall provide sufficient information to the Central Competent Authority as part of the notification in Regulation 8 or an update under Regulation 12(2), and at any time at the request of the Central Competent Authority, on the risks arising from an establishment, necessary for the fulfilment of the Authority's functions under this Regulation, and in particular to ensure that technical advice on those risks for land-use planning purposes is available.

(12) Where the Central Competent Authority or a planning authority becomes aware, in the exercise of their functions under these Regulations or under the Planning and Development Act and the Planning and

Development Regulations 2001, of the possibility of a major accident with transboundary effects originating in an upper-tier establishment, it shall provide sufficient information to the competent authorities that have responsibility for the preparation and implementation of external emergency plans in respect of such establishments in the potentially affected other Member State so as to permit the latter to ensure that all relevant provisions contained in Articles 12 and 13 of the Directive can, where applicable, be applied by those authorities.

Appendix 2 - Significant Modification Assessment Procedure

1. *Significant Modification*

Under the COMAH Regulations 2015, an operator is required to consider, at the conceptual stage, whether a modification, of the type listed below, could have significant consequences for major accident hazards:

Box 1: Types of modification to be considered by an operator

A modification to:

- an establishment (*the whole area under the control of the operator where dangerous substances are present in one or more installations*);
- an installation (*a technical unit within an establishment where dangerous substances are produced, used, handled or stored*);
- a storage facility;
- a process;
- the nature or physical form or quantity of dangerous substances.

2. *Preliminary Consequence Analysis*

A robust consequence analysis should be carried out on proposed modifications falling into those categories. This initial assessment is to determine whether the modification will increase the current consequences of the major accident hazards at or outside the establishment.

The hazards that should be considered are those arising from:

- fire,
- energy release / explosion,
- toxic release

and their consequent effects on human health and the environment. The consequence endpoints to be used for this assessment are:

Box 2: Consequence Endpoints

Hazard	*Consequence*	*Endpoint to be used*
Fire	Thermal Radiation	To 6.8 KW/m2
Explosion	Overpressure	To 168 mbar[1]
Toxic Release	Fatality	Threshold of fatality –1%- using a probit from Guidance on technical land use planning advice document[2].
Fire/explosion/toxic release	Environmental Damage	Increase in number of receptors affected or more severely affected or more likely to be affected.

[1] For persons outdoor: people inside a building may actually be **more vulnerable** if building damage occurs.
[2] People indoors will typically be exposed to lower concentrations than those outside.

The preliminary assessment should examine the major accident potential of the proposed modification, before any additional preventive or protective measures have been considered. The relevant endpoints in box 2 are taken from the HSA's Guidance on technical land use planning document[3].

The operator may have to update the Hazid/Risk Assessment on foot of this initial assessment. It should be clear at this point whether at least some of the relevant documents will have to be updated (even if the modification is ultimately deemed not to be significant).

Box 3: Relevant documents that may require update prior to a modification

- notification under Regulation 8;
- MAPP and safety management system under Regulation 10;
- safety report under Regulation 11.

If the initial assessment suggests that the distance at which consequences (endpoints listed in box 2) could be experienced will increase, then a detailed analysis is expected.

If the consequence distance would not increase as a result of the modification, but the consequences are intensified (more receptors affected or affected to a greater extent or are more likely to be affected) then this could also constitute a significant modification and detailed analysis will be expected.

3. *Detailed Analysis*

a. *Introduction*

If it becomes clear from the preliminary analysis that the proposed modification has the potential to be significant, then it must be evaluated in more detail. This is referred to as *detailed analysis*. At this point the modification is considered to be potentially significant and Regulation 12 applies.

Some of the questions to be answered at this stage include:

Box 4: Second stage analysis of a modification

- Are more persons now likely to be affected (how many) or affected for a longer period (how long)?
- Is more of the environment likely to be affected (how much) or affected for a longer period (how long)?
- Are more persons or the environment now at increased risk?
- Broadly, how much more likely is it that the major accident will happen?
- Broadly, how much greater is the risk to receptors?

