



<b>ONR GUIDE</b>			
<b>Guidance on the Demonstration of ALARP (As Low As Reasonably Practicable)</b>			
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## 1. INTRODUCTION

- 1.1 This Technical Assessment Guide (TAG) represents specific guidance for ONR inspectors on what they should expect of a nuclear licensee, requesting party (RP) or dutyholder<sup>1</sup> in meeting its legal requirement to reduce risks so far as is reasonably practicable (SFAIRP). The concept of SFAIRP is normally expressed in terms of reducing risks to 'As Low As Reasonably Practicable' (ALARP), the terms SFAIRP and ALARP being synonymous in guidance documents.
- 1.2 This TAG is part of a sequence of documents, headed by 'Reducing Risks, Protecting People' (R2P2) [1] and the series of ALARP Guides for use by health and safety inspectors published on the Health and Safety Executive's (HSE) and our websites. It is intended that ONR inspectors make use of all these documents when considering licensees' cases or arguments.
- 1.3 The requirement for risks to be ALARP is fundamental and applies to all activities within the scope of the Health and Safety at Work etc. Act 1974 (HSWA). It