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| ONR Technical Assessment Guide  Regulating duties to reduce risks to ALARP |



ONR Technical Assessment Guide

Regulating duties to reduce risks to ALARP

**Authored by:** Inspector

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| 12 | Major revision:   * Change of title to better reflect the purpose and scope of the guidance * Consolidation of similar content and removed repetitive content * Improved presentation of a key concept – relevant good practice (RGP) * Signposted information that are better hosted elsewhere * Updated relevant information and deleted those no longer relevant * Removed references to discipline-specific risks * Inclusion of key concepts that are relevant to making a judgement on reducing risks to ALARP * Clarification of concepts |
| 12.1 | Minor update to correct issue with references, bibliography and cross-references. |

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# Introduction

1. The Office for Nuclear Regulation (ONR) has established its   
   [Safety Assessment Principles](http://www.onr.org.uk/saps/saps2014.pdf) (SAPs) [1] which apply to the assessment by ONR specialist inspectors of safety cases for nuclear facilities that may be operated by potential licensees, existing licensees, or other dutyholders.   
   The principles presented in the SAPs are supported by a suite of guides to further assist ONR’s inspectors in their technical assessment work in support of making regulatory judgements and decisions. This technical assessment guide (TAG) is one of these guides although the scope of this TAG extends beyond assessment of safety cases (refer to Section [2](#_Purpose_and_Scope)).
2. The concept of ‘reasonably practicable’ sits at the heart of the British health and safety system, it sets goals for dutyholders, rather than being prescriptive. It is a key part of the general duties set out in the Health and Safety at Work etc. Act 1974 (HSWA) and many sets of health and safety regulations that are enforced by ONR on dutyholders it regulates. It is also a fundamental consideration for ONR during the Generic Design Assessment (GDA) for new nuclear installations.
3. There are two terms commonly used: ‘so far as is reasonably practicable’ (SFAIRP) or ‘as low as reasonably practicable’ (ALARP). They have a similar meaning, which involves weighing the risk of a hazard causing harm to people against the money, time or trouble needed to control it. As such, they are often used interchangeably and health and safety regulators in Great Britain (GB) consider the same legal tests to be applied during their judgements and decision-making, although legal proceedings will have stricter reference to the specific term used in the relevant legislation. For the purpose of the TAG, the term ‘ALARP’ is adopted unless referencing specific legal duties included in legislation.
4. Industrial activities are often associated with risks and dutyholders have legal obligations to reduce these risks to ALARP. In the nuclear industry where activities often involve high hazards, complex and/or novel situations, making the appropriate ALARP judgement and associated decisions in accordance with the risk profile of those activities can be challenging, but it is an essential part of ONR’s regulatory decision-making process (refer to Section [5.3](#_ONR’s_approach_in)). This guidance, alongside other ONR guidance as referenced and associated training, has been produced to support ONR staff in making such judgements.

# Purpose and scope

1. Although the duty to control and reduce risks to ALARP lies with the dutyholders, and ultimately, the courts decide whether dutyholders have complied with the law; ONR as a regulator is responsible for making adequate arrangements for enforcement of the law where relevant and applicable. In fulfilling its duty, ONR has produced this TAG to provide guidance and advice to its regulatory staff who have to judge whether the measures put in place or proposed by dutyholders to control and reduce risks to ALARP are adequate. It also applies to those ONR staff who are making policies and decisions that set out ONR’s regulatory expectations and regulatory outcomes, as well as those providing regulatory advice to colleagues within ONR and dutyholders. As such, this TAG is intended to be used by all relevant functions within ONR.
2. It is important to recognise that not all legal duties are qualified by the requirement to reduce risks to ALARP. There are duties set out in specific parts of law that are ‘absolute’, this means that the duty must be met, and it is not permissible to argue that it is impracticable, costly, or difficult to do. There are also specific legal duties required by law that must be carried out ‘so far as is practicable’, which means it must be undertaken, if it is possible, regardless of money, time or trouble; the standard of practicability means it is within current knowledge and invention. These duties often exist in the same legislation and should be distinguished carefully. Judgements and decisions made against the non-ALARP duties are outside of the scope of this TAG.
3. This TAG is underpinned by several key ONR publications such as the   
   ‘Risk-informed regulatory decision making’ [2] (RIRDM) framework document, which explains the role of ALARP within the overall framework by which ONR makes regulatory decisions; and ‘Licensing nuclear installations’ document [3], which provides an overview of the nuclear regulatory regime and the processes for licensing and delicensing nuclear sites.
4. It is important to note that this TAG is complementary to the existing ALARP suite of guidance produced by the Health and Safety Executive (HSE) [4] and is not intended as a replacement.

# Relationship to licence and other relevant legislation

1. Key pieces of law for ONR’s regulation of safety in GB are the Nuclear Installations Act 1965 (NIA 1965), HSWA and the fire safety legislation (Regulatory Reform (Fire Safety) Order 2005 (commonly known as RR(FS)O or FSO) as amended by the Fire Safety Bill 2021 in England and Wales, and the Fire (Scotland) Act 2005 (F(S)A) in Scotland). For the nuclear installations that are within the scope of NIA 1965, ONR is the enforcing authority for HSWA, FSO/F(S)A, and NIA 1965, the latter through provisions of the Energy Act 2013 (TEA).
2. HSWA places duties on all employers to ensure, SFAIRP, the health, safety and welfare of persons by controlling and reducing risks in all workplaces, including nuclear installations. FSO/F(S)A places duties on the responsible person of a premises, including nuclear installations, to take general fire precautions ensure, SFAIRP, the safety of employees and relevant persons and reduce risks from dangerous substances. NIA 1965 requires certain installations to have a nuclear site licence with a set of Licence Conditions (LCs) attached by the regulator in the interests of safety and with respect to the handling, treatment, and disposal of nuclear matter. Fundamental to demonstrating that nuclear safety risks are reduced to ALARP for a nuclear installation, is the requirement on licensees to produce an ‘adequate safety case’ (LC 23). Failure to comply with the duties outlined in the law or contravening the LCs attached by the regulator is a criminal offence.
3. It is important to note that legal systems outside of the UK may differ in their approach, as non-UK legislation tends to set out absolute levels of safety to be met through prescriptive requirements on dutyholders to adhere to specific standards and ‘good engineering practice’, rather than applying the ALARP concepts. This difference sometimes presents challenges to dutyholders and regulators, particularly when deploying technology established under an alternative regulatory system outside of UK, for example, the GDA process.
4. Internationally, the term ‘as low as reasonably achievable’ (ALARA) is used almost exclusively in relation to optimization of reducing ionising radiation exposure. ONR considers this to have equivalent meaning to ALARP in the context of ionising radiation exposure.
5. This TAG assists ONR in demonstrating that the International Atomic Energy Agency (IAEA) Safety Standards and Western European Nuclear Regulators’ Association (WENRA) Safety Objectives and Safety Reference Levels (SRLs) are part of the UK’s regulatory oversight of nuclear safety (refer to Section [4](#_Relationship_to_Safety)).

# Relationship to Safety Assessment Principles, WENRA Reference Levels, and IAEA Safety Standards and Guides

1. IAEA Safety Standards [5] are developed by international consensus.   
   They provide fundamental principles, requirements and recommendations to ensure nuclear safety. They serve as a global reference for protecting people and the environment and contribute to a harmonized high level of safety worldwide.
2. The WENRA SRLs represent a consensus view from its member states of the main requirements to be applied to ensure nuclear safety of existing reactors [6], waste and spent fuel storage [7], radioactive waste disposal facilities [8], decommissioning [9], radioactive waste treatment and conditioning [10] and research reactors [11]. In addition to the SRLs, WENRA also published Safety Objectives for new nuclear power plants [12].
3. ONR’s SAPs [1], herewith referred to as ‘SAPs’, were developed against the background of the UK legal requirements and have been benchmarked against the IAEA Safety Standards and WENRA SRLs and Safety Objectives. This benchmarking is outlined within each of ONR’s TAGs.
4. The SAPs set out ONR’s regulatory expectations that inspectors use to guide their judgements. The legal requirement for dutyholders to reduce risks to ALARP and demonstrate they have done so is an overriding and   
   all-embracing principle that informs an inspector’s use of the SAPs.   
   Paragraph 16 of the SAPs emphasises that:

“The principles are used in helping to judge whether reducing risks to ALARP is achieved ... priority should be given to achieving an overall balance of safety rather than satisfying each principle or making an ALARP judgement against each principle. The principles themselves should be met so far as is reasonably practicable” [1].