[3] Guidance on technical land use planning

In planning for a modification, an operator should always apply good practice: application of good practice will be the starting point for deciding whether all the necessary measures for the prevention and mitigation of major accidents, required by Regulation 7, are being taken. For environmental hazards, good practice can be obtained from published sources, including relevant guidance or from BAT reference documents (BREFs) and the associated BAT conclusions (BATC) documents.

If it is established that there are potentially significant consequences from the proposed modification, then the operator should address additional relevant measures and their implementation, so as to prevent and mitigate those consequences and minimise the risk. The general principles of prevention[4] give a good hierarchical approach to this:

Box 5: The General Principles of Prevention

1. The avoidance of risks.
2. The evaluation of unavoidable risks.
3. The combating of risks at source.
4. The adaptation of work to the individual, especially as regards the design of places of work, the choice of work equipment and the choice of systems of work, with a view, in particular, to alleviating monotonous work and work at a predetermined work rate and to reducing the effect of this work on health.
5. The adaptation of the place of work to technical progress.
6. The replacement of dangerous articles, substances or systems of work by safe or less dangerous articles, substances or systems of work.
7. The giving of priority to collective protective measures over individual protective measures.
8. The development of an adequate prevention policy in relation to safety, health and welfare at work, which takes account of technology, organisation of work, working conditions, social factors and the influence of factors related to the working environment.
9. The giving of appropriate training and instructions to employees.

If an operator proposes not to implement the best available options, a case should be prepared to justify such an approach.

Operators should respect the spirit of their Major Accident Prevention Policy and the requirement to **ensure a high level of protection of human health and the environment** and their commitment to **continuously improve the control of major accident hazards** (Regulation 10(3)): the prevention and mitigation measures proposed should reflect those duties.

Regulation 24 (3)(c) requires the CCA to review proposed modifications to assess whether additional technical measures consistent with the Regulation 7 obligations should be taken, so that the modifications will not increase the risks to human health and the environment.

[4] See Schedule 3 of the Safety Health & Welfare at Work Act 2005

Additional Technical Measures (ATMs) are not defined in the Regulations. However they are measures additional to current good practice (which include procedural and administrative measures) and are 'technical' in nature. The JRC's land-use planning guidelines[5] (in Part A, Section 6) provide a definition of additional technical measures in the context of Article 12 (covering the land-use planning aspects of the Directive) as:

'measures that reduce the likelihood and/or mitigate the consequences of a major accident as effective as the establishing of a distance to the relevant vulnerable recipient; this involves consideration of whether there are measures at or outside the establishment in addition to those already in place'.

Typically ATMs will involve additional 'layers of protection' or 'lines of defence', whose reliability can be quantified to a level that allows an informed assessment to be made.

