HID'S APPROACH TO 'AS LOW AS REASONABLY PRACTICABLE' (ALARP) DECISIONS - (SPC/PERMISSIONING/09)

PURPOSE

This note summarises the approach that HID expects inspectors to take when making case-specific decisions on whether risks are as low as reasonably practicable (ALARP) during assessment of safety cases/reports (or other formal documents) or enforcing compliance with the law. This note does not cover the normal management arrangements (adequate supervision, peer review, etc.) that are in place to ensure that the approach is properly implemented.

BACKGROUND

1. Hazardous Installations Directorate's (HID's) approach to ALARP decisions mirrors that explained in "Reducing Risks, Protecting People (R2P2); HSE's decision-making process" and "Principles and Guidelines to assist HSE in its judgements that duty holders have reduced risks as low as reasonably practicable".
2. R2P2 emphasises that people increasingly rely upon regulators like HSC/E as a source of reassurance about the arrangements put in place by duty holders for protecting people. If that trust is not to be threatened, HID must properly discharge its function to ensure that duty holders have put in place all necessary measures to prevent major accidents and limit their consequences.
3. HID's approach to ensuring compliance with the requirements of the permissioning regimes within its remit needs to be fully consistent with the Governments Enforcement Concordat as amplified in HSC's enforcement policy statement.
4. HID's approach to ALARP decisions needs1[1] to ensure that all staff involved in case-specific ALARP decisions:
    a. have a clear understanding of the interpretation of ALARP (including any cost and proportionality issues); and
    b. accept and share HSE's approach to these matters.

INTERPRETATION OF THE LEGAL BASIS OF ALARP JUDGEMENTS

5. Generic guidance on the legal basis for making ALARP judgements is given in the HSE principles and guidelines document. The main points are:
    a. Reducing risks 'so far as is reasonably practicable' (SFAIRP) or 'as low as is reasonably practicable' (ALARP) call for the same tests to be applied. It follows that when risks are SFAIRP they are also ALARP.
    b. It is the risk posed by reasonably foreseeable hazardous events from the duty holders' work activities to **employees and others not in their employ** that have to be addressed.
    c. On the basis of case law, ALARP decisions require an assessment of the **risk** that might be avoided;

i. an assessment of the **sacrifice** (in money, time and trouble) involved in taking further measures to avoid that risk;

ii. the **benefits** derived from those further measures (in terms of fatalities, etc. avoided); and

iii. a **comparison** of the two relative to the baseline **risk**.

The **sacrifice** (normally expressed in monetary terms) is that needed to implement additional measures to reduce risks. **Benefits** gained by duty holders (eg reduced plant replacement costs) should be offset against costs. The **comparison** is between the net sacrifice and the benefits of risk reduction (lives saved, reduced costs of the emergency services etc). The assessment needs to be proportionate (see sector specific guidance for further information on proportionality).

d. For a measure to be not reasonably practicable the degree of disproportion between costs and benefits must be gross ie the **test of gross disproportion**. The HSE ALARP guidelines states that in all cases 'the disproportion must always be gross' but does not define what is gross. However, it suggests an examination of what was done in comparable circumstances may be useful in coming to a view.

e. Both **individual risk** and **societal risk** (or societal concern in certain, well defined circumstances; (see Annex) should be considered when applying the test of gross disproportion. Individual Risk should be addressed in terms of hypothetical people at greatest risk. For onshore activities, this includes people off-site. Societal concern arises when an accident with adverse socio-political consequences occurs eg the Ladbroke Grove incident (30 fatalities) which resulted in a public inquiry, raised concerns about the performance of the rail industry and the regulator and lead to major cost and staffing repercussions for HSE. However, only societal risk should be taken into account when making the comparison for a particular ALARP

demonstration. The other elements of societal concern are taken into account when developing the regulatory framework.

f. If a measure results in a **transfer of risk** to other people, the added risk to those people should be offset against the benefits the measures provide. For example, reducing the inventory of a hazardous substance by "just-in-time" delivery in road tankers rather than storage on site may be a transfer of risk. The added risk to those on the transportation route must be considered when making the ALARP decision but only to the extent over which the duty holder exercises control.

g. **Relaxation** of control measures will be exceptional, eg when new evidence shows that a substance is far less toxic than originally thought or when there is a significant reduction of the number of people at risk.

h. Inspectors should ensure that **relevant good practice** is in place. This can be found in Approved Codes of Practice (AcoPs), HSE guidance, recognised standards, and industry practice appropriate to the duty holders' activities. This is the minimum compliance standard. Good practice may not exist for, or be relevant to, some hazards that are regulated through safety case regimes or may exist but be of insufficient scope to fully meet the ALARP standard e.g. for onshore industries, most guidance does not adequately deal with risks to the public.

i. Where good practice fully meets the ALARP requirements, the duty-holder is relieved of the need (but not the legal duty) to take explicit account of individual risk, costs, technical feasibility and the acceptability of residual risk, since these will have been considered when the good practice was established. The duty holder has to demonstrate that the good practice is relevant and up-to-date.

j. There is a continuing duty for duty holders to keep risks and possible risk reduction measures under review to take account of changing circumstances, advances in technology, new knowledge and information. Good practice may change over time; **new technology** may make a higher standard reasonably practicable. Application of the ALARP principle means challenging the adequacy of existing measures and considering any additional identified practicable measures.

k. When a number of **options for risk reduction** exist all options, or combination of options, that are reasonably practicable must be implemented. The legal requirement to reduce risks as low as is reasonably practicable rules out HSE accepting a less protected but significantly cheaper option. At the design stage a life-cycle approach should be adopted. (ALARP in Design – Policy and Guidance)

l. Evaluation of each of the different options, or combination of options, available for controlling a particular hazard should be made against the **same baseline case**.

m. It may not be reasonably practicable to **retrospectively apply a measure** to an existing plant, that would be required to reduce risks ALARP for a new plant (even if that measure has become, in effect, good practice for every new plant). Whether the measure can be applied, or not, will depend on the site-specific circumstances, the risk levels, and whether the costs of the measure are grossly disproportionate.