1. It is important to note that the SAPs are considered broader in scope than the IAEA Safety Standards and WENRA SRLs and Safety Objectives.
2. In addition to SAPs, the IAEA Safety Standards and the WENRA SRLs and Safety Objectives are considered by ONR to represent relevant good practice (RGP) for nuclear safety. RGP is an important concept in ONR’s judgements and decisions regarding ALARP (refer to Sections [5.1.6](#_5.1.6._Relevant_good) and [5.2.4](#_5.2.4._Appropriate_use)).

# Concepts supporting regulatory judgements on reducing risks to ALARP

## Core concepts

### 5.1.1. Hazard

1. A hazard is something that can cause harm, otherwise known as adverse effects, to people. It can be an object, a property of a substance, a phenomenon, or an activity. Examples include water on a staircase that could result in slippage and fall, loud noise that could cause hearing loss, or breathing in harmful substances that could cause cancer, radioactive waste in a drum etc.

### 5.1.2. Risk

1. Risk is a two-part concept comprising the likelihood[[1]](#footnote-2) and severity, and both should be used in describing a risk accurately. Risk can be expressed qualitatively or quantitatively.
2. In any given workplace there are a wide range of hazards and a large number of risks which dutyholders must consider. The scope of those risks are limited to those the dutyholders can exercise control or mitigate the consequences through the conduct of their undertaking, including risks arising from external events or circumstances over which the dutyholder has no control, but can mitigate the consequences.
3. Requiring dutyholders to address all risks would be unrealistic and impose a disproportionate burden on the dutyholders. Thus, the regulators expect dutyholders to only take account of the circumstances where the hazards that are reasonably foreseeable to cause harm, known as the ‘foreseeable risk’[[2]](#footnote-3).

### 5.1.3. Sacrifice

1. The sacrifice is the cost incurred to a dutyholder as a consequence of the measures they have taken to avert or reduce the risks identified within their undertaking. The sacrifice is defined to be money, time or trouble[[3]](#footnote-4).   
   Benefits gained by dutyholders as a result of their instituting a health and safety measure should be offset against the costs they incur.
2. Individual dutyholder’s 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. ONR must present dutyholders with a level playing field. Thus ONR cannot take into account the size and financial position of the dutyholder when making judgements on whether risks have been reduced to ALARP.

### 5.1.4. Grossly disproportionate

1. Determining whether a risk has been reduced to ALARP involves an assessment of the risk to be avoided or reduced, of the sacrifice involved in implementing the measures to do so, and a comparison of the two, also known as the test of ‘gross disproportion’. In any such assessment, measures to reduce or avoid the risk can only be ruled out if the sacrifice involved in taking them is judged grossly disproportionate to the benefits of the risk reduction, i.e. it is not about balancing the costs (money, time or trouble, refer to Section [5.1.3](#_5.1.3._Sacrifice)) and benefits of the measures. The judgement is weighted in favour of health and safety because the regulatory presumption is that the dutyholder should implement the risk reduction measure.
2. There is no authoritative guidance from the courts as to what factors should be considered in determining whether the cost is grossly disproportionate to the risk. There is no algorithm that can be used to determine, in any case, when the degree of disproportion can be judged as ‘gross’, the judgement is made on a case-by-case basis, and in most cases it is qualitative, rather than quantitative.
3. For the purposes of this TAG, it is suggested that the evidence given by John Locke, then Director General of HSE, at the Sizewell B Public Inquiry provides a starting point. Although this evidence was produced some time ago, no subsequent legal proceedings or public inquiries have countered these views or provided alternatives. In his evidence, Locke suggested a gross disproportion factor of up to three for workers. For risks to the public, he added that the factor would depend on the level of risk, and where the risks were low (consequence and likelihood) a factor of about two was suggested, whereas for higher risks the factor should be about ten.
4. Gross disproportionality is an important concept relevant to ALARP judgements including less commonly applied cost benefit analysis (CBA) (refer to [Appendix 1](#_Appendix_1:_Cost)).

### 5.1.5. Assessment of foreseeable risks

1. For a dutyholder to demonstrate whether a risk has been reduced to ALARP, they need to have an adequate level of understanding of the risk first. This can be achieved through a decision-process called risk assessment.
2. Much health and safety legislation requires employers (or responsible persons) to carry out ‘suitable and sufficient’ risk assessments for specific hazards. Such assessments involve dutyholders 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 to reduce the risks.
3. The determination of control measures to reduce risks to ALARP is part of a dutyholder’s risk assessment. For those risks that are well-known and well-understood, there are often well-established standards for control measures in the form of relevant good practice (RGP) (refer to Section [5.1.6](#_5.1.6._Relevant_good)) that the dutyholder may choose to follow. For less well-understood and novel hazards/risks (where greater inherent uncertainty is present), and complex high hazard situations that often involve many risks at different stage, often competing and associated with each other, the determination of control measures should include more thorough and careful considerations by the dutyholder to ensure a balanced approach to reducing risks to ALARP is achieved (refer to Section [5.2.1](#_5.2.1._Consideration_of)).
4. The legal requirement for a dutyholder to carry out a suitable and sufficient risk assessment is an absolute duty and cannot be argued against on the grounds that the costs involved are grossly disproportionate.   
   Nevertheless, the scope, depth and effort put into the risk assessment should be proportionate to the level of the intrinsic hazards.   
   Risk assessments vary in form, size, and complexity. They can be carried out by individuals as well as teams and range from qualitative to quantitative. There is no “one-size-fits-all” approach to risk assessment. It is important to note that a written risk assessment by a dutyholder in itself does not necessarily mean it is suitable and sufficient, as it was only used to record and evidence the decision-making process to understand the risks.
5. Risks should be kept under review and reduced further if it is reasonably practicable for the dutyholder to do so, because the duties to carry out risk assessment and reduce risk to ALARP are ongoing duties. This means that over a period of time, changes in circumstances may have led to changes to risks, their tolerability, as well as the measures taken to reduce the risks to ALARP. It is therefore prudent for the dutyholder to revisit the risk assessment and control measures periodically, to ensure they are still suitable and sufficient.

### 5.1.6. Relevant good practice (RGP)

#### 5.1.6.1. The concept of RGP

1. In many commonly-encountered situations it is well understood what measures are needed to reduce a risk to ALARP and it is unnecessary to revert to a detailed, first-principles analysis. This is where the concept of RGP is useful. In short, the RGP in a particular situation is the collection of controls that, if implemented, would usually lead to the risk being reduced to ALARP based on the experience of similar circumstances.
2. For the purposes of this TAG, the legal standard is the requirement to reduce the risk to ALARP. It is worth noting that the concept of RGP is also used to refer to other goal-setting requirements such as ‘suitable and sufficient’ and ‘adequate’ as used in relevant health and safety law and nuclear site licence conditions. RGP is also applied within other safety and non-safety legal obligations such as goal-setting safeguards and security requirements.
3. Whenever RGP is being used, it must be clear what the underlying goal-setting requirement is to which the RGP is being applied. The rest of this section focuses on the use of RGP for demonstration risks are reduced to ALARP.

#### 5.1.6.2. Relevant and good-enough

1. RGP refers to the body of ‘practice’ that is ‘good’ and ‘relevant’.   
   The meaning of each of these three words is important:

* A ‘practice’ can refer to a wide range of safety measures, controls and activities relating to reducing risks to health and safety. This can include:
  + physical measures, for example the design of plant and equipment, the type and number safety mechanisms, the mitigating and emergency measures, and the use of particular items of personal protective equipment;
  + administrative aspects, such as training practices, maintenance/inspection/testing schedules, decision-making processes, operating instructions;
  + any other concept such as fault, hazard or risk analysis methodologies, design principles, safety policies, risk targets etc., providing they are relevant to reducing risks to health and safety.
* The word ‘good’ refers to the need for the practice to be ‘good-enough’ such that, if used, the risk will be reduced to ALARP. It is important to note that ‘good’ is not the same as ‘best’. Best practice may represent the very highest standard of control, but is beyond what the law requires and is not something that regulators would normally consider in their judgements.
* The word ‘relevant’ is crucial. There are a large number of potential practices, but it is only those good practices that are relevant to the circumstances that matter when applied to a specific situation. This requires careful consideration of the source of the good practice (refer to Section 5.1.6.5), the underlying legal requirement to reduce risk to ALARP, the specific circumstances, any constraints (including those coming from the need to meet other legal requirements), cross-discipline considerations and the overall outcome.