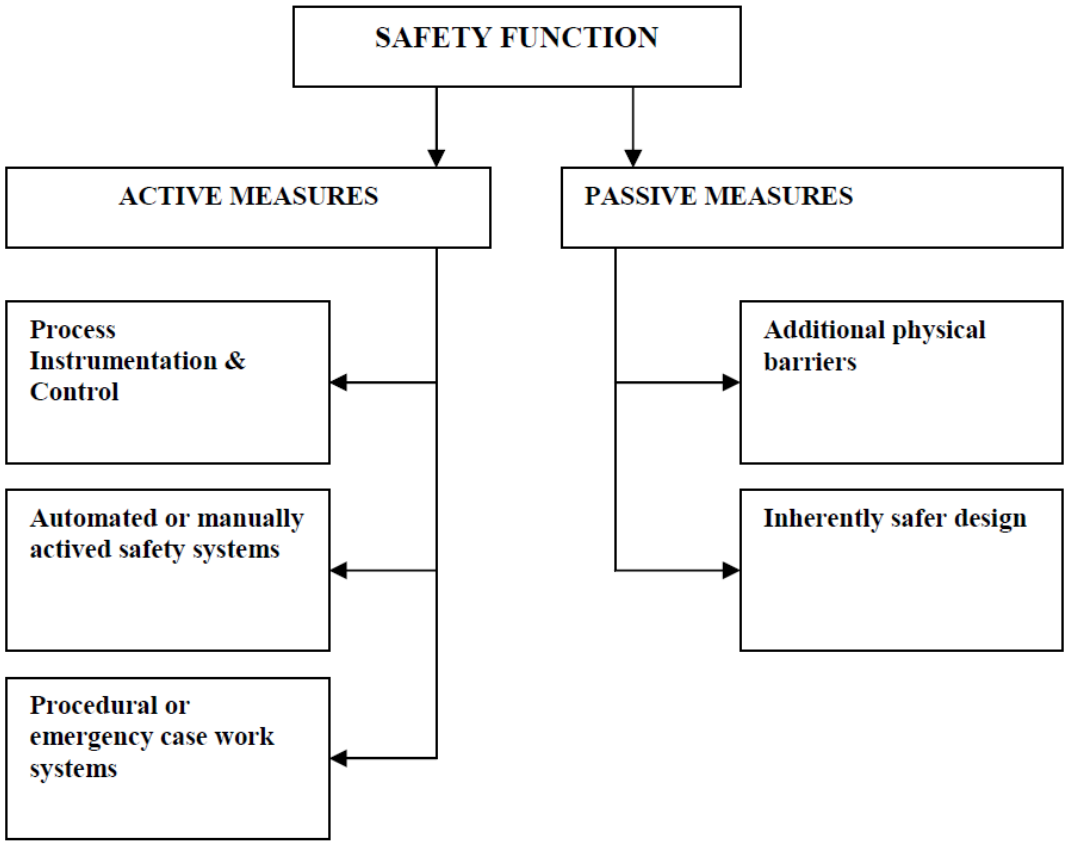


Figure 7: Active and passive measures for risk reduction and emergency response[6]

The following sections will set out in more detail

- the way in which on-site and off-site human health and the environmental risks and proposed prevention and mitigation measures should be addressed in the documentation submitted to the CCA and
- how the CCA will go about its assessment.

[5] Land Use Planning Guidelines in the Context of Directives 96/82/EC and 105/2003/EC, JRC 2008

[6] From 'Overview of Roadmaps For Land-Use Planning In Selected Member States', JRC 2008, ISSN 1018-5593

b. On-site Risk Analysis

As it has already been established in the preliminary analysis that there are significant consequences from the proposed modification, some quantification of the additional risk will now be necessary.

In analysing a change in onsite risk, as part of the detailed analysis, the following questions will provide a useful starting point:

Box 6: Significant onsite risk analysis (stage 2)

- Has the loss of containment (including energy loss) event become more likely as a result of the modification?
- How many additional people are affected by the increased consequence?
- To what extent are they affected?
- How much has the risk (fatality) been increased to those people?
- Has the environmental risk increased?
- What additional receptors are potentially affected?
- To what extent are they affected?
- Has the extent, severity or duration rating moved up a band (if using the CDOIF[7] methodology)?

Major hazard risks to employees are additional to the normal industrial risks and should be kept as low as reasonably practicable. Ideally, any modification should improve the safety of employees and be in accordance with the principles the operator has committed to in the MAPP (to ensure a high level of protection of human health and the environment and to continuously improve the control of major accident hazards). Where there is a potential for a risk increase, it should be avoided or, at the very least, kept to a minimum.

Where there is a potential for a risk increase, the existing level of risk and the new level of risk are both relevant.

The Guidance on technical land use planning advice document provides relevant loss of containment frequencies and appropriate modelling parameters for the analysis. These should be used in establishing the risk level before and after the modification – for the onsite risk element, it will be only be necessary to do this in the area of the establishment affected by the increase in risk, where people may be present (so this will exclude bunds, for example).

The case presented in the documentation submitted to the CCA in relation to the proposed modification will be assessed by the CCA as follows:

- If the overall predicted major accident fatality risk in an affected location is greater than 1 x 10^{-4} per year after a modification, then the CCA will not permit the modification (although on-site fatality risk of 1 x 10^{-3} per year is considered just tolerable within the ALARP framework on existing risk, the CCA policy is that, in keeping with the spirit of the MAPP and

[7] Chemical and Downstream Oil Industries Forum publication : *Guideline on Environmental Tolerability for COMAH Establishments*, v2.0

Article 11 of the Directive and the requirement to continuously improve the control of major accident hazards, significant modifications leading to overall increased[8] on-site risk above the 10^{-4} level will not be permitted).