MAKING ALARP JUDGEMENTS

6. HSE is only concerned with the risks to people although we should be mindful that measures intended to reduce risks to people may conflict with the need to reduce risks to the environment. For the risks to people to be reduced ALARP all necessary measures must be in place. HID will assess this by scrutinising the duty holders conclusions that:

    i. the risks to workers – Health and Safety at Work (HSW) Act S2 risks – are ALARP; and

    ii. the risks to people not in their employ – HSW Act S3 risks – are ALARP.

7. Some duty holders may regard this as a new approach, but it is not; being inherent in the 1974 Health and Safety at Work Act.

JUDGING WHETHER RISKS TO PEOPLE ARE ALARP

8. Under the legislation specific to HID, as for the HSW Act, it is for duty holders to demonstrate that the necessary measures are in place to reduce risks ALARP, and for HID to assess that demonstration and/or verify through inspection that duty holders are complying with their legal obligations. How duty holders make the demonstration is for them to decide, but clearly they, at least, need to address the arguments that are outlined in HSE's approach (see R2P2, particularly Part 3) to decision taking in respect of tolerability of risk.

9. HID will therefore expect that:

    i. both the level of individual risk and the societal risks created by the activity or process are taken into account – in a proportionate way - when deciding whether a risk is unacceptable, broadly acceptable, or tolerable if ALARP;

    ii. the decision-making process and criteria adopted by duty holders are such that action taken is inherently precautionary, i.e. when the degree of uncertainty is large or the consequences of the worst-case scenario give rise to significant societal risks, measures that are "prima-facie reasonable" should be implemented.

10. In the interests of transparency and consistency, HID Inspectors should consider HSW Act S2 and S3 risks separately (if appropriate) and proportionately. However, the approach for S2 and S3 risks is identical:

    i. First consider the site-specific circumstances and decide whether the implementation of relevant good practice makes the risks ALARP; if so implementation of those requirements and those of COMAH (MAPP etc) will suffice.

    ii. When good practice is insufficient to make the risks ALARP, duty holders must consider all risk reduction options, and implement all

those that are reasonably practicable or are necessary to reduce risks to a broadly acceptable level. Demonstrations that the costs of implementation are grossly disproportionate must be proportionate and consider both individual risk and societal concerns.

11. If neither HID nor the operator can identify further prima-facie **risk reduction measures**, over and above the measures described in the duty holders demonstrations, then the risks are ALARP. Views on options for risk reduction measures are a team effort; face-to-face discussions with the duty holder are required whenever the societal risks are appreciable.

JUDGING GROSS DISPROPORTION

12. HSE has not provided any specific guidance, but the disproportion must be gross for all possible options. Consistent and proportionate judgements can be supported by the **R2P2 TOR framework** (see R2P2 paragraphs 118 et seq.) by considering individual and societal risks separately. If either consideration indicates that a risk reduction option is reasonably practicable it must be implemented. The **judgement on gross disproportion** must be a collective one by the assessment team (AT) in the case of safety case/report assessment or by the Inspection team in the case of enforcement action.

13. Consideration of costs and benefits requires estimates of the likelihood and consequences of particular accidents. Both estimates involve uncertainty, which in the case of event frequency may be an order of magnitude or more. Many decisions can be made by exercising professional judgement based on estimates of the costs of a measure and the number of casualties saved by implementation, possibly informed by a crude cost benefit analysis (CBA).

14. R2P2 (paragraphs 101-108 and Annex 3), discusses CBA and the estimation of the cost of preventing a fatality (CPF, i.e. the total final cost of the risk reduction measure divided by the total fatalities prevented). By comparing this with the value of preventing a fatality (VPF, ~£1m) an estimate of the **proportion factor** i.e. CPF/VPF can be made (this should not be confused with **proportionality** which relates to depth of assessment, etc.). When the proportion factor is 1 or less (or even 2 or less)1[2] the measure must be implemented, even when the risks are close to being broadly acceptable. Judgement on whether the proportion factor is grossly disproportionate depends on the levels of individual and societal risks (and possibly the societal concern in certain circumstances). Inspectors should also consider the significance of uncertainties in the calculation of CPF.

15. Providing the risk analysis is based on cautious best estimates and the costs are realistic (not needlessly inflated beyond the provision of a fit for purpose solution), HID will use the following as the **basis for exercising judgement:**

    a. The proportion factor is at least 1 (and possibly at least 2) for risks which are close to being broadly acceptable risks.

    b. The proportion factor is at least 10 at the tolerable/unacceptable risk boundary.

    c. For risks between these levels the proportion factor is a matter of professional judgement, but the disproportion between CPF and VPF must always be gross for a measure not to be reasonably practical.

16. HID will (see Principles and Guidlelines document, paragraph 34) attach more weight to consequences where a hazard has attributes which makes it likely that it will give rise to societal risks, such as the potential for severe detriment,

eg a major explosion in a built-up area. Other factors such as vulnerable groups where societal concerns have previously been expressed will also be considered as appropriate. For example, for Land Division sites, the number of children and elderly persons likely to be affected, and the presence of hospitals and schools may be an input to the ALARP decision.

17. HID will expect **new technology** to be implemented in line with HSC/E policy on harnessing new technology, unless gross disproportion can be demonstrated unequivocally (see R2P2, text box after paragraph 118).

18. The precautionary principle (see R2P2 paragraph 91) will be invoked where:

    i. there is good reason, based on empirical evidence or plausible causal hypothesis, to believe that serious harm and societal risk might occur, even if the likelihood of harm is remote; and

    ii. the scientific information gathered during the risk assessment is sufficiently uncertain (see R2P2 paragraphs 86 et seq.) to make it impossible to confidently rule out a particular measure by CBA considerations.

19. HID expect that the vast majority of decisions can be made relatively quickly once a safety case/report or other form of demonstration has been assessed. Risk reduction measures that are judged prima facie reasonable should be discussed with the duty holder and the way forward agreed. HID expects inspectors to take a "firm but fair" line to ensure that HID and HSC/E policy on enforcing what is required by the regulations is not compromised.