#### 5.1.6.3. How and where a RGP is used

1. RGP is a regulatory concept used to reduce the time and effort in commonly-encountered circumstances where there is well-established good practice and where a detailed, first-principles analysis of ALARP is not needed.   
   This includes many aspects of site health and safety, fire safety, and the common aspects of nuclear and radiological safety. RGP has no legal basis and is not referenced in legislation. Therefore, although the regulator’s view of what constitutes RGP is likely to be persuasive in a court case, there is no requirement in law for a dutyholder to apply RGP to a particular situation. Dutyholders are free to choose an alternative approach to RGP, providing they have satisfied the legal requirement of reducing the risk to ALARP.
2. The concept of RGP is less helpful for novel or unusual circumstances, because typical standards and practices are often not fully relevant to the situation and there may be little to no experience from other similar situations. In these cases, RGP is only a starting point for a more detailed demonstration by the dutyholder against the legal requirement to reduce risks to ALARP. Whilst any available RGP should still be used as a starting point, the dutyholder may be able to demonstrate an ALARP approach that does not meet all aspects of the usual RGP standard in the specific circumstances. ONR’s Tolerability of Risk (TOR) policy (refer to   
   Section [5.3.1](#_5.3.1._Tolerability_of)) also expects dutyholders to undertake a more detailed exploration of ALARP justifications, beyond RGP, in situations that ONR judge to be higher in risk, especially where the underlying risks are at the ‘intolerable’ region in the TOR framework.

#### 5.1.6.4. Determining RGP

1. It is usually the role of ONR, or other relevant regulators, to determine what is considered as RGP in a particular situation, and this will inform the regulatory decision. In the event that a case is taken to court, or subject to a judicial review, the decision on whether or not the dutyholder had reduced a risk to ALARP would be determined, conclusively, by the court. This decision would either underpin the RGP or show that it hadn’t aligned to the legal standard and therefore had not been correctly determined.
2. In practice, as part of demonstrating a risk has been reduced to ALARP, a dutyholder may wish to consider and judge what itself considers to be RGP in order to be able to make an argument for the reasonable practicability of the approach it has taken. ONR expects the arguments and evidence supporting such ALARP justifications to be included within the relevant safety case or safety report.
3. What is accepted as RGP by a regulator may change over time because there may be increased knowledge about the hazard and/or change in the acceptability of the level of risk control achieved by existing good practice, or new legislation may change the level of acceptance, or technological innovation may reduce the cost of implementing a higher standard. For these reasons, regulators keep RGP under regular review.

#### 5.1.6.5. Sources of RGP

1. There are a number of sources of RGP and there is a hierarchy to their significance (i.e. the weight it would carry if a case was brought before a court) based on its source and pedigree:

* Approved Codes of Practice (ACoPs)[[4]](#footnote-5), which carry the strongest weight and have a special legal status.
* Published regulatory guidance, for example, ONR Technical Inspection Guidance (TIG) and TAG, HSE guidance.
* Other written sources which may be recognised as good practice, including guidance produced by other government departments and regulators, national and international standard-setting bodies, industry bodies and professional institutes.
* Unwritten sources of good practice, for example through well-defined and well-established practices across a particular industrial sector.

1. There may be instances, although unusual, where industry guidance does not meet ONR’s expectations on RGP. In such circumstance, the difference in expectations should be noted in the relevant ONR TAG, and ONR makes effort to work with industry body to influence their guidance to align with ONR’s expectations on RGP.
2. The mixing of different standards is discouraged where there is an applicable all-encompassing standard, particularly for those set-out in regulatory expectations or those from authoritative national and international bodies, such as British Standards or IAEA Safety Standards. However, a case can be made in some circumstances to draw upon standards from different sources if the situation warrants it. The important point is to consider the overall outcome against the ALARP requirement.

#### 5.1.6.6. Replication

1. In the context of building a new fleet of nuclear power reactors of a specific design over a period of a number of years, replication is a principle where a design and associated arrangements (for example supply chain etc.) are implemented in multiple instances. Usually, this is an iterative process where a design from a previous project is used again at a new location. The extent of the design that can be replicated is limited to areas where the location has no impact on the design.
2. The overarching requirement for a dutyholder to demonstrate that risks have been reduced ALARP remains. Nevertheless, ONR recognises that, providing the overall nuclear safety risks are low, timescales are reasonable and a suitable case (rationale, strategy and scope) is made by the dutyholder, then the previous as-built plant can serve as a template for the next-to-be-built plant. In general, this may be achieved without needing to   
   re-open previously-justified ALARP arguments. Effectively, the previous plant design provides the RGP for the next plant and serves as a starting point. There are several exclusions that ONR expects the dutyholders to have considered in determining the scope of replication, for example when learning from previous build or operational experience indicates replication would no longer reduce risks to ALARP.
3. This balances ONR’s risk-informed and enabling approach to regulation   
   [13] and the ongoing continuous improvement in safety resulting from operating experience, evolution of standards and the development of new technology. For example, ONR has put in place a regulatory strategy on replication at Sizewell C that sets out the advantages and limitations of the approach [14].

## ONR’s expectation of a dutyholder’s ALARP demonstration

1. There are several factors that ONR expects dutyholders to have considered in developing a balanced approach to reduce risks to ALARP.

### 5.2.1. Consideration of all risks and constraints

1. The risk profile of an ONR regulated site can be complex and often includes a variety of risks ranging from those that are well-characterised across different industries, to those that are novel, such as a new design of a plant/facility/component/system etc., and to those that are unique to a nuclear installation.
2. ONR expects dutyholders to consider the holistic risk of the facility as a whole, as well as individual risks at component/system level in their risk assessments. This is because the integration of separate components and systems may increase the risks and require further measures to reduce those risks to ALARP. There may also be further opportunities arising from the integration to reduce risks from each component and system through collective measures.
3. ONR expects dutyholders to ensure that any risk-reduction measures adopted to address one hazard do not disproportionately increase risks from other hazards or compromise the associated risk control measures overall. ONR also expect dutyholders to have considered all operating modes and plant state, for example, what the implications of a proposed severe accident risk-reduction measure are for doses in routine maintenance.
4. There are situations where two sites are located adjacent or in close proximity such that a risk created on one site affects the other and may require risk reduction sacrifices to be taken on either or both sites. ONR expects each site to take consideration of foreseeable risks that are originated from neighbouring site as part of their risk assessment, in the same manner as any other external hazards (refer to Section [5.1.5](#_5.1.5._Assessment_of)).
5. When determining the appropriate control measures in these situations, ONR recognises that the consideration required of a dutyholder is limited to its undertaking (i.e. its business and the activities and decisions under its control) and should remain as such. For example, the ALARP justification for Site A (such as in arguing a further risk control measure is not reasonably practicable) should not include the sacrifice born by Site B in controlling the resulting risk on its site. In such cases, care must be exercised by both dutyholders in determining the boundaries of their legal duties and developing the appropriate independent ALARP justifications. A combined ALARP justification on shared risk reduction sacrifices can only be made if the sites are within the same legal entity i.e. owned by the same operating company. ONR inspectors considering such situations should seek specialist advice and support from the ALARP Working Group in making the appropriate judgement.
6. For older facilities there may be situations where the overall facility/system risk has been considered low, but a review against modern standards reveals a specific risk that may be high in certain conditions or circumstances (e.g. asbestos management). ONR expects dutyholders to take the specific risk into account and demonstrate it has been, or will be, reduced to ALARP (refer to Section [5.2.2](#_5.2.2._Consideration_of) and [Appendix 2](#_Appendix_2:_Time) that may be relevant in some cases).
7. ONR expects dutyholders to take cognisance of relevant legislation such as safety, safeguards, security, and environmental, each with ‘risks’ in their own field, when determining an optimised option to reduce risks to ALARP in the context of HSWA. The term ‘optimisation’ is used to refer to the level of protection that meets the legal requirements of ALARP and legal requirements such as Best Available Techniques (BAT)/Best Practicable Means (BPM). Optimisation is also the term used in the IAEA Safety Fundamentals [15] Principle 5 which states:

‘protection must be optimised to provide the highest level of safety that can reasonably be achieved.’

ONR inspectors for safety, safeguards, and security work together in making their judgements. ONR works with the environmental agencies in GB to ensure a joint and aligned approach in reaching regulatory judgements and decisions, especially on the regulatory application of ALARP and BAT/BPM principles. The arrangements are captured in the Memorandum of Understanding (MoU) between the regulators [16].