- If, following the modification, the overall fatality risk to employees in an affected location is greater than 1 x 10^{-6} per year and less than 1 x 10^{-4} per year (including where the existing risk falls within this range), then the operator will be required to carry out and document a cost benefit analysis in relation to the provision of additional technical measures, for consideration and approval by the CCA. Potential ATMs should be identified. A cost benefit analysis (CBA)[9] should be undertaken where it is not intended to implement any identified ATMs and a robust case should be presented to the CCA. Where a significant number of people are subject to this level of risk, some societal risk evaluation will be necessary.
- If the overall on-site fatality risk following the modification is less than 1 x 10^{-6} per year then no action is necessary and the CCA will, after confirmatory review, allow the modification to proceed without any further requirements.

Independent of the above criteria, the following also applies:

- If the risk of a MATTE on-site exceeds an intolerable level[10] (this is thought to be very unlikely based on current range of establishments) in the table below (taken from the CDOIF) then it will not be permitted, whereas if it is in the tolerable region it will be permitted. Where it is between these values (tolerable if ALARP) a CBA will be required.

Box 7: Environmental Criteria (Frequency per receptor per establishment per year)		
MATTE Type	*Intolerable: Risk >*	*Broadly Acceptable. Risk <*
A	1 x 10^{-2}	1 x 10^{-4}
B	1 x 10^{-3}	1 x 10^{-5}
C	1 x 10-4	1 x 10^{-6}
D	1 x 10^{-5}	1 x 10^{-7}

For the cost benefit analysis (CBA) the second-stage risk figures should be used. The cost of the ATM should be set out and the benefits of implementing the measure (fewer fatalities, less damage to environment[11]) should be set against the cost. If the costs of the ATM are not grossly disproportionate then the measure should be implemented. An example of a CBA can be found here: https://www.hse.gov.uk/managing/theory/index.htm

The CCA will assess correctly submitted documentation and respond within 4 weeks.

[8] A reduction in risk from the existing status within the 10^{-3} to 10^{-4} band will, of course, be permitted.
[9] Example of CBA : https://www.hse.gov.uk/managing/theory/index.htm
[10] The environmental risk framework described here is assessed independently of the overall risk to people criteria and zonal advice system that is set out in the Guidance on technical land use planning advice).
[11] See Guidance on assessing and costing environmental liabilities, EPA 2014.

c. *Off-site risk Analysis*

As well as requiring the approval of the CCA, significant modifications that increase the off-site risk may also have to be referred by the CCA to the planning authority with appropriate technical advice[12], in line with the requirements of Article 15 of the Directive.

Relevant questions to be considered at this stage:

Box 8: Significant off-site risk analysis (stage 2)

- What is the increase in the hazard consequence off-site?
- Has the location-based risk level increased (as estimated by the methodology in the Guidance on technical land use planning advice document)?
- If so, by how much?
- What ATMs have been considered?
- What level of risk reduction has been obtained through the use of ATMs?
- What ATMs have been rejected and why have they been rejected?

A cost benefit analysis should be undertaken, identifying ATMs that could prevent or reduce the risk and a robust case should be presented where it is intended not to implement identified ATMs.

The case presented in the documentation submitted to the CCA in relation to the proposed modification will be assessed by the CCA as follows:

- If, following the proposed modification, the location-based fatality risk level outside the establishment (or outside any adjacent uninhabited land in the ownership and control of the operator) is below the 1 x 10^{-6} per year level and the increased expectation value is not above 450 (see Annex 1 of this Appendix for background to these figures), or the risk of MATTE is estimated to be in the 'broadly acceptable' range, then the modification will be allowed to proceed by the CCA and will not be referred to the planning authority.
- If the off-site risk level will be above the 1 x 10^{-6} per year level but below the level 5 x 10^{-6} per year level and the increased risk will affect only industrial activities in the vicinity and the increased expectation value will not be above 450 (allowing for industrial patterns of attendance), then the change will be permitted by the CCA and will not be referred to the planning authority.
- If, following the proposed modification, the off-site location based risk increase will be above the 1 x 10^{-6} per year fatality level or the expectation value will be greater than 450, or the risk of MATTE will be in the 'tolerable if ALARP' range, then the Authority will consider such modifications 'significant' and will engage with the operator under Regulation 24(4) to determine whether additional technical measures can be implemented that would bring the risk below those levels.