20. A significant shift in societal concern following the accident or the recommendations from a public inquiry could have financial consequences for HID regulated activities because measures which were deemed grossly disproportionate before the accident may no longer be considered to be so after the accident. An example may be the requirement to mound certain Liquefied Petroleum Gas (LPG) tanks where passive protection might previously have been considered adequate. A second example might be a requirement for dedicated stand-by vessels for offshore platforms where previously these had been shared between a number of installations.

FURTHER INFORMATION

For further information, please contact HID CD2.4 (0151 951 3411).

ANNEX

SOCIETAL CONCERN AND SOCIETAL RISK

(Adapted from R2P2, see paras. 25-27 and 134-136)

1. Societal concern is often associated with hazards that give rise to risks which, were they to materialise, could provoke a socio-political response, eg risk of events causing widespread or large scale detriment or the occurrence of multiple fatalities in a single event1[3]. Typical examples relate to large chemical plants, nuclear power generation, railway travel, or the genetic modification of organisms.

2. Duty holders' action on societal concern is limited (see paragraph 7 of R2P2) to instituting the measures set out by HSC/E in the control regimes which are required by regulations enacted to address the hazard concerned, and in associated guidance. Societal concern is addressed by ensuring that societal

risks are ALARP or broadly acceptable. This requires due weight to be given to societal concern when deciding whether the costs of further risk reduction are grossly disproportionate or not.

3. Hazards giving rise to societal concerns share a number of common features. They often give rise to risks which could cause multiple fatalities; where it is difficult for people to estimate intuitively the actual threat; where exposure involves vulnerable groups, eg children; where the risks and benefits tend to be unevenly distributed - for example between groups of people with the result that some people bear more of the risks and others less, or through time so that less risk may be borne now and more by some future generation. People are more averse to those risks and in such cases are therefore more likely to insist on stringent Government regulation. The opposite is true for hazards that are familiar, often taken voluntarily for a benefit, and individual in their impact. These do not as a rule give rise to societal concerns.

4. In addition to the direct societal concerns about the impact of the hazards on those affected, there is also, and importantly, a concern that, in the wake of an event giving rise to such concerns, confidence in the provisions and arrangements in place for protecting people against risks to health and safety, and the institutions responsible for setting out and enforcing these provisions and arrangements, would be undermined, however remote was the chance of the event happening in the first place. The result would be a consequential loss of trust by the public not only in the duty holders with the primary responsibility for reducing the risk, but also in the regulator and Government - even if current provisions and arrangements were very good.

5. HID attaches more weight to consequences where a hazard has attributes which makes it likely that it will give rise to societal risks, such as the potential for severe detriment, eg a major explosion in a built-up area. Gauging the extent of the societal risks caused by such a hazard is likely to be a major consideration when deciding whether the costs of risk reduction are grossly disproportionate or not.

6. When making comparisons with previous decisions on gross disproportion at a site, Inspectors need to consider whether changes are warranted and, if so, what. For example, levels of protection that were considered at the time to be good practice may no longer be regarded as such as a result of new knowledge, advances in technology or changes in the level of societal concerns.

7. Developing criteria on tolerability of risks for hazards giving rise to societal concerns is difficult. Hazards giving rise to such concerns often involve a wide range of events with a range of possible outcomes. Estimating the 'cost' of the detriment may call for the attribution of weighting factors for which, at present, no generally agreed values exist as, for example, the death of a child as opposed to an elderly person, dying from a dreaded cause, eg cancer, or the fear of affecting future generations in an irreversible way.

8. Nevertheless, HID has adopted the criteria below (see R2P2 paragraph 136) for addressing societal concerns arising when there is a risk of multiple fatalities occurring in one single event. These were developed through the use of so-called FN-curves (obtained by plotting the N). frequency at which such events might kill N or more people, against The technique provides a useful means of comparing the impact profiles of man-made accidents with the equivalent profiles for natural disasters with which society has to live. The method is not without its drawbacks but in the absence of much else it has proved a helpful tool if used sensibly1[4]. Moreover, the criteria are based on

an examination of the levels of risk that society was prepared to tolerate from a major accident affecting the population surrounding the industrial installations at Canvey Island on the Thames. Reports on the risk from the installations at Canvey Island were discussed in Parliament, and (after improvements) the risk was deemed by Ministers to be just tolerable. The limit was subsequently endorsed by the HSC's Advisory Committee on Dangerous Substances in the context of major hazards transport1[5]. These criteria are, however, directly applicable only to risks from major industrial installations.

9. Thus, where societal concerns arise because of the risk of multiple fatalities occurring in one event from a single major industrial activity1[6], HID proposes the following 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.

10. When several sites contribute to the **local societal risk**, the unacceptable region will be taken as an order of magnitude above the corresponding line for case societal risk.

1[1] See Civil Service Commission recommendations on the BG Armada safety case

1[2] Bear in mind that the disproportion must always be gross, 2 may not be significantly different from 1 when uncertainty is considered.

1[3]Societal risk results from the occurrence of multiple fatalities in a single event. **Societal concern** includes other issues as well as the numbers affected. Societal risk is therefore a subset of societal concerns.

1[4]For a review of the merits and disadvantages of FN curves - see Ball D. J. and Floyd P J (1998), Societal risks. Report available from the Risk Policy Unit, HSE1.

1[5]HSC, Advisory Committee on Dangerous Substances, Major hazard aspects of the transport of dangerous substances, 1991, ISBN 0 11 885676 6.

1[6]Here a single major industrial activity means an industrial activity from which risk is assessed as a whole, such as all chemical manufacturing and storage units within the control of one company in one location or within a site boundary, a cross-country pipeline, or a railway line along which dangerous goods are transported.