### 5.2.2. Consideration of lifecycles and changes

1. The risk profile of an ONR regulated site changes throughout the lifecycle of the site, as operations and activities differ in each stage of the lifecycle.   
   For example nuclear site health and safety related risks are likely to be higher at the construction, outage, and decommissioning stage of a plant/facility/installation/project than when it is in operation, whereas radiation and nuclear safety related risks are likely to be lower at the construction/decommissioning stage than at operational stage. ONR expects dutyholders to have considered the changing risk profile during the lifecycle of a plant/facility/installation/project in their risk assessments.
2. The Construction (Design and Management) Regulations 2015 (CDM15) has a wide scope and applies to all construction projects, big or small, from concept to completion, i.e. the whole lifecycle. There are specific duties that dutyholders, including those regulated by ONR, have to comply with.   
   For example, the application of the principles of prevention to reduce risks arising from construction activities to ALARP during different stages of a construction project, in particular during the design phase. More details on ONR’s regulation of CDM15 is included in ONR’s TIG titled, ‘Construction (Design and Management) Regulations’ [17].
3. During the lifecycle of a project, dutyholders may need to consider a selection of design options at any stage of the project. This could include choosing between different design concepts for the whole project at initial stage, more detailed design options at a later stage, and different methodologies to realise the design at the implementation stage.   
   This process is known as ‘optioneering’. Where safety cases or safety reports are required to be submitted by dutyholders to ONR at the design stage, ONR will assess the option presented by the dutyholder. Where ONR judges that option does not reduce risks ALARP, it will inform the dutyholder of its decision, and it may reject the case and ask the dutyholder to consider alternative options, and/or use its enforcement powers to prevent further work, depending on the situation. [Appendix 3](#_Appendix_3:_Optioneering) outlines ONR’s expectations on optioneering in more detail.
4. ONR seeks to protect future generations at least as well as it seeks to protect the present one. Therefore, ONR expects dutyholders to demonstrate that risks to future generations are reduced to at least the levels of risk that are judged to be tolerable for the present generation. Some projects in the nuclear industry run over many years, including new-build nuclear power plant and those associated with radioactive waste management and decommissioning. The resultant risks may affect future generations of workers and the public, as well as the present generation. For such cases, ONR expects dutyholders to assess risks in a holistic manner and not be restricted to part of the overall time period or part of a process.
5. There may be circumstances where risks increase for a short period of time due to actions taken that are intended to:

* sustain normal operation, for example carrying out maintenance activities, temporary disconnection of safety measures to allow completion of essential tasks;
* upkeep of ageing facilities with eroded safety margins, i.e. higher risk than newer facilities that are designed to modern standards, but have limited remaining operating life;
* reduce the hazard of the facility at the end of its life, for example clean-out, decommissioning and/or dismantling plant or structure;
* reduce risks in an emergency condition.

ONR expects dutyholders to have considered these circumstances, also known as ‘time at risk situations’, in the risk assessment and demonstrate such risks are appropriately monitored and controlled. [Appendix 2](#_Appendix_2:_Time) outlines our expectations in more detail.

### 5.2.3. Written assessment of foreseeable risks

1. The requirements on dutyholders to carry out suitable and sufficient risk assessments and identify control measures to reduce risk to ALARP are set out within multiple health and safety regulations manifested from HSWA. Nevertheless, the law does not often specify how risk assessments must be carried out by the dutyholders. It is therefore the dutyholder’s responsibility to decide how to demonstrate their existing or proposed control measures have reduced or will reduce the risks to ALARP. Options include demonstrating by:

* adherence with applicable RGP for well-characterised risks;
* using a suitable alternative to applicable RGP;
* using a first-principles assessment approach, which is commonly used for novel and less understood risks or combination of risks.

1. In the case of complex/high hazard situations such as a nuclear power reactor or a fuel reprocessing facility, a comprehensive probabilistic safety analysis (PSA) is expected to be developed by the dutyholder to complement the deterministic safety demonstration.
2. In addition to the above duties, the Management of Health and Safety Regulations 1999 (MHSWR) Regulation 3(6) places an overarching duty that requires employers with five or more employees to record the significant findings of the assessment and any groups of the employees identified by it as being especially at risk. This is a duty that has been included in other health and safety legislation, for example, but not limited to, the Ionising Radiation Regulations 2017 (IRR17) (Regulation 8), the Control of Substances Hazardous to Health Regulations 2002 (COSHH) (Regulation 6(4)), the Dangerous Substances and Explosive Atmospheres Regulations 2002 (DSEAR) (Regulation 5(4)) etc. For licensees of nuclear installations, LC 23 also requires them to produce an adequate safety case on any operation that may affect safety to demonstrate the safety of that operation and to identify the conditions and limits necessary in the interests of safety. Similarly, the Control of Major Accident Hazards Regulations 2015 (COMAH) Part 3 requires the operator of an upper tier establishment, who can be a part or whole of a nuclear licensed site, to prepare a safety report for the purpose of demonstrating that the major accident hazards and possible major accident scenarios in relation to the establishment have been identified, and the necessary measures have been taken to prevent such accidents, and to limit their consequences for human health and the environment.
3. It is important to note that although there are legal duties to record risk assessments, produce safety cases and safety reports, there is no explicit legal requirement for a dutyholder to produce a specific document to demonstrate that risks are reduced to ALARP. However, in making its judgement on whether a dutyholder has reduced, or will reduce risks to ALARP, ONR expects dutyholders to be able to provide the relevant evidence that may be captured in a written form. In court proceedings, dutyholders will also be asked to present evidence to demonstrate they have reduced risks to ALARP.
4. Many dutyholders will have quantitative risk assessment methodologies as part of their safety case processes. ONR recognises the importance these analyses may have to inform engineering choices and demonstrating the effectiveness of decisions made to reduce risks. ONR may take such analysis into consideration when making a judgement against one or more of the numerical targets in the SAPs.

### 5.2.4. Appropriate use of RGP

1. When making judgements on the adequacy of a dutyholder’s evidence to support the demonstration that risks are reduced to ALARP, ONR may accept the application of RGP in an appropriate manner as a sufficient demonstration (refer to Section [5.1.6](#_5.1.6._Relevant_good)). ONR does not normally accept a lower standard of protection than those outlined in the current RGP.   
   Where dutyholders choose to adopt a different approach to reduce risks to ALARP than those outlined in the RGP, ONR may seek further assurance that the risks from the dutyholders’ approach are no greater than the level achieved by adopting the RGP.
2. The appropriate use of RGP at the design stage of a project/facility is key to have considered the risks involved in the whole lifecycle of a project/facility, including end of life considerations. This should include the proportionate use of inherently safer design principles as well as codes, standards and guidance. ONR’s SAPs follow the general principles of prevention outlined in Schedule 1 of MHSWR, by aiming to eliminate a hazard in preference to controlling the hazard, and controlling the hazard in preference to relying solely on good behaviours from people involved, and collective protective measures in preference to individual protection measures. ONR makes its judgements on whether a design, or a particular approach, reduces risks to ALARP based on its knowledge as a regulator, including its knowledge of RGP in that area, and its knowledge of other possible design options.
3. ONR expects dutyholders to ensure risks arising from a new facility or activity meet the BSLs set out in the SAPs as a minimum (refer to Section [5.3.1](#_5.3.1._Tolerability_of)). However, even if the BSLs are met, the risks may not be reduced to ALARP. In such circumstances, ONR expects dutyholders to have considered other potential options to reduce the risks to ALARP and implement those options unless they can be adequately justified as not being reasonably practicable by applying the test of ‘gross disproportion’ (refer to Section [5.1.4](#_5.1.4._Grossly_disproportionate)).
4. When reviewing health and safety measures on an existing facility for the purpose of retrofitting, safety reviews or upgrades, for example, in a Periodic Safety Review (PSR), ONR expects dutyholders to compare existing measures against current RGP [18]. This could include modern standards which were not in force when the facility was designed and constructed.   
   It may not be reasonably practicable in all cases to retrospectively apply RGP expected for a new facility to an existing facility, i.e. older facilities may satisfy the ALARP demonstration at higher risks than new ones (refer to Section 6 of [19] for case law information on ‘time’ and [Appendix 2](#_Appendix_2:_Time)). However, there may still be ways for dutyholders to further reduce risks to ALARP, such as by partial solutions or alternative measures or when new technology/ practices become available. ONR expects dutyholders to take due account of aspects such as the age of the facility, its future lifetime, future operations and the degree and importance of any shortfall, when considering compliance and the reasonable practicability of improvements.

