Principles and guidelines for the spaceflight regulator in assessing ALARP and acceptable risk

1. Introduction

Before granting either a launch operator licence, return operator licence or spaceport licence, the spaceflight regulator must be satisfied that applicant has taken all reasonable steps to ensure the health and safety risks arising from their activities are as low as reasonably practicable (ALARP)¹. The applicant will make a demonstration of ALARP within the safety case required as part of the application process.

The regulator must also determine whether the residual risk is acceptable when considering the siting assessment for the spaceport² and the risks from the launch operator's spaceflight activities to persons who are not onboard the launch vehicle and their property³.

The aim of this guidance is to support consistent and transparent decision-making by the regulator's staff by setting out the principles that underpin the regulator's view on acceptable levels of residual risk, and providing guidelines on judging whether a licence applicant has met the requirements to reduce risks to ALARP. The guidance does not apply to the risk assessment for human participants under section 9(2) of the Space Industry Act (SIA), or in-orbit risk (e.g. risk of collisions)⁴.

ALARP is a fundamental concept in UK health and safety law. Alongside the requirements in the SIA it applies to all activities within the scope of the Health and Safety at Work etc. Act 1974 (HSWA). It is widely adopted within engineering good practice and across many sectors as a proportionate approach to safety risk management. To ensure a consistent and proportionate approach in making judgements on ALARP, this guidance draws extensively on existing published material and should be read in conjunction with <u>Reducing Risks: Protecting</u> <u>People</u> and the <u>ALARP suite of guidance available on the HSE website</u>. This document should also be read alongside the Space Industry Regulations and accompanying guidance, which set out the legal requirements in more detail.

2. Risk Acceptability - Principles to consider when determining when risk is "acceptable to the regulator"

There are four factors which the regulator will need to take into account when determining whether the level of risk is acceptable: policy goals, legal principles, comparisons with other sectors and public concern. Figure 1 sets these out in more detail.

¹ Space Industry Act 2018 section 9(4)(a) and section (10)

² Space Industry Regulations 2020 regulation 41(3)

³ Space Industry Act 2018 section 9(4)(b)

⁴ Note that this document is focused on decision-making around launch (and return) operator and spaceport licences under the SIA; it does not apply to orbital operator licences, for which different considerations around risk need to be made. See the guidance for orbital operator licence applications for further information.

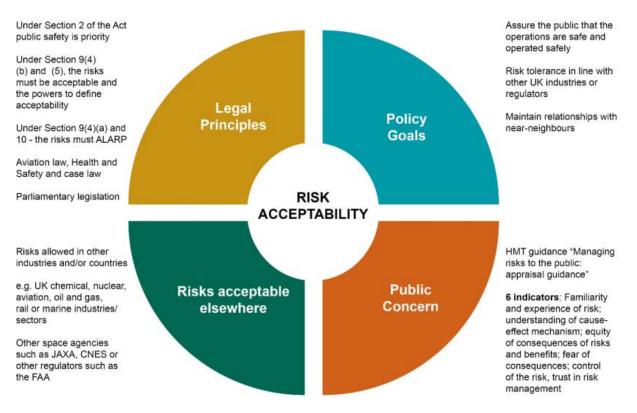


Figure 1 - Factors to be considered when determining risk acceptability

This framework leads to six principles which form the basis of the regulator's decision-making process in determining if the risk is acceptable. It is recognised that the relative importance of these principles (and the supporting evidence) may vary over time and they will be kept under review.

Policy goals

Principle 1 - The regulator must be satisfied the applicant has taken all reasonable measures to ensure that the relevant risks from their operations are ALARP.

In determining the risks are ALARP, the regulator will assess whether applicants⁵ have made a compelling argument (supported with evidence) to show they have taken (or will take) all reasonable measures including:

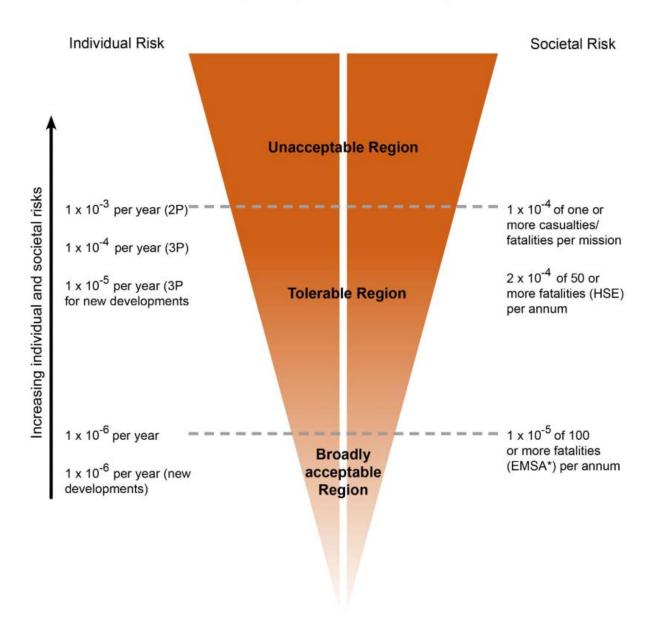
- compliance with the Space Industry Regulations and other relevant health and safety legislation as far as it is within the scope of the licensed activities;
- implementing appropriate standards where they exist and recognised good practice;
- consideration of further risk reduction measures.