If the risk is above the 1 x 10^{-6} per year level or the expectation value increase is above 450 and if no technical measures can be identified (and implemented under the third bullet point above) so as to

[12] Appropriate technical advice is described in the Guidance on technical land use planning advice document

reduce the risk to an acceptable level, or if the ATMs evaluated by CBA cannot to be justified, then the CCA will refer it to the planning authority as a 'significant' modification.

If the risk of MATTE is in the 'intolerable' range then the CCA will refer it to the planning authority as a 'significant' modification.

The referral to the planning authority is necessary because Article 15 of the Directive applies in such situations. The CCA will provide technical advice in line with the *Guidance on technical land use planning advice* document (where environmental receptors are involved, the CDOIF methodology and risk criteria will apply). The final decision will lie with the planning authority.

4. Identification and Assessment of Additional Technical Measures

The implementation of identified technical measures may eliminate any additional consequence or increased risk identified in the detailed analysis stage, so the operator must explicitly consider whether additional technical measures (ATMs) could be implemented, such that there would be no increase in consequence or risk arising from the modification.

If the outcome of that consideration is that there are ATMs that will eliminate or reduce the increased risk and /or consequences and if the operator intends to implement them, then the proposed modification will no longer fall into the 'significant' category. The relevant documents must still be updated and forward to the CCA in advance so that it may perform the necessary assessment to confirm this.

If the outcome of that consideration is that ATMs are not justified, then the anticipated increase in risk will have to be evaluated, both to on-site and off-site human and environmental receptors and the relevant documents will have to be updated and sent to the CCA well in advance of the proposed modification.

Because ATMs may, in some situations, relate to the use of alternative locations, substances or processes, the operator must make the ATM assessment well in advance of a modification and submit it to the CCA before irrevocable decisions have been made.

5. Tier Change

Notwithstanding the above, if an operator proposes to change inventory to such an extent that the establishment will move from lower-tier to upper-tier status, then this modification type in itself will be considered to be 'significant' under Regulation 12 and the relevant documents must be created/modified and submitted to the CCA in advance of proceeding with the modification and the CCA will refer it to the planning authority.

Inventory change not leading to a tier-change could constitute a significant modification and should be considered as described in the preceding sections.

6. Permission from the CCA

Under Regulation 12, significant modifications must be notified in advance to the CCA accompanied by relevant supporting documentation and, under Regulation 24(6), the operator may only proceed if the specified ATMs are put in place.

Where a modification is referred to a planning authority, the modification may not proceed until permission has been received from the planning authority or, if the referral has been declined by the planning authority, the CCA.

Annex 1 –Minimum Risk in the LUP Referral Context

Minimum or insignificant risk is the risk associated with a modification that will not require referral to a planning authority under paragraphs 4 and 5 of Regulation 24. Exceedance of this risk level will be the trigger for public participation under the Directive's Article 15 and the point at which referral to the planning authority will be appropriate. The technical advice the CCA provides to a planning authority will be in accordance with the *Guidance on technical land use planning advice* document.

Minimum (insignificant) Risk

The legal doctrine of '*de minimis non curat lex*' (the law does not concern itself with trifles)[1] by which a court will refuse to consider trivial matters is frequently abbreviated to the '*de minimis*' level of risk.

In this context, it is the level of off-site risk above which a significant modification under Regulation 12 of the COMAH Regulations would require referral[2] to planning authorities and below which modifications could be appropriately addressed by the CCA.

The 'de minimis' level of risk to human health in the significant modification context

Fatality statistics are conventionally expressed in annual risk of fatality per million of population per year. They can also be expressed in terms of lifetime risk.

In the COMAH planning context, risk must be looked at over the lifetime of the potentially affected persons, so lifetime risk is an appropriate risk metric.

Lifetime risk is the annual risk of fatality multiplied by the projected number of years of life.

A lifetime can, in this context, be taken as 80 years.