## ONR’s approach in regulating duties to reduce risks to ALARP

### 5.3.1. Tolerability of risk

1. The concept of tolerability of risk (TOR) was set out in HSE’s   
   ‘The Tolerability of Risk from Nuclear Power Stations’ [20] and expanded by ‘Reduce Risk and Protecting People (R2P2)’ [21], which divides risks into three regions: broadly acceptable; tolerable; unacceptable (Figure 1).



Figure 1 - Tolerability of risk (TOR) framework

1. Although TOR was developed for nuclear power stations, the principles carry over to all safety risks management, and was adopted by regulators in GB, for example, HSE, Office of Rail and Road (ORR), Civil Aviation Authority (CAA). TOR does not come from the law, but is a well-established regulatory policy used to inform regulators on their regulatory decisions and areas of attention. ONR’s ‘Risk-informed regulatory decision making’ document [2] and Section [5.3.3](#_5.3.3._Risk-informed_regulatory) explain in more detail how ONR makes its regulatory decisions incorporating the ALARP judgements.
2. As explained in R2P2, “tolerability” refers to the general willingness of society as a whole to live with a risk so as to secure certain benefits [21]. Broadly acceptable risks are those that are commensurate with or smaller than the ordinary day-to-day risks that most people accept as part of their daily life (for example, in crossing the road or undertaking routine rail and air travel). Unacceptable risks are those that would be considered too high even for those who tolerate higher personal or professional risks (such as workers in the highest risk professions such as offshore fishing or mining) and, save for some exceptional minority groups, would not be tolerated for the majority for any significant period.
3. It is important to note that the legal duty for dutyholders to reduce risks to ALARP is independent from the TOR concept. Dutyholders are required by law to reduce risks to ALARP regardless of whether the level of risk is judged to be tolerable or not by the regulators. It is possible for a risk to be ‘unacceptable’ (i.e. in terms of its magnitude to wider society and thus subject to the highest level of regulatory attention) even if the dutyholder has met its legal obligation to ensure that the risk, despite its magnitude, is still reduced to a level that is ALARP. Likewise, it is possible for a risk to be ‘broadly acceptable’, and therefore not attract any significant regulatory attention, while the dutyholder has not, or is yet to, demonstrate the risk is reduced to ALARP.
4. The TOR framework has been translated into nine numerical targets in ONR’s SAPs, which are in the form of Basic Safety Levels (BSLs) and Basic Safety Objectives (BSOs). These give numerical values for the BSL and BSO across a series of different measures of risk associated with nuclear safety, from the risk to individuals to groups and in both normal operation and under fault/accident circumstances. In each case, the BSL provides the boundary between the ‘unacceptable’ and ‘tolerable’ regions of TOR and the BSO gives the boundary between the ‘tolerable’ and ‘broadly acceptable’ regions.

### 5.3.2. Risk-informed targeted engagement

1. It is ONR’s policy to use its resources responsibly and in a targeted manner to make timely judgements and decisions, without placing an unnecessary burden on the dutyholders and recognising the finite resource available to ONR for delivering its regulatory activities [22]. This means ONR will focus primarily on those activities that give rise to the most serious risks, where the hazards or vulnerabilities are least well controlled, or where ongoing compliance with the law needs to be established. These target areas are informed by the intelligence and insights ONR collects through its regulatory activities.
2. In prioritising its resources, ONR will generally not seek further improvements from a dutyholder where risks have been demonstrably reduced to within the ‘broadly acceptable’ region of the TOR framework (BSOs) (refer to Section [5.3.1](#_5.3.1._Tolerability_of)), and only a small reduction in risk could be achieved from those further improvements. However, the legal duty to reduce risks to ALARP remains on the dutyholder, and this includes reducing risks in the broadly acceptable region (refer to paragraph 701 of the   
   SAPs [1]).
3. If ONR decides a dutyholder’s activity falls into the ‘tolerable’ region of the TOR framework (between BSOs and BSLs), which is the case for most activities a dutyholder undertakes, ONR’s regulatory attention and resource allocation will be dependent on the nature of the risks, the adequacy of dutyholder’s demonstration on reducing risks to ALARP, and the risk gap.
4. If ONR decides a dutyholder’s activity leads to a level of risk that is elevated to a level such that it falls into the ‘unacceptable’ region of the TOR framework (exceeds BSLs), this will be an area of priority for ONR’s regulatory attention and resources will be allocated accordingly. In such cases ONR expects the dutyholder to be actively managing and prioritising the situation to reduce the level of risk to at least a level that is tolerable and ALARP, as quickly as possible.

### 5.3.3. Risk-informed regulatory decision-making

1. ONR’s ‘Risk-informed regulatory decision making’ (RIRDM) document [2] includes Figure 2, which illustrates the key elements of ONR’s regulatory decision-making framework, incorporating relevant law and policies.
2. ONR recognises that dutyholders may need to conduct their undertakings in a given way in order to secure certain societal or public interest benefits such as activities in ‘the interests of national security’ or ‘keeping the lights on’, or because ‘the priorities for a fixed national (government) budget lie elsewhere’. Claims related to such factors can sometimes appear in safety cases or safety reports in the context of ‘time’, or ‘trouble’ aspects, on the sacrifice side of the ALARP balance. Furthermore, ONR recognises that dutyholders do not have unlimited resource, and some form of work prioritisation is often necessary. Claims related to these factors can sometimes appear in safety cases under the banner of ‘group or global ALARP’, ‘programme ALARP’, ‘holistic ALARP’ or ‘dynamic ALARP’. Dutyholders use these terms to convey prioritisation, strategic factors and/or wider national factors.
3. Similarly, there may be cross-dutyholder industry projects where a high-level consideration is given to risk optimisation for particular hazards across the activities of more than one dutyholder. Individual dutyholders may cite related strategic ‘risk optimisation’ decisions within their overall ALARP claim. While such a study may be useful to inform the overall project risks, it is important to recognise that dutyholder duties to reduce risks ALARP only apply to risks the dutyholder controls.
4. Although it is understandable that dutyholders seek to include wider factors in their ALARP arguments, they are outside the scope of health and safety legislation. Therefore ONR’s judgements on whether dutyholders have demonstrated reducing risks to ALARP are independent of these factors.
5. If the level of a risk has not been reduced to ALARP by the dutyholder, ONR can and should consider the relevant dutyholder and strategic factors in making its regulatory decisions. However, wider national factors do not influence ONR’s regulatory decisions, as ONR does not have the legal authority or sufficient knowledge of the factors involved to make a judgement of their significance and then balance this against the safety of a facility or an activity (refer to [2] for more detail).