Risks in the tolerable region (figure 2) can only be considered acceptable where it is clearly demonstrated that it is not reasonably practicable to do more to reduce the risk.

⁵ The term 'applicants' is used throughout this document to refer either to licence applicants or to existing licensees who wish to make a variation to their safety case

Principle 2 - The regulator will consider both individual and societal risk.

The regulator will compare the applicant's numerical estimates of risk with the framework in figure 2 (see section 1.2 for further information).



Spaceflight Regulator Tolerability of Risk

Figure 2 - Draft spaceflight tolerability of risk⁶

⁶ 2P and 3P refer to second and third parties respectively, i.e. people directly involved with the activity (excluding spaceflight participants) compared with people who are not involved; EMSA is the European Maritime Safety Agency

Principle 3 - The regulator will take into consideration the transboundary impact of spaceflight activity with a view to maintaining good relationships with near neighbours.

Legal duties

Principle 4 - The regulator will give priority to public safety when making a licensing decision.

Section 2(1) of the Space Industry Act imposes a duty on the regulator to carry out its functions relating to spaceflight activities with a view to securing public safety. This duty has primacy over the various other matters that the regulator must consider in exercising its functions under the Act.

Section 2(2) also requires the regulator to exercise its functions in the way that the regulator thinks best calculated to take into account:

- a) the interests of persons carried by spacecraft or carrier aircraft;
- b) the requirements of persons carrying out spaceflight activities;
- c) the interests of any other persons in relation to the use of land, sea and airspace;
- d) the requirements of persons with interests in property carried by spacecraft;
- e) any environmental objectives set by the Secretary of State;
- f) the interests of national security;
- g) any international obligations of the United Kingdom;
- h) any space debris mitigation guidelines issued by an international organisation in which the government of the United Kingdom is represented.

Consideration of these matters is secondary to securing public safety. This list from (a) to (h) does not represent a further hierarchy of interests and requirements.

Comparison of risks in other industries and/or countries

Principle 5 -. The regulator's tolerance for risk will be in line with the UK's regulation of other high hazard industries and will take account of the risk tolerance of other launching states.

In the proposed framework (figure 2) the boundaries of the tolerable region for individual risks are consistent with the general criteria used in the HSE tolerability of risk triangle. For societal risk, two values that are indicative of typical thresholds the regulator would consider have been placed at the unacceptable/tolerable region boundary. These are based on the societal risk tolerability proposed by HSE, and the acceptability criteria of other launching nations.

Regulation	Metric	Threshold per mission	Threshold per year
14 CFR 417.107 ⁷ ,	Ec	<1x10 ⁻⁴ for launch	
USA		1x10 ⁻⁴ for re-entry	
	IR	1x10 ⁻⁶	
French Space Operations Act technical regulations ⁸ , France	Ec	2x10 ⁻⁵ for launch 1x10 ⁻⁴ for orbital re-entry	
Flight safety code ⁹ , Australia	Ec	1x10 ⁻⁴ for launch 1x10 ⁻⁴ for re-entry	
	IR	1x10 ⁻⁶	1x10 ⁻⁵

⁷ https://www.law.cornell.edu/cfr/text/14/417.107

⁸ Decree on Technical Regulation issued pursuant to Act n°2008-518 of 3rd June 2008, 31 March 2011

⁹ https://www.industry.gov.au/regulations-and-standards/regulating-australian-space-activities

Figure 3 – Risk thresholds for other launching nations (Ec is expected casualties, a measure of societal risk and IR is individual risk)

Public concern

Principle 6 - The regulator will take account of any public concern surrounding the proposed spaceflight activities.

The tolerability of risk framework (figure 2) takes account of public attitudes to risk. HM Treasury published guidance¹⁰ provides a framework for assessing public concern, which attempts to capture of the views of the public on the hazards and risks of an activity. Six indicators are used for this:

- familiarity and experience of the risk;
- understanding of the cause-effect mechanism;
- equity of the consequences of the risk and the associated benefits;
- fear of the risk consequences;
- control of the risk;
- trust in risk management.