So lifetime risk is:

$$Annual\ fatality\ rate\ per\ million\ per\ year\ *\ 80\ =\ Lifetime\ risk\ per\ million \qquad (1)$$

Literature sources[3] suggest that a lifetime risk level of ~ 1 x 10^{-4} or one in 10,000 (equivalent to **100 in a million**) meets the *de minimis* level of insignificant risk, in comparison to the other risks that are faced by the general population.

[1] Narrowing the Range: A Framework for Risk Regulators, Byrd & Lave, Issues in Science and Technology, 3, 4, 92-100.
[2] The Guidance on technical land use planning advice document sets out the basis for technical advice to planning authorities to inform their decision making; this paper sets out the risk levels at which the CCA determines a significant modification should be referred to the planning authority so that they may make that decision.
[3] Criteria for Establishing De Minimis Levels of Radionuclides and Hazardous Chemicals in the Environment, David C. Kocher, U.S. Department of Energy, 1996

To put this in context, such a risk level is slightly greater than the lifetime risk of being struck by lightning[4] (because significant modifications are expected to have both economic and social benefits, a slightly higher risk level is considered tolerable).

For comparison with other common risks, there were 196[5] fatalities from road traffic collisions in Ireland in 2014. For a population of 4.95 million, this equates to 40 fatalities per million per year[6]).

How does this translate to lifetime risk from road traffic collisions?

From Equation (1), it is the fatality rate per million per year multiplied by the number of lifetime years, so it is

$$40 \times 80 = 3{,}200\ per\ million (= 1\ in\ 312.5)$$

which is considerably greater than the *de minimis* level of 1 in 10,000 suggested above.

By rearranging equation (1) it is possible to find the annual level of risk associated with the *de minimis* lifetime level:

$$Annual\ fatality\ rate\ per\ million\ per\ year\ =\ Lifetime\ risk\ per\ million/80 \qquad (2)$$

which means it is 100 per million divided by 80:

$$100 \div 80 = 1.25\ per\ million\ per\ year\ fatality\ risk$$

The HSA Guidance on technical land use planning advice document[7] sets out the context and mechanism by which LUP advice is developed by the CCA in relation to off-site development. It sets out a zoned system of technical LUP advice, based on three fatality risk bands:

Box 1: LUP fatality risk levels

- Risk greater than 1 x 10^{-5} per year
- Risk between 1 x 10^{-6} and 1 x 10^{-5} per year
- Risk between 1 x 10^{-7} and 1 x 10^{-6} per year

For consistency with this approach, the *de minimis fatality risk* level is set at 1 x 10^{-6} per year, as calculated using the approach set out in the *Guidance on technical land use planning advice* document.

Under the current *Guidance on technical land use planning advice document*, the only developments that would be advised against at *de minimis* risk levels (if referred to the CCA for technical advice by a planning authority) are institutional accommodation or very large outdoor use by the public (see also section on societal risk evaluation, below).

[4] http://www.lightningsafety.noaa.gov/odds.shtml
[5] http://www.rsa.ie/en/Utility/News/2014/ROAD-DEATHS-RISE-FOR-SECOND-CONSECUTIVE-YEAR/
[6] At the time of writing, fatalities for 2018 were reported as having reduced to 150: ~ 31 per million per year.
[7] Guidance on technical land use planning

The risk consideration used here is of location-based individual risk – under the LUP document framework, an individual does not even have to be present to calculate this, but as the risk level will affect the type of permitted development at the affected offsite location in the future (and therefore any persons that will be within those developments in the future), it is considered to be an appropriate metric for this purpose.

Multiple Modifications

An operator may seek to make multiple modifications (subject to the requirements of Regulation 7) over time. Provided the risk level off-site remains below the *de minimis* fatality level of 1 x 10^{-6} per year and subject to the societal risk evaluation outlined below, then such changes would be permitted by the CCA without referral to a planning authority.

Multiple Receptors – Societal Risk

How should the number of people affected by increased risk be taken into account?

What should be the societal risk trigger point for the CCA in deciding that the Directive's Article 15 provisions should apply?

Societal risk is influenced by population and reflects the increased number of deaths that are possible as a result of a major accident, as the potentially affected population increases, along with society's aversion to multiple fatality events. It is also clear that society's aversion is greater when vulnerable populations are affected, so this should also be reflected in the societal risk evaluation.