PRINCIPLES AND GUIDELINES TO ASSIST HSE IN ITS JUDGEMENTS THAT DUTY-HOLDERS HAVE REDUCED RISK AS LOW AS REASONABLY PRACTICABLE

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Introduction

1. The Health and Safety Executive is responsible for making adequate arrangements for enforcement. In fulfillment of its duty the Executive provides guidance to its regulatory staff who have to judge whether measures put in place or proposed, by those who are under a duty to control and reduce risks "as low as is reasonably practicable" (ALARP), are acceptable.
2. The principles and guidelines set out below are based on what the Courts have decided is required of duty-holders, and are intended to help HSE regulatory staff reach decisions about the control of risks and make clear what they should expect from duty-holders.
3. Ultimately, it is for the Courts to decide whether or not duty-holders have complied with the law. However, HSE needs to have a coherent view of its own, consistent with relevant case law, as to what the law requires from duty-holders, both as a basis for any action it may wish to take and to provide guidance to staff on what they should expect from duty-holders.
4. This guidance for staff therefore sets out in plain terms what HSE believes the law requires of those who are under a duty to reduce risks as low as is reasonably practicable. It is not intended to cover all possible circumstances which might arise when these judgements are made, or usurp the fundamental role of individual inspectors of having to make professional judgements in particular circumstances. It aim is to give clarity to HSE's interpretation of the law and thus lead to consistent and transparent decision-making by HSE's staff.

'SFAIRP' and 'ALARP'

5. In terms of what they require of duty-holders, HSE considers that duties to ensure health and safety so far as is reasonably practicable ("SFAIRP") and duties to reduce risks as low as is reasonably practicable ("ALARP") call for the same set of tests to be applied. However, SFAIRP and ALARP are not always interchangeable because legal proceedings will have to employ (for example, in complaints or informations) the particular term cited in the relevant legislation.

What does HSE expect from duty-holders who have to reduce risks ALARP?
6. There is little guidance from the courts as to what reducing risks as low as is reasonably practicable means. The key case is Edwards v. The National Coal Board.1 In that case, the Court of Appeal considered whether or not it was reasonably practicable to make the roof and sides of a road in a mine secure. The Court of Appeal held that -

> , "... in every case, it is the risk that has to be weighed against the measures necessary to eliminate the risk. The greater the risk, no doubt, the less will be the weight to be given to the factor of cost."2

and

> "'Reasonably practicable' is a narrower term than 'physically possible' and seems to me to imply that a computation must be made by the owner in which the quantum of risk is placed on one scale and the sacrifice involved in the measures necessary for averting the risk (whether in money, time or trouble) 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 defendants discharge the onus on them."3

7.The Courts will look at all the relevant circumstances of the particular case when reaching decisions.

Determining that risk has been reduced ALARP
8 Thus, determining that risks have been reduced ALARP involves an assessment of the **risk** to be avoided, of the **sacrifice** (in money, time and trouble) involved in taking measures to avoid that risk, and a **comparison** of the two.
9 This process can involve varying degrees of rigour which will depend on the nature of the hazard, the extent of the risk and the control measures to be adopted. The more systematic the approach, the more rigorous and more transparent it is to the regulator and other interested parties. However, duty-holders (and the regulator) should not be overburdened if such rigour is not warranted. The greater the initial level of risk under consideration, the greater the degree of rigour HSE requires of the arguments purporting to show that those risks have been reduced ALARP.

Risk
10. The assessment of risk is confined to those matters with which the legislation in question is concerned. It is risks to health, safety and welfare that are covered by the Health and Safety at Work Act 1974,4 and its subordinate legislation such as the Management of Health and Safety at Work Regulations 1999.5
11. Other legislation for which HSE is responsible may include other risks, such as the Control of Major Accident Hazards Regulations 1999 (COMAH) which include environmental risks.6 Requirements for environmental protection may constrain the options available to duty-holders for controlling health and safety risks.7
12. The risks must be only those over which duty-holders can exercise control or mitigate the consequences through the conduct of their undertaking. Some risks arise from external events or circumstances over which the duty-holder has no control, but whose consequences duty-holder can mitigate. Such risks should be included in the assessment.
13. In any given workplace there would be a large number of hazards which duty-holders could address. However, requiring duty-holders formally to address them all would place an excessive and largely useless burden on them. So as not to impose

unnecessary burdens on duty-holders, HSE will not expect them to take account of hazards other than those which are a reasonably foreseeable cause of harm, taking account of reasonably foreseeable events and behaviour.8

14. The risk will be not only to the duty-holders' employees but may also affect other workers and members of the public, including the local community which would be affected by an accident or incident such as an explosion on site.

15. Risk should be assessed in relation to a hypothetical person,9 eg. the person most exposed to the hazard, or a person living at some fixed point or with some assumed pattern of life, such as a person who is in good health and works exactly forty hours a week with the hazard, or a child present continuously in a house sited at the closest point to a major hazard. To ensure that all significant risks for a particular hazard are covered, it may be necessary to construct a number of hypothetical persons, to cover the different populations exposed, such as 'a person who is in good health', 'young persons'.

16. The actual persons who are to be exposed to the risk will have to be considered when the control measures determined via risk assessment are applied in practice because these measures may need to be adapted to meet the particular abilities of these persons, for example, their ability to read instructions, or whether they are colour-blind.

17. Risks should be assessed in an integrated manner by duty-holders. It is important that duty-holders consider the 'full picture' when assessing risk and not a partial view from considering hazards in isolation, or in a slice of time, or location by location rather than across the whole system.

18. Location by location consideration of risks should however be carried out to determine whether, even if application of a control measure system-wide would be ruled out on the grounds of excessive costs, application is reasonably practicable in certain locations, such as those that present a particularly high risk and/or low cost.

Sacrifice

19. The sacrifice under consideration here is that which would be incurred by duty-holders as a consequence of their taking measures to avert or reduce the risks identified. In the Edwards case, Asquith LJ referred to the sacrifice in terms of money, time or trouble. These costs which should be considered are only those which are necessary and sufficient to implement the measures to reduce risk.

20. For any particular measure, these might include the cost of installation, operation, and maintenance, and the costs due to any consequent productivity losses resulting directly from the introduction of the measure (for example, a new guard may cause a machine to operate less efficiently).

21. Temporary shutdown costs incurred during implementation must be included since these clearly constitute part of the duty-holders' 'sacrifice'. HSE will expect duty-holders to take full advantage of opportunities to reduce shutdown costs to a minimum, such as implementing control measures during planned maintenance. It may be reasonably practicable to implement control measures during shutdown for planned maintenance, even though not to shut down solely to implement control measures.

22. Individual duty-holders' ability to afford a control measure or the financial viability of a particular project is not a legitimate factor in the assessment of its costs. HSE must present duty-holders with a level playing field. Thus HSE cannot take into account the size and financial position of the duty-holder when making judgements on whether risks have been reduced ALARP.