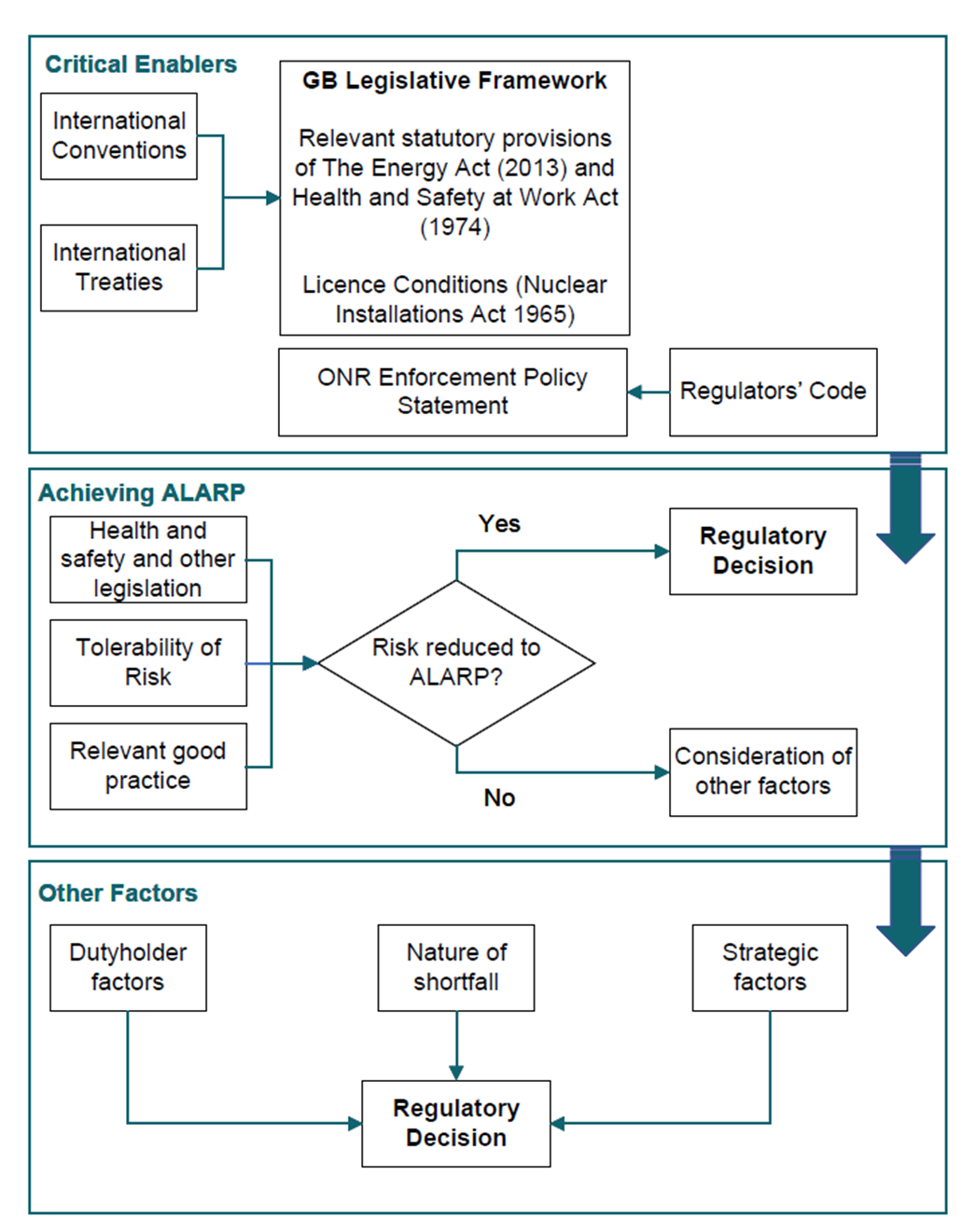


Figure 2 - Key elements of ONR’s regulatory decision-making process.

# Advice to Inspectors

1. In addition to the concepts outlined in Section [5](#_Concepts_supporting_regulatory), ONR developed this section to provide guidance to its inspectors on the law, its interpretation by the courts, and on RGP. This section also provide guidance to inspectors in exercising discretion to promote consistency in assessing compliance and delivering proportionate outcomes.
2. An inspector’s judgement on whether dutyholders have met their legal obligations in reducing risks to ALARP is often complex or multifaceted. There is no simple formula for computing what constitutes ALARP, which means the judgement is primarily qualitative rather than quantitative, taking into account the full range of hazards, operating states and levels of defence in depth. In some cases, dutyholders may choose to use quantitative measures to support their arguments demonstrating risks have been reduced to ALARP, and inspectors may use the numerical targets set out in the SAPs to inform their own judgement, but there is not a single numerical measure for judging whether risks have been reduced to ALARP.
3. It is for dutyholders to carry out suitable and sufficient risk assessment on risks under their control and ensure that existing or proposed measures reduce risks to ALARP. This is an ongoing legal duty. ALARP should not be used by a dutyholder to argue against other statutory duties that may mandate certain control measures to be implemented. (refer to Section [5.2](#_ONR’s_expectation_of))
4. In certain situations, as a result of specific legislation or licence conditions (refer to Section [5.2.3](#_5.2.3._Written_assessment)), dutyholders are required to present a written, reasoned safety case or safety report justifying the safety of an operation or an establishment/installation (including the design) and satisfy ONR that the safety case or safety report is adequate. Inspectors should use a risk-informed and proportionate approach in sampling the dutyholder’s safety case or safety report to reach an appropriate judgement.
5. It is important for regulators to understand why and how a dutyholder considers it meets the legal obligations to reduce risks to ALARP. Inspectors may offer guidance to assist dutyholders. However, inspectors need to reach a judgement in inspection, assessment, permissioning, and formal enforcement, as to whether a dutyholder has met their legal obligations to reduce risks to ALARP. This judgement is an essential part of ONR’s decision-making process. (refer to Section [5.3](#_ONR’s_approach_in))
6. Inspectors should ensure their engagements with dutyholders are appropriately targeted and deliver balanced, proportionate and consistent judgements on whether dutyholders have met their legal obligations to reduce risks to ALARP. (refer to Section [5.3.2](#_5.3.2._Risk-informed_targeted))
7. The indicators below provide guidance to inspectors as part of informing their judgement on whether a safety case or safety report submitted by a dutyholder is adequate or not:

* The rigour of a safety case or safety report should be propotionate to the level of hazard in the scenario under consideration.
* There should be evidence of an adequate and fit-for-purpose risk assessment that underpins the ALARP demonstration (refer to Section [5.2](#_ONR’s_expectation_of)).
* The dutyholder’s risk assessment and ALARP demonstration should take adequate account of all relevant types of foreseeable risks that are under their control. This should include all permitted operating states and different levels of defence in depth. On complex high hazard facilities this will almost certainly involve utilising PSA to completement a deterministic safety demonstration (refer to Sections [5.2.1](#_5.2.1._Consideration_of) and [5.2.3](#_5.2.3._Written_assessment)).
* There are nine numerical targets in the SAPs. These should be used to target ONR’s attention for nuclear safety hazards.
* Where dutyholders have provided a quantitative risk assessment such as a reactor PSA, inspectors should be mindful of any limitations in such assessment, which should include a deterministic safety assessment in the overall ALARP argument. For example, a reactor PSA may not address the full scope and modes of operations such as routine and maintenance operations.
* RGP is a generic term for those control measures, standards, policies and other practices which are relevant to a situation and that, if implemented, would usually be considered to meet a goal-setting obligation or expectation. These must be good practices that are sufficient to meet the overall legal requirement (for example, reducing risk to ALARP), and not best practices which go beyond the legal requirement (refer to Sections [5.1.6.1](#_5.1.6.1._The_concept), [5.1.6.2](#_5.1.6.2._Relevant_and) and [5.2.4](#_5.2.4._Appropriate_use)).
* RGP is a regulatory concept and not the law. A dutyholder is always free to do something different providing it meets the legal requirement to reduce the risk to ALARP (refer to Section [5.1.6.1](#_5.1.6.1._The_concept)).
* For commonly-encountered situations where the control measures are well-established and understood, application of RGP may be sufficient to demonstrate risks are reduced to ALARP. In novel or unusual circumstances, or in cases where the underlying risk is high, RGP is usually only a starting point to a more detailed assessment against the legal requirement (refer to Section [5.1.6.3](#_5.1.6.3._How_and)).
* It is role of the ONR specialisms and regulatory teams to determine what is the appropriate RGP from a range of potential good practices, if available, for their particular interventions, especially in permissioning and assessment (refer to Section [5.1.6.4](#_5.1.6.4._Determining_RGP)).
* Dutyholders should implement measures to reduce risks to ALARP unless they can demonstrate mesures are not reasonably practicable by applying the the test of ‘gross disporpotion’ (refer to Section [5.1.4](#_5.1.4._Grossly_disproportionate)).
* Where measures are concluded not to be reasonably practicable by the dutyholder, partial implementation or alternative measures should have been considered before applying the test of ‘gross dispropotion’.
* A CBA on its own is not acceptable as a standalone ALARP demonstration and should only be used if necessary (refer to   
  [Appendix 1](#_Appendix_1:_Cost)).
* All relevant options at different stages of the lifecycle of the plant/facility/installation/project/establishment should have been considered by the dutyholder and the optioneering should start with the option that reduces the risk the most (as opposed to the cheapest) (refer to Section [5.2.2](#_5.2.2._Consideration_of) and [Appendix 3](#_Appendix_3:_Optioneering)).

1. It is important to ensure appropriate cross-discipline working within ONR to make balanced and proportionate judgements. ONR Inspectors and relevant staff are advised to seek advice from the ALARP Working Group and relevant technical specialists in making their judgements, especially on complex and/or novel cases.