Expectation Value (EV) is one of the simpler measures of societal risk[8]. Broadly, it is the product of the individual level of risk – expressed in this context as chances per million - and the number of people affected. It is also sometimes referred to as the 'potential loss of life' or PLL.

The expectation value under the lower criterion line of the FN curve from N = 1 to N = 100 is approximately 450 and an increase of this order will trigger a requirement for a more detailed societal risk evaluation by the operator in the form of an FN curve: evaluation of that curve will determine whether the CCA will refer the modification to the planning authority.

Modifications increasing the Expectation Value by 450 will require a more detailed assessment by the operator.

The expectation value does not reflect aversion to large casualty events or the events affecting sensitive populations. The CCA will also weigh up these factors when considering proposed modifications and when advising planning authorities.

Example

100 people could be affected by a fatality risk of 1 x 10^{-6} per year subsequent to a modification.

So the EV_A increase would be:

$$EV_A = \Delta R_{cpm} \times N = 1 \times 100 = 100$$

[8] Section 1.7 of the Guidance on technical land use planning addresses societal risk in more detail.

This would not exceed the criterion value increase of 450 and would not require more detailed analysis.

50 people could be affected by a fatality risk of 1 x 10^{-5} per year subsequent to a modification.

So the EV_A increase would be:

$$EV_A = \Delta R_{cpm} \times N = 5 \times 100 = 500$$

This would exceed the criterion value increase of 450 and would require further analysis and evaluation and could be referred to the planning authority.

Technical Advice in Referred Cases

The technical advice the CCA will provide on referral to the planning authorities will be in line with the Guidance on technical land use planning advice document (currently it would be 'not against' for most types of development in these example circumstances) but it would allow those potentially affected, as well as the general public, to participate in the process, as required by Article 15 of the Directive.

The threshold values set out above indicate the upper limits of modification-associated risk that will be addressed by the CCA. Where the values are greater, the modifications will be referred to the planning authorities with recommendations in line with the Guidance on technical land use planning advice document.

Appendix 3 – Log for a modification requiring preliminary analysis only

This form should be completed and retained by the operator.

A modification to:

[*details of installation / facility / process / nature or physical form or quantity of a dangerous substance …*]

at our establishment:

[*establishment details…*].

was the subject of a preliminary analysis on: [*dd/mm/yyyy*]

Following the analysis, using the approach outlined in the CCA's *Guidance on Significant Modifications under the COMAH Regulations*, it was determined that, in relation to on and off-site major hazard risk:

- *the risk would be below 1 x 10^{-6} per year fatality level following the modification* ✓ ☐

and/or

- *the environmental risk of a MATTE would be in the broadly acceptable region.* ✓ ☐

The supporting documentation will be held on site with this log, available for inspection, for a period of 3 years. ✓ ☐

Appendix 4 – Communicating risk analysis to CCA

Form to be completed following conclusion of detailed analysis on a proposed modification and sent to the CCA in advance of making the modification

Section 1 - Risk is broadly acceptable: on and off-site risk less than $1x10^{-6}$ per year without application of additional technical measures (ATMs) ✓ ☐		
[Enter risk value on-site]		
[Enter risk value off-site]		
Further ATMs are **not** required ✓ ☐		
Section 2 – Onsite risk is in the tolerable range of $1x10^{-4}$ to $1x10^{-6}$ per year (including following implementation of ATMs). ✓ ☐		
Individual on-site risk	[Enter risk values before ATMs]	[Enter risk values after ATMs]
Societal Risk	[Enter increased Expectation Value]	
Were ATMs were required to achieve this?	Yes ✓ ☐	No ✓ ☐
	[Enter brief summary of ATMs:]	
	Attach full detail of ATMs, demonstration that risk is ALARP, justification of non-implementation of ATMs – CBA etc.	
Environmental Risk	[Enter environmental risk category]	
Section 3 – Onsite risk is greater than $1x10^{-4}$ per year ✓ ☐		
Individual on-site risk	[Enter risk values before ATMs]	[Enter risk values after ATMs]
Societal risk	[Enter increased Expectation Value]	
Additional Technical Measures	[Provide summary of ATMs implemented and those considered and not implemented]	
	Attach full detail of ATMs, justification of non-implementation of ATMs – CBA etc.	
Environmental Risk	[Enter environmental risk category]	
Section 4 – Offsite risk greater than $1x10^{-6}$ per year and/or EV increase >450 ✓ ☐		
Individual off-site risk	[Enter risk values before ATMs]	[Enter risk values after ATMs]
Societal Risk	[Enter increased Expectation Value]	
Additional Technical Measures	[Provide summary of ATMs implemented and those considered and not implemented]	
	Attach full detail of ATMs, justification of non-implementation of ATMs – CBA etc.	
Environmental Risk	[Enter environmental risk category]	