23. Benefits gained by duty-holders as a result of their instituting a health and safety measure should be offset against the costs they incur.

Comparison

24. The basis on which comparison is made is provided by the Edwards case: the test of '**gross disproportion**'. In any assessment as to whether risks have been reduced ALARP, measures to reduce risk can be ruled out only if the sacrifice involved in taking them would be grossly disproportionate to the benefits of the risk reduction.
25. That gross disproportion is required before a measure can be ruled out on the grounds of sacrifice can be interpreted as applying a bias on the side of safety. From the statement of Tucker LJ, that -

> "The greater the risk, no doubt, the less will be the weight to be given to the factor of cost",

we believe that the greater the risk, the more that should be spent in reducing it, and the greater the bias on the side of safety. This can be represented by a 'proportion factor', indicating the maximum level of sacrifice that can be borne without it being judged 'grossly disproportionate' -

$$\frac{\text{sacrifice}}{\text{benefits of risk reduction}}$$

26. Although there is no authoritative case law which considers the question, we believe it is right that the greater the risk: the higher the proportion may be before being considered 'gross'. But the disproportion must always be gross.
27. HSE has not formulated an algorithm which can be used to determine the proportion factor for a given level of risk. The extent of the bias must be argued in the light of all the circumstances. It may be possible to come to a view in particular circumstances by examining what factor has been applied in comparable circumstances elsewhere to that kind of hazard or in that particular industry.10
28. Taking greater account of the benefits as the risk increases also compensates to some extent for imprecision in the comparison of costs and the benefits. It again errs on the side of safety, since the consequences of the imprecision have greater impact, in terms of the degree of unanticipated death and injury, as the level of risk rises.11
29. In measuring the risk to be reduced, and the sacrifice involved in measures to achieve that reduction, the starting point should be the present situation. If there are several options, therefore, they should each be considered as against the present situation. (See paragraph 47 for further discussion on choosing between options.)
30. In some situations, it will not be possible to assess options in this way. For example, where an installation is being built, it will not be possible to separate the costs of risk reduction measures from the costs of building. In such situations, the starting point should be an option which is known to be reasonably practicable (such as one which represents existing good practice). Any other options should be considered as against that starting point, to determine whether further risk reduction measures are reasonably practicable.

Societal concerns

31. Societal concerns can arise when the realisation of a risk impacts on society as a whole. The impact may produce an adverse socio-political response (which has its origins in the public aversion to certain characteristics of the hazards concerned). The harm which results is a loss of confidence by society in the provisions and arrangements in place for protecting people and, consequently, a loss of trust in the regulator and duty-holders with respect to control of the particular hazard and hazards more generally.
32. This might arise where large numbers of people are killed at one time (which we call "societal risk"), where potential victims are particularly vulnerable (such as children), or where the nature of the risks inspire dread (such as long-term or irreversible effects).

33. There is no guidance from the courts as to whether societal concerns should be taken into account by duty holders in deciding what is grossly disproportionate. In deciding whether to propose regulations, or in setting enforcement priorities, HSC considers that risk and sacrifice must be assessed in its social context. As well as taking account of individual risk, HSC considers societal concerns.
34. We believe it is right that, in all cases, the judgment as to whether measures are grossly disproportionate should reflect societal risk, that is to say, large numbers of people (employees or the public) being killed at one go. This is because society has a greater aversion to an accident killing 10 people than to 10 accidents killing one person each.
35. Where HSC considers that duty-holders should take other societal concerns into account, Regulations, ACoPs or other HSE guidance will state *how* duty-holders should take such concerns into account and *what* those concerns are.

Transfer of risks
36. Introduction of a health and safety measure to control a hazard may transfer risk to other employees or members of the public.
37. If the transferred risk arises from the *same* hazard, then it should be offset against the benefit from the measure under consideration. For example, the introduction of mechanical exhaust ventilation may transfer the risk from the same hazard (fumes) from the employee to the general public as the fumes are pumped outside the workplace. The added risk to the public should be offset against the benefits the measure otherwise brings to employees.
38. If the transferred risk arises from a *different* hazard, it should be treated as a separate matter for which control measures must be introduced to reduce its risk ALARP. For example, providing scaffold fans to protect members of the public from being struck by objects dropped from the scaffold will transfer some of the risk from the public to the scaffolders involved in erecting the fans. Since a different hazard is involved (ie. scaffolders falling from a height), the fans should be provided to reduce the risks to the public ALARP, but at the same time, the duty holder must ensure that the risks of the scaffolders' working methods are reduced ALARP. However, if the risks from the health and safety measure to be introduced (in this example, scaffolding fans) when properly controlled are still greater than the risks which it is sought to prevent (injury to members of the public) when properly controlled, the measure should not be introduced.

Changed circumstances
39. Duty-holders may wish to alter the conditions in which equipment is operated or to relax or otherwise alter some or all control measures in response to changed circumstances. This is permissible provided that the altered control measures continue to ensure that risks are reduced ALARP.

Good practice
40. The determination of control measures forms part of the statutory risk assessment duty-holders are required to undertake. Such assessments involve duty-holders identifying the hazards in their workplace, determining who might be harmed and how; evaluating the risk from the hazards and deciding whether the existing control measures are sufficient or whether more should be done.
41. In reality, there is often only a limited number of options for dealing with a particular health and safety issue and the optimum option is in many cases likely to have been already established as relevant good practice accepted by HSE as reducing risks ALARP. Often HSE staff will be able to rely on authoritative documented sources of good practice, such as HSC ACoPs12 and HSE Guidance, on legal standards which require risks to be reduced ALARP.