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# Glossary

ACoP Approved Code of Practice

ALARA As low as reasonably achievable

ALARP As low as reasonably practicable

BAT Best Available Technique

BSL Basic Safety Level

BSO Basic Safety Objective

BPM Best Practicable Means

CAA Civil Aviation Authority

CAR Control of Asbestos Regulations 2012

CBA Cost Benefit Analysis

CDM15 The Construction (Design and Management) Regulations 2015

COMAH The Control of Major Accident Hazards Regulations 2015

COSHH The Control of Substances Hazards to Health Regulations 2002

DSEAR The Dangerous Substances and Explosive Atmospheres Regulations 2002

F(S)A The Fire (Scotland) Act 2005

FSO The Regulatory Reform (Fire Safety) Order 2005

GB Great Britain

GDA Generic Design Assessment

HSE The Health and Safety Executive

HSWA The Health and Safety at Work etc. Act 1974

IAEA International Atomic Energy Agency

IRR17 The Ionising Radiation Regulations 2017

LC Licence Condition

MHSWR The Management of Health and Safety at Work Regulations 1999

NIA 1965 The Nuclear Installations Act 1965

ONR Office for Nuclear Regulation

ORR Office of Rail and Road

PSA Probabilistic Safety Analysis

PSR Periodic Safety Review

R2P2 Reducing Risk and Protecting People

RGP Relevant Good Practice

RR(FS)O The Regulatory Reform (Fire Safety) Order 2005

SAP Safety Assessment Principle(s)

SFAIRP So far is reasonably practicable

SRL WENRA’s Safety Reference Levels

TEA The Energy Act 2013

TOR Tolerability of Risk

UK United Kingdom

WENRA Western European Nuclear Regulators’ Association

# Appendix 1: Cost benefit analysis (CBA)

1. There may be circumstances where established good practice does not exist, or is out of date, or where multiple hazards are present and the RGP for one hazard is not foreseen in the RGP for another. This may introduce conflicts between RGPs, and the ALARP judgement is complex. CBA aids the decision-making process by giving the cost (sacrifice) and benefit a common unit, usually monetary values, so the test of ‘gross disproportion’ (refer to Section [5.1.4](#_5.1.4._Grossly_disproportionate)) is easier to understand for the decision makers.
2. It is important to note that a CBA on its own:

* does not constitute an ALARP case,
* cannot be used to argue against legal duties, and
* cannot justify risks that are intolerable or caused by evidently poor engineering.

1. A CBA cannot be used to argue against the implementation of RGP, unless the alternative measures are demonstrated unequivocally to be at least as effective.
2. One of the difficulties in making a robust quantitative argument is that many of the factors, both in determining the sacrifice and safety benefits, are subject to sizeable uncertainties. Hence, in making a case, particularly where it uses quantitative methods, appropriate sensitivity studies to test the robustness of the arguments are usually required. Paragraph 30 of the SAPs [1] follow the same precautionary approach as outlined in HSE’s publication “Reducing Risk and Protecting People” (R2P2) [21] in the face of uncertainty, i.e. assume that precautions should be taken unless there is good evidence to suggest that the risk is insignificant.
3. Due to the uncertainties and limitations of CBA, ONR does not expect dutyholders to undertake a detailed CBA for the majority of ALARP demonstrations. In circumstances where a CBA is used by a dutyholder, the degree of quantification in CBA is case dependent, but it should be sufficient to make the case fit-for-purpose, i.e. more rigour is required where the risk is higher, or the consequences themselves are severe, such as resulting in multiple fatalities. There should also be a process of systematic identification and assessment of benefits and detriments, supported by a suitable sensitivity analysis. In such cases, ONR will follow the published HSE guidance on CBA in support of making ALARP judgements on a case-by-case basis [4].

# Appendix 2: Time at risk situation specific considerations

1. There are three main types of situation in which ONR may consider the acceptability of increased risk for a short period for longer term benefit when making judgements on whether risks are reduced to ALARP (refer to   
   Section [5.2.2](#_5.2.2._Consideration_of)): through-life risk, residual facility life, and end of life legacy. There are many reasons that may cause elevated short-term risks, as such, ONR will consider each specific situation on a case-by-case basis.

## Through-life risk

1. This is the situation where a short-term increase in risk may be justified to enable the continued normal operation of a facility. Examples include undertaking certain maintenance activities, temporary disconnection of safety measures to allow completion of essential tasks, or other intermittent activities that are required to sustain safe operation of the facility, such as during an emergency condition.
2. ONR does not accept cases based solely on the argument around the extent of time, i.e. short-term, for which the risk is increased without considering appropriate RGP and whether additional measures are necessary.
3. During those operations that impose a planned and justified increase in short-term risk, ONR expects the dutyholder to undertake additional monitoring of the actual plant state to ensure that the mode of operation and the time during which it persists meet the assumptions in the demonstration that risks are maintained at such level that is ALARP.
4. Unexpected failures of plant and equipment may lead to an increase in specific risks that are elevated to a level such that they are judged by ONR to be ‘unacceptable’ using the TOR framework (refer to Section [5.3](#_ONR’s_approach_in)). In such cases the dutyholder should be actively managing and prioritising the situation to reduce the risks back to at least a level that is tolerable and ALARP, as quickly as possible. ONR expects the dutyholder to not allow such facility to operate at this level of risk, unless there is no safer alternative (paragraphs 699-700, [1]).

## Residual Facility Life

1. This is the situation where, as a facility ages, its safety margins may be eroded (paragraph 35, [1]), for example due to ageing effects, or its risks may appear high when compared to newer facilities designed to more modern standards. Dutyholders might argue in their ALARP justifications that the short remaining operating life of the facility means that investment required to upgrade the facility is unreasonable.
2. In making judgements on these situations, ONR expects the remaining lifetime should be short in comparison to the total design or operational life of the facility. This can be difficult where the ageing is gradual and there is no obvious transition from 'safe' to 'not safe'. Therefore, ONR expects the dutyholder to carry out careful monitoring and regular review, as required through the compliance with their LC 15 arrangements on PSR [18] and asset management [23].
3. ONR expects dutyholders to update their ALARP demonstration to take account of any relevant new knowledge or experience and data appropriate to the current and predicted future state and mode of operation of the facility. Comparison with modern standards of engineering and operation and risk criteria should be undertaken by the dutyholder.
4. ONR expects dutyholders to show that the risks from a facility remain tolerable and ALARP for future operations through the revised risk assessment. For example, the numerical risk for nuclear safety estimates should not be greater than BSLs (the ‘unacceptable’ region of TOR framework, refer to Section [5.3](#_ONR’s_approach_in)). If ONR judges risks to be intolerable, it expects the dutyholder to stop operating the facility and not undertake further operations, unless there is no safer alternative or risks are reduced to a tolerable level. Proposed limits on remaining lifetime may be invoked by dutyholders in making the ALARP argument, but this cannot be used by dutyholders to justify a facility operating in the intolerable region.
5. ONR does not accept arguments from dutyholders to not make an improvement based largely on limited future lifetime, unless where the maximum extent of the future operational life is irrevocably fixed. In cases where the planned lifetime is not irrevocably fixed, a minimum period of ten years (or the unavoidable necessary life of the facility, if longer) would be considered by ONR for the purposes of the ALARP demonstration (paragraph 35, [1]).

## End of life legacy

1. This is the situation where clean-out and decommissioning of a facility at its end of life that may lead to justified increase in risks for the short-term to enable the longer-term risks to be reduced or eliminated. Dutyholders may argue this is reasonably practicable if remediation of the facility is to be completed to reach a safer end state.
2. ONR expects dutyholders to balance such increased risks against the continuing risks arising from doing nothing, and to take due consideration of alternatives available to address the hazard. During the course of hazard reduction, which may be for a significant period of time, ONR expects dutyholders to put in place suitable engineering and/or operational arrangements to reduce the magnitude and time of the higher risk to ALARP. For example, balancing operational doses and the potential for accidental releases [24]. ONR does not accept arguments from dutyholders for extensive delays to hazard reduction by invoking CBA with significantly discounted future costs, or based simply on time at risk arguments (refer to [Appendix 1](#_Appendix_1:_Cost)).

# Appendix 3: Optioneering

1. Inspectors make judgements as to whether dutyholders are taking all reasonably practicable steps to ensure that risks are reduced to ALARP.   
   As a start to making these judgements, inspectors will generally look for evidence that a dutyholder has applied appropriate RGP to control the risks (refer to Sections [5.1.6](#_5.1.6._Relevant_good) and [5.2.4](#_5.2.4._Appropriate_use)). When turning to specific risks under certain circumstances, inspectors may sometimes seek further evidence that the dutyholder has looked at a range of options and has good reasons for choosing a preferred option. Furthermore, when those risks are significant, novel, complex or uncertain, then inspectors may expect the dutyholder to have followed a methodical process for making that choice (known as “optioneering” – refer to Section [5.2.2](#_5.2.2._Consideration_of)). Inspectors may then expect the dutyholder to show a proportionate level of evidence of their optioneering in their safety case or safety report documentation. This appendix describes some of the characteristics that ONR considers a robust optioneering process should have and key steps it should cover.