Appendix 5 – Layers of Protection Analysis, Individual Risk & QRA

LOPA

This technique is comprehensively described in *Layer of Protection Analysis: Simplified Process Risk Assessment* (2001) published by the American Institute of Chemical Engineer's Centre for Chemical Process Safety and is further elaborated on in *Guidelines for Enabling Conditions and Conditional Modifiers in Layers of Protection Analysis* (2013) and *Guidelines for Initiating event Guidelines for Initiating Events and Independent Protection Layers in Layer of Protection Analysis* (2015) from the same source.

LOPA is described in the introduction to the 2015 publication as a 'simplified quantitative tool for analysing and assessing risk'. Order of magnitude categories are employed for initiating event frequencies, consequence severities and the probability of failure of independent protection layers.

The technique is applied to single cause-consequence pairs for a specified consequence, which are assessed successively. It seeks to establish that the layers of protection in place are sufficient to meet the establishment's own tolerable risk threshold.

That threshold is often established in the knowledge that there are several cause-consequence pairs within a process contributing to a specified consequence and risk in a particular location and indeed, that there may be several processes contributing to the overall risk. Setting the threshold at a suitably conservative level allows a degree of comfort in deciding that the overall risk level will be tolerable.

As noted in section 1.2 of CCPS (2013), there are pertinent variations to the basic methodology, where greater resolution can be obtained.

It is expected that establishments that have carried out LOPA's on their existing processes will perform a LOPA on any altered or new process (as a significant modification) and therefore will be able to use those analyses to demonstrate that the overall risk is ALARP. In the absence of a LOPA, or in more complex situations, more elaborate methods will be required to demonstrate this.

Individual risk

The individual risk at a particular location is primarily a function of the frequency of the event occurring and the probability of a fatality from that event, taking into account all of the scenarios that could cause a fatality at that location i.e.:

$$\sum F_i \times P_{OFi} \times P_{pp}$$

Where
F_i = Frequency of event (yr^{-1})
P_{OFi} = Probability of fatality (fractional) from that event.
P_{pp} = Probabilty person present (fractional) for that event

Widely accepted Individual Risk Criteria relate to the frequency of ALL initiating events of major accident scenarios that contribute to the risk of the people in an affected area. For complex sites or processes, this may require the summation of risks from a large number of scenarios before a determination can be made on whether a threshold is exceeded and it can be difficult to judge the tolerability of risk from a particular modification. It is often more convenient to 'allocate' a proportion of the risk criteria to the scenario under consideration, against which the risks can be assessed.

The simplest way to achieve this is to estimate the total number of scenarios that contribute to the individual risk of the personnel in the affected area and divide the risk criteria by that number to define a scenario based risk criterion.

Approach to QRA/FTA

Initially, in carrying out a quantified risk assessment, the frequency figures, modelling parameters and consequence endpoints of the *Guidance on technical land use planning advice* document should be used. When a more detailed analysis (QRA - Quantified Risk Analysis - or FTA - Fault Tree Analysis - for example) is required, then loss of containment frequency figures from reputable sources (BEVI[9] or FRED[10] for example) may be used, provided they are applied in a consistent way and respect the modelling parameters and endpoints associated with the use of those sources (including within the related modelling software).

[9] Reference Manual Bevi Risk Assessments: http://infonorma.gencat.cat/pdf/AG_AQR_2_Bevi_V3_2_01-07-2009.pdf
[10] Failure Rates for use within risk assessments: http://www.hse.gov.uk/landuseplanning/failure-rates.pdf

Appendix 6 – Flow Chart description of process (individual risk)