42. HSE staff should ensure that duty-holders are using good practice which is appropriate to their activities, relevant to the risks from their undertaking, and covering all the risks from that undertaking. Such documents may only deal with some of the risks which the duty-holder must consider. Good practice which covers all the risks which a duty-holder must address in order to reduce risks ALARP may not be available, and this is particularly likely to be so for major investments in safety measures or where hazards are regulated through safety case regimes.
43. A universal practice in the industry may not necessarily be good practice or reduce risks ALARP. Duty holders should not assume that it is. HSE must keep its acceptance of good practice under review since it may cease to be relevant with the passage of time; new legislation may make it no longer acceptable; new technology may make a higher standard REASONABLY PRACTICABLE. Similarly HSE expects duty-holders to keep relevant good practice under review.
44. Probably the majority of judgements made by HSE involves it in comparing duty-holders' actual or proposed practice against RELEVANT GOOD PRACTICE. Relevant good practice provides duty-holders with generic advice for controlling the risk from a hazard. In so far as they can adopt relevant good practice, this relieves duty-holders of the need (but not the legal duty) to take explicit account of individual risk, costs, technical feasibility and the acceptability of residual risk, since these will also have been considered when the good practice was established.
45. In practice therefore, explicit evaluations of risk rarely need to be made in relation to day-to-day hazards. However, duty-holders have to make them where there is no relevant good practice establishing clearly what control measures are required.

Choosing between options
46. A selection amongst options may be needed at any stage of a particular project: at the design stage, involving choice between different design concepts for the whole project, and, as the project is developed, between more detailed options. In making these options, duty-holders must consider the risks involved in the whole life-cycle of a project.
47. At the design stage, where safety cases or plans are required to be submitted to HSE, HSE will assess the option which duty-holders put before it, but where that option does not reduce risks ALARP, HSE may reject a safety case, ask duty holders to consider a different option, or use its enforcement powers to prevent further work (depending on the situation in question). HSE will make its judgement as to whether the design presented to it reduces risks ALARP based on its knowledge as a regulator, including its knowledge of good practice in that area, and its knowledge of other possible design options. Where the option put forward does not reduce risks ALARP, HSE may intervene according to the situation in question - for example, to prevent further work or to inform the duty-holder of its opinion.
48. The *reason* for the design chosen will be a relevant factor in considering what it is reasonably practicable to do. Depending on the particular legal context and the circumstances in question, where the very essence or ethos of the business could not be achieved without following the design suggested, then HSE could not reject the option so as to prevent the undertaking proceeding. The question would be how to reduce the risks of that option ALARP. But such situations will be rare. In most cases, there will be several options for achieving the essence of the business in question.
49. At a more detailed level, HSE would consider judgements as to whether risks are or will be controlled ALARP as central to deciding between options, though again the reason for the option chosen may still be a relevant factor. For example, HSE may have to accept a process using intrinsically more dangerous components since only these components will provide the products essential to the duty-holder’s undertaking.

50. In practice, duty-holders may have a number of options where an assessment would show that costs are not grossly disproportionate. The option, or combination of options which achieves the lowest level of residual risk should be implemented, provided grossly disproportionate costs are not incurred. The legal requirement to reduce risks as **low** as is reasonably practicable rules out HSE accepting a less protected but significantly cheaper option.

New versus existing plant

51. It should be borne in mind that reducing the risks from an existing plant ALARP may still result in a level of residual risk which is higher than that which would be achieved by reducing the risks ALARP in a similar, new plant. Factors which could lead to this difference include the practicability of retrofitting a measure on an existing plant, the extra cost of retrofitting measures compared to designing them in on the new plant, the risks involved in installation of the retrofitted measure (which must be weighed against the benefits it provides after installation) and the projected lifetime of the existing plant.

52. All this may mean, for example, that it is not reasonably practicable to apply retrospectively to existing plant, what may be demanded by reducing risks ALARP for a new plant (and what may have become good practice for every new plant).

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1 [1949] 1 KB 704; [1949] 1 All ER 743.
2 Tucker LJ.
3 Asquith LJ.
4 The Court of Appeal, in R v. Board of Trustees of the Science Museum [1993] 3 All ER 853, held that the term “risk” in s.3, HSWA, means the possibility of danger rather than actual danger.
5 SI 1999/.
6 SI 1999/743. Reg. 4 requires “all necessary measures” to be taken to prevent major accidents and limit their consequences to persons and the environment. HSE regards this as equivalent to a requirement to reduce the risk of a major accident ALARP.
7 The relationship between health and safety and environmental legislation may depend on the terms of the particular legislation in question.
8 Whether a reasonably foreseeable, but unlikely, event - such as an earthquake - should be considered depends on the consequences for health and safety of such an event.
9 See Annex 1 to Reducing Risks, Protecting People for a fuller discussion.
10 A study has been undertaken by ESAU of proportion factors arising in HSE’s regulatory decisions: see RALG paper RALG/SEP00/10 (available from RAPU).
11 It should be noted, however, that the greatest uncertainties generally occur for the less likely but higher consequence events.
12 Approved Codes of Practice have a special status under s.17, HSWA, and therefore a special status as good practice. If it is proved that a duty-holder did not follow the relevant provisions of an ACoP, he will need to show that he complied with the law in some other way or he will be found in breach of the law on which the ACoP gives guidance.

Added to HSE website 13 December 2001
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Policy and Guidance on reducing risks as low as reasonably practicable in Design

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INTRODUCTION

1. HSE attaches particular importance to reducing risks to people as a result of appropriate consideration of health and safety in design. During the design stage, which covers concept selection through to detailed design specification (drawings, calculations, specifications, etc), there is the maximum potential for reducing risks, by application of the principles of inherently safer design.
2. This note gives guidance to HSE staff engaged in assessing designs and design concepts where it is a requirement that risks be reduced as low as reasonably practicable. It sets out HSE's policy and gives guidance on the procedures and principles to be used by staff in implementing that policy. It should be read in conjunction with the more general guidance in reference (1), the guidance on good practice in reference (2), and any more specific Directorate or Divisional guidance.
3. In this document, 'design' is taken to include:

- The design of items from equipment and systems through to complete facilities and installations, and
- The design of processes, e.g. different means of producing an end product.
- The mode of operation and the definition of operating parameters, e.g. safe limits of operation, and
- Consideration of human factors, including the man-machine interface - see reference (3) for more information

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POLICY

4. Reference (1) gives 'Principles and guidelines to assist HSE in its judgements that duty-holders have reduced risk as low as reasonably practicable'. These principles and guidelines apply equally to design, which should provide for safety throughout subsequent construction, commissioning, operation, maintenance and decommissioning.
5. HSE's intervention policy with respect to design is based on the following key principles:

1. It is for duty-holders to ensure that their chosen design or design concept reduces risks as low as reasonably practicable.
2. Inspectors may offer guidance to assist duty-holders. However, Inspectors will need to reach a judgement in specific cases as to whether duty-holders have met their legal obligations.
3. HSE should expect duty-holders to be able to provide evidence that demonstrates that a design reduces risks as low as reasonably practicable.
4. In certain situations, as a result of specific legislation, duty-holders must present a written, reasoned case for the safety of a facility or installation (including the design), and satisfy HSE that the case is satisfactory. This note should be read in conjunction with such legislation and any supporting documentation.
5. HSE involvement and intervention in considering a duty-holder's design proposals should be proportionate and risk-based, i.e. the effort spent should be in keeping with the risks which may arise from poor design.