## Transparency

1. Optioneering should make clear the reasons why an option has been chosen and others discounted to support the overall demonstration that risks have been reduced to ALARP. These reasons are expected to be presented in safety case documents produced by dutyholders, or by requesting parties under the GDA process. Paragraph 102 of the SAPs concerning safety case characteristics (SC.4) states:

“the safety case should a) identify and document all the options considered for risk prevention or reduction b) provide evidence justifying the criteria used in decision making or option selection c) justify the options chosen” [1].

## Proportionality

1. Optioneering should give proportionate consideration to all options which could realistically improve safety, and then implement the option or combination of options, which achieves the lowest level of risk provided this is reasonably practicable. The depth and rigour of optioneering is always expected to be proportionate to the associated risk. For example, for situations which lack applicable RGP or where the solution has fallen short of applicable RGP in significant areas, then ONR expects the dutyholder to demonstrate that robust optioneering has been undertaken.
2. For design projects the optioneering should be proportionate to the scale and nature of the project and should cover the whole intended life-cycle, including end of operations and future decommissioning. For major new, complex or novel projects involving staged safety case submissions, optioneering is expected to branch out and cover individual functions of the design involving specialist disciplines. The process should converge upon a refined design solution covering each function while allowing root decision-making to be revisited. If detailed options appear to challenge good practice or foreclose options covering other functions, the process should allow for iteration. For simpler projects, only one iteration may be required.   
   For example, a modification to existing plant, or where change is limited to the operation of the plant or its maintenance, such as de-rating of plant or enhanced inspection or monitoring.

## Balance of risk

1. Optioneering should be proportionate in taking into account of the impact of all relevant health and safety risks (including nuclear) alongside other constraints to reach a balanced decision. Examples of other constraints include other legislative requirements covering safeguards, security, and environment.

## Key optioneering steps

1. Figure 3 illustrates an indicative optioneering process. This includes a number of steps up to the final decision-making step where one or more options may be selected for further design development and implementation.
2. An optioneering process covering the key steps in Figure 3 in a proportionate manner for the given circumstances could be considered by inspectors to meet RGP. The points below expand upon these key steps:

* Every option must meet the requirements/constraints informed by the applicable defined standards, these being minimum standards as specified by Acts, Regulations, Orders and appropriately informed by ACoPs.
* Each option should be informed by established standards, these being CoPs or other published or commonly known standards, for example SAPs.
* Each option should be evaluated against clearly selected factors including safety factors that cover all relevant risks of harm and which are accorded appropriate weighting and importance.
* When evaluating the options, priority should be given to achieving an overall balance of risk that is ALARP.
* Evaluation should prioritise options which minimise risk over life and for accident risks generally prioritise options with characteristics as near as possible to the top of the following list:
  + 1. avoidance of the hazard;
    2. fault tolerant design;
    3. passive safety measures that do not rely on control systems, active safety systems or human intervention;
    4. automatically initiated safety measures in preference to manually;
    5. safety measures which prevent or protect in preference to mitigate.
* When evaluating the options, implementation time can be an important factor for existing facilities where risk is already present. A risk-reduction option or combination of options which can be implemented sooner may remove more risk over remaining life than a more capable or robust option which takes longer to implement. In these circumstances the dutyholder should be able to demonstrate how the optimal risk reduction option has been reached.
* The study team should cover all relevant engineering disciplines and operating and maintenance roles and always cover the potential safety case and human performance impact.
* Decisions should be recorded along with the rationale behind them.
* Study reports should be produced in advanceof making decisions and appropriately maintained as records supporting the safety case.
* For major projects/GDA, optioneering is expected to be an ongoing process which branches into increasing levels of design detail and engages a wider spread of specialist disciplines as successive milestones are reached, and the associated safety case is developed. On reaching milestones a final review should confirm that key assumptions remain valid, and that the design continues to meet them before the relevant approval.

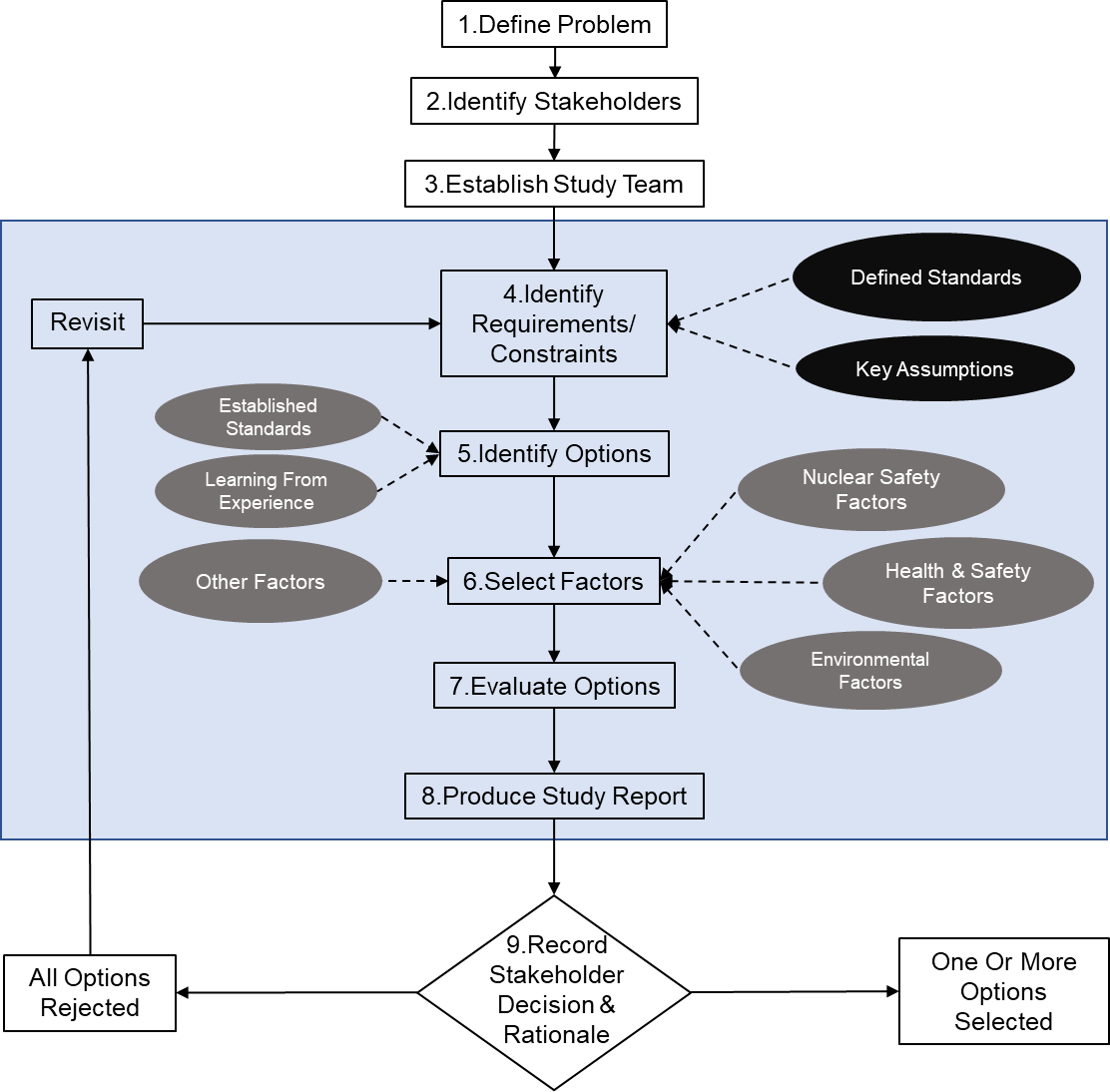


Figure 3 - Indicative optioneering process.

1. R v Board of Trustees of Science Museum [1993] ECWA Crim 2 reinforced this definition, but also established that a risk does not have to be realised in the context of health and safety legislation. [↑](#footnote-ref-2)
2. R v Tangerine Confetionery Ltd and Veolia (UK) ES Ltd [2011] EWCA Crim 2015. [↑](#footnote-ref-3)
3. Edwards v National Coal Board [1949] 1 ALL ER 743 (CA). [↑](#footnote-ref-4)
4. Including Code of Practice approved under The Energy Act 2013. [↑](#footnote-ref-5)