It is recognised that public attitudes to spaceflight activity will change over time and this will be kept under review.

3. Determining that risk has been reduced ALARP

In simple terms, for risks to be ALARP, applicants are required to take all measures to reduce risks where doing so is reasonable. Where relevant good practice and standards exist, it is not necessary to carry out an explicit comparison of costs and benefits. The development of relevant good practice and standards includes ALARP considerations so in many cases meeting them is sufficient (see the callout box on page 9 on identifying good practice). In other cases, where standards and relevant good practice are either less evident or not fully applicable, the onus is on the applicant to implement measures to the point where the cost of any additional measures (in terms of money, time or trouble – the sacrifice) would be grossly disproportionate to the further risk reduction that would be achieved.

Determining that risks have been reduced ALARP involves:

- an assessment of the **risk** to be avoided;
- an assessment of the **sacrifice** (in money, time and trouble) involved in taking measures to avoid that risk and;
- a **comparison** of the two.

These steps should be proportionate to the nature of the hazard, the extent of the risk and the control measures to be adopted. The more systematic the approach presented by the licence applicant, the more rigorous and more transparent it is to the regulator and other interested parties. However, applicants (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 the spaceflight regulator requires of the arguments purporting to show that those risks have been reduced ALARP.

¹⁰ <u>HMT. Managing risks to the public: appraisal guidance.</u>

1.1. Risk

The assessment of risk is confined to those matters with which the legislation in question is concerned; in this case, the SIA, and the regulations made under it. Other legislation may apply to other risks or activities connected to spaceflight activities (such as HSWA, for which HSE is responsible).

Licensees can exercise control or mitigate the consequences of risks through the conduct of their undertaking. Some risks arise from external events or circumstances over which the licensee has no control, but whose consequences a licensee can mitigate. Such risks should be included in the assessment.

The SIA, read with the Space Industry Regulations, specifies that an applicant for an operator licence should assess the risks to the health, safety and property of individuals who are not on board the launch vehicle. This means that the risks to both workers and the public (but not crew and spaceflight participants) and property are in scope. Spaceport licence applicants need to include the risks to public safety under the SIA.¹¹

Risks should be assessed in an integrated manner by applicants. It is important that applicants 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.

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, the application of that control measure is reasonably practicable in certain locations (such as those that present a particularly high risk and/or low cost).

Individual Risk

When determining risks to the individual, risk should be assessed in relation to a hypothetical person, e.g. 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'.

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.

Societal Risk

Societal risk can be defined where there is a large number of deaths at once, 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).

In the event of a spaceflight accident occurring, it is credible that it would affect multiple people and society has a greater aversion to an accident resulting in the deaths of 10 people than to 10 accidents resulting in the death of one person each. Therefore, the regulator requires that

¹¹ "Public safety" is defined in section 2(6) as "the health and safety of members of the public...and the safety of their property". For the purposes of section 10 (grant of spaceport licence), "members of the public" are defined in regulations 40 and 41

any judgement as to whether measures are grossly disproportionate should reflect societal risk, although there is no guidance from the courts on this matter.

1.2. Sacrifice

The sacrifice under consideration here is that which would be incurred by licensees as a consequence of their taking measures to avert or reduce the risks identified. Only costs (money, time, or trouble) necessary and sufficient to implement the measures to reduce risk can be considered.

For any particular measure, these might include the cost of installation, operation, and maintenance, and the costs due to any consequent opportunity losses resulting directly from the introduction of the measure (for example, a change in launch azimuth or the introduction of a dog-leg reducing the launch payload capacity).

Individual applicants' 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. The regulator must present applicants with a level playing field. Thus, the regulator cannot consider the size and financial position of the applicant when making judgements on whether risks have been reduced ALARP.

The benefits gained by applicants as a result of their implementing a health and safety measure should be offset against the costs they incur.

1.3. Transfer of risks

Introducing a risk reduction measure may transfer risk to other employees or members of the public.

If the transferred risk arises from the *same* hazard, then it should be offset against the benefit from the measure under consideration. For example, moving fuel storage tanks away from a spaceport building (e.g. an integration facility) but closer to a public right of way transfers risk from employees to the public. The added risk to the public should be offset against the benefits the measure otherwise brings to employees (e.g. the public right of way is rarely used, and so the comparable benefit to workers outweighs the additional risks to the public).

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, moving the fuel storage tank away from the integration facility may introduce an additional hazard to workers who transfer fuel around the spaceport (i.e. a longer distance to be travelled with flammable material), so some risk has been transferred to the transport workers. Since a different hazard is involved, the tank should be used to reduce the risks to the integration facility workers to ALARP, but at the same time, the duty holder must ensure that the risks to fuel transport workers are reduced ALARP. However, if the risks from the health and safety measure to be introduced when properly controlled are still greater than the risks which it is sought to address, the measure should not be introduced.

1.4. Comparison

In comparing the risk to be avoided or reduced, and the sacrifice involved in measures to achieve that reduction, the starting point should be the present situation. If there are several options, they should each be considered against the present situation.

In some situations, it will not be possible to assess options in this way. For example, where an installation or launch vehicle 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 against that starting point, to determine whether further risk reduction measures are reasonably practicable.

The basis on which the comparison is made is provided by the definition of reasonably practicable set out by the Court of Appeal (in its judgment in Edwards v. National Coal Board, [1949] 1 All ER 743):

"Reasonably practicable' is a narrower term than 'physically possible' ... 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."

The concept of gross disproportion requires applicants to weigh the costs of a proposed control measure against its risk reduction benefits. Specifically, it states that a proposed control measure must be implemented if the 'sacrifice' (or costs) are not grossly disproportionate to the benefits achieved by the measure.

There is no authoritative guidance from the Courts as to what factors should be taken into account in determining whether cost is grossly disproportionate but the spaceflight regulator expects operators to take account of both the level of individual risk and the extent and severity of the consequences of significant incidents or major accidents. For a given benefit, the higher these risks, the higher the degree of disproportion (i.e., the ratio costs to benefits) can be before being judged 'gross'.

No algorithm has been formulated 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.

Taking greater account of the benefits as the risk increases 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.

There is no expectation for applicants to provide a detailed cost benefit analysis to support their licence application. Where one is provided, the spaceflight regulator will follow the published guidance HSE principles for Cost Benefit Analysis (CBA) in support of ALARP decisions when reviewing the cost benefit analysis as part of application process.

1.5. Using these principles and guidelines in practice

The regulator will assess an applicant's safety case and (for spaceport licence applications) siting assessment against set criteria to make a judgement on whether the risks are ALARP and whether the residual level of risk is acceptable.

If the engineering and operation of the facility and launch vehicle and the design of any mission gives no cause for concern, and the risks are adequately demonstrated to be broadly acceptable then this is sufficient for assessment purposes.

Where the risks are intolerable the regulator will consider rejecting licence application on the grounds of safety.

If the risks fall into the tolerable region then the regulator will consider specifically whether these are reduced to ALARP. Where appropriate they will also take account of any issues of transboundary impacts and significant public concern.

The following checkpoints may be relevant in reviewing applicants' safety cases or arguments that the risks are ALARP:

- There is evidence of an adequate and fit-for-purpose evaluation of risks that underpins the ALARP case.
- The ALARP argument only refers to those risks for which the applicant is responsible.
- Whether arguments made about affordability as a factor in the assessment of costs are legitimate.
- ALARP is not used to argue against statutory duties.
- The ALARP argument take adequate account of all relevant types of risks (ground base and during flight).
- All relevant options have been considered by the applicant and the study of the options begins with the safest (as opposed to the cheapest) option.
- Where measures are deemed not reasonably practicable, partial implementation has been considered.
- The rigour of ALARP case made is commensurate with the level of risk in the scenario under consideration.
- For measures deemed not reasonably practicable, the applicant demonstrated gross disproportion. The costs considered should only be those necessary and sufficient for the purpose of implementing the risk reduction measure (the regulator should be wary of gold plating or "deluxe" measures unduly inflating the cost).
- The ALARP arguments include explicit consideration of qualitative features related to engineering and other types of relevant good practice (see the box "Identifying good practice").
- The ALARP argument is based on comparisons with relevant good practice, informed as necessary by cost benefit analysis, rather than the other way around. A cost benefit analysis on its own is not acceptable as an ALARP case.
- ALARP always applies and arguments employing Time at Risk may need special consideration.

Identifying good practice

In judging and recognising good practice, the regulator must be satisfied that the practice is correctly formulated in that it:

- 1. takes account, where relevant, of:
 - a. individual risk, societal risks and societal concerns;
 - b. the sacrifice and benefits;
 - c. the technical feasibility of proposed control measures and the level of risk control
- 2. maximises the use of:
 - a. inherent safety and the elimination of hazards;
 - b. the avoidance of risk;
 - c. the control of risk at source using physical engineering controls;

whilst it;

- 3. minimises the need for:
 - a. procedural controls; and,
 - b. personal protective equipment;
- and it is in a form that:
 - 4. clearly defines the scope of the good practice and the circumstance where it is relevant; and,
 - 5. can be clearly specified, e.g. it is either written down or a well-defined and established practice adopted by an industrial/occupation sector.