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STRATEGY

6. HSE's overall strategy for ensuring compliance during design embodies an appropriate mix of the following activities:

1. Education of those involved in the design process such as designers, clients and other duty-holders, so as to improve the knowledge and safety culture within relevant stakeholders.
2. Promulgation of good design principles, such as those in Schedule 1 to the MHSW Regulations (4), in publications such as 'Successful health & safety - by design' (5) and 'Five steps to risk assessment' (6), and in numerous other documents.
3. Support to the development of codes, standards and guidance, to ensure that good practice is agreed for the generic use of repetitively-used items including components, equipment and discrete subsystems.
4. Regulation to require a written demonstration of a case for the safety (including the design) of a more complex facility or installation that consists of a number of interdependent systems or where there is the potential for a major accident or incident.
5. Targeted intervention in design processes, to ensure that relevant good practice is used and that facilities (particularly those of a complex nature) are subject to suitable and sufficient risk assessment.

7. Item 6a) is addressed through many promotional activities undertaken by HSE staff as well as specific initiatives such as Action point 34 in 'Revitalising health and safety' (7). This note deals primarily with items 6b) to e) above. Guidance on these items is given below.

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GUIDANCE

Good design principles

8. Schedule 1 to the MHSW Regulations identifies a number of good engineering principles that apply to design. It is good practice to apply these principles as a hierarchy (see also Ref 2), by aiming to eliminate a hazard in preference to controlling the hazard, and controlling the hazard in preference to providing personal protective equipment. In many cases, this hierarchy will automatically be realised if the duty-holder makes decisions which err on the side of safety and which take account of the integrity and effectiveness of various risk control measures. Other principles and hierarchies exist in specific regulations and guidance; these should be applied as appropriate.

9. An holistic approach is important in order to ensure that risk-reduction measures that are adopted to address one hazard do not disproportionately increase risks due to other hazards, or compromise the associated risk control measures. Where appropriate, consideration should also be given to the balance of risk between workers and the public, and to the increased risk due to action taken during normal operation which is intended to reduce risks during an emergency condition. Reference (1) gives general guidance regarding the transfer of risk.

Development of codes, standards and guidance

10. HSE aims to influence the development of appropriate codes, standards or guidance, through the provision of operational intelligence (from inspection and investigation) and expert advice. Reference (2) gives guidance on the link between recognised product standards, etc, and compliance.

Regulation of complex/high hazard facilities

11. Specific legislation requires HSE intervention at certain stages in the design of facilities or installations. These are described further in Directorate or Divisional guidance. The design of a complex/high hazard facility, whilst based on the adoption of appropriate good practice at component and system level, must also involve explicit consideration of the risks of the facility as a whole to both workforce and the public. This is because the integration of separate systems and subassemblies may increase the risks and further measures may be needed to reduces risks as low as reasonably practicable. The integration may also create opportunities for further reduction of risk.

Assessing compliance through intervention

12. As part of judging whether the proposed design will reduce risk to people as low as reasonably practicable, Inspectors will often examine a duty-holder's management system to see if it appears to be capable of delivering an appropriate design. This is a useful approach and can give confidence that the design will reduce risks as low as is reasonably practicable. However, a distinction is made here between the two aspects. Guidance on assessing whether risks have been reduced as low as reasonably practicable is given first. This is followed by guidance on

assessing a duty holder's management system, including optimum points for intervention and the types of evidence that can be sought.

Demonstrating that risks to people are as low as reasonably practicable

General

13. Reference (1) indicates that the majority of judgements made by HSE are likely to involve a comparison of duty-holders' actual or proposed practice against relevant good practice; reference (2) discusses good practice further. 'Relevant' in this case means it should be appropriate to the activity and the associated risks, and should be up to date.

14. It is acknowledged in reference (1) that good practice covering all relevant risks may not be available, e.g. for major investments in safety measures or where hazards are regulated through safety case regimes. In these cases, difficulties are particularly likely when choosing between different options during the early stages of design, as there may be little information available that can be used to evaluate risks. There may also be a variety of practices in use so that which of these constitutes good practice may be open to debate. In these cases, the duty holder's design should be examined using a combination of:

- what relevant agreed good practice does exist, and
- good design principles, as discussed earlier.

This process may also take account of societal concerns, where required to do so.

15. However, it is expected that a new facility or installation would not give rise to a risk level greater than that achieved by the best of existing practice for comparable functions. This statement reflects HSE's general expectation for improvement in standards over time, and therefore the particular need to keep relevant good practice under review and the possibility that a higher standard may be achievable in due course. Where certain duty holders are achieving a higher standard ('best practice'), it is reasonable to challenge other duty holders engaged in similar activities whether such a standard is now, in effect, good practice.

16. The following table shows how this can be applied in the design of new major hazard facilities and of significant modifications to them:

Project stage	**Elements in demonstration that risks are as low as is reasonably practicable**
Choosing between options or concepts	• Risk assessment and management according to good design principles • Demonstration that duty-holder's design safety principles meet legal requirements • Demonstration that chosen option is the lowest risk or justification if not • Comparison of option with best practice, and confirmation that residual risks are no greater than the best of existing installations for comparable functions. Risk considered over life of facility and all affected groups considered • Societal concerns met, if required to consider.
Detailed design	• Risk assessment and management according to good design principles • Risk considered over life of facility and all affected groups considered • Use of appropriate standards, codes, good practice etc. and any deviations justified • Identification of practicable risk reduction measures and their implementation unless demonstrated not reasonably practicable.

Further actions expected of duty-holders

17. Risk assessment - The MHSW Regulations (4) require that a suitable and sufficient assessment is made of risks to people, and other more specific legislation has similar requirements. Such assessment is clearly important in helping to guide decisions made during the design process. General guidance on 'suitable and sufficient' is given in the ACoP to the MHSW Regulations. A number of assessment techniques are available, and these can be useful in appropriate circumstances. For complex facilities or installations, duty-holders should consider using a range of techniques to gain confidence in their findings rather than relying on one

particular technique. Uncertainty should be recognised when using the results to inform decisions (e.g. by sensitivity analysis).

18. Optioneering - There is no explicit general duty to record the range of options that has been considered, although it is difficult to see how a duty-holder could show that risks are as low as reasonably practicable without making reference to other, discarded options. An effective approach for demonstrating that risks are as low as reasonably practicable is to start with the safest design option within the range of practicable solutions. This should be chosen by the duty holder unless they can show that this is not reasonably practicable; in which case attention should pass to the next safest option. The procedure is repeated until the lowest risk option is found which is reasonably practicable. This approach is particularly useful in identifying step changes in risk or sacrifice between the various options which will give a strong indication of the lowest risk option that is reasonably practicable.

19. Life cycle approach - The overall risk assessment and selection of options must have regard to the intended life cycle, including construction, commissioning, operation, maintenance, foreseeable modifications and eventual decommissioning or disposal. There is a duty in Section 6 of the HSW Act for 'any article for use at work', which applies 'at all times when it is being set, used cleaned or maintained'. Similar duties are required by certain specific regulations. Enforcement of these duties would need to take account of the foreseeability of the particular activity when carrying out design. It may be appropriate to 'trade-off' risks between different stages of the life cycle in order to obtain the safest solution overall.

Powers for intervention

20. Section 6 of the HSW Act allows intervention in the design of 'any article for use at work'. There may be facilities or installations which can not be considered as an 'article for use at work' and for which specific legislation does not require formal intervention during design. In such cases, intervention is justified by virtue of item paragraph 5(c) of the Policy described earlier using more general requirements (HSW Act and MHSW Regulations) as the legal basis. Although there may be no formal powers to halt the design if serious concerns arise in such a case, Inspectors should seek to persuade the duty-holder to consider the issues further by highlighting possible future enforcement problems when the facility is brought into use.

21. It should be noted that certain items of plant and equipment that are covered by European Article 95 (ex-100A) legislation are subject to Essential Health and Safety Requirements (EHSRs). These effectively define a maximum enforceable standard for a given item being used for a particular purpose. Inspectors can not expect a higher standard unless they can show that the application of the item is outside the scope of the EHSRs or that the EHSRs do not represent the current 'state of the art'. In the latter case, there are formal procedures which need to be followed to inform the European Commission about the deficiencies.

22. HSE Inspectors should be careful to explain the extent to which they are intervening in design. There may otherwise be an assumption by duty holders that HSE has given blanket approval to a design rather than consideration of a specific aspect.

23. When considering enforcement action in connection with design, the Enforcement Management Model framework should be followed. Directorate or Divisional guidance should assist in defining the risk gap and the authority of the appropriate standard(s).

Assessing duty holder's management systems for design

24. This section of guidance is intended to assist Inspectors when planning the extent and timing of intervention during design, although account should also be taken of all relevant aspects of the specific situation under consideration. Communicating any plan for intervention to duty-holders is encouraged.

25. The optimum points for intervention will depend on the nature of the article or equipment, the facility or installation being developed, and the past performance of the duty-holder. Inspectors should consider intervening when:

- early discussions are taking place about a possible development
- various options or concepts for the overall scheme have been reviewed and ranked
- alternatives within the detailed design of the chosen scheme have been considered
- further risk reduction measures are being considered for the completed detailed design
- construction or fabrication, assembly and commissioning are in progress, in order to check that the design philosophy is not being undermined

26. For major hazard facilities, the following table shows various stages of a new design or the design of significant modifications, with indications where intervention is likely to be appropriate and the aspects of the management systems which could be examined. This may also be appropriate for selective use when intervening in design in other areas.

Design stage	What to look for?	Basis for intervention
Prior to concept selection (at or before project sanction)	• Policy for safety in design • Criteria for concept selection (e.g. life cycle aspects considered) • Roles, responsibilities and competence of relevant personnel • Adequacy of health and safety advice	Sector specific - generally Advice.
Detailed design	As above, and: • Application of relevant and current good practice • Effective approval processes, including interaction with risk assessment • Application of formal and structured risk assessments and their effectiveness in reducing risks • Effective change control procedures • Development of appropriate information to enable safe operation, maintenance and repair	Sector specific legislation. Also: codes, standards and other good practice.
Construction	As above, and: • Effective material control • Effective quality control (e.g. leak testing, welding procedures) • Conformity to design	Sector-specific and general legislation (e.g. CDM). Also: codes, standards and other good practice.
Commissioning	As above, and: • Effective quality control (e.g. commissioning and testing procedures) • Effective recording of the 'as-built' condition	Sector-specific and general legislation. Also: good practice.

27. Directorates and Divisions may find it helpful to identify particular legislation that applies to the various stages of the design, as indicated in the third column of the table above.

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REFERENCES

(1) Principles and guidelines to assist HSE in its judgements that duty-holders have reduced risk as low as reasonably practicable. HSE internal draft.
(2) Assessing compliance with the law in individual cases and the use of good practice. HSE internal draft.
(3) Reducing error and influencing behaviour (HSG48). HSE Books
(4) Management of Health and Safety at Work Regulations 1999: Approved code of practice and guidance L21.
(5) Successful health & safety - by design. Guidance on the inherently healthier and safer approach to design [HSE document - in draft]
(6) Five steps to risk assessment. HSE leaflet INDG163(rev 1)
(7) Revitalising health and safety - Strategy statement - June 2000. Department of the Environment, Transport and the Regions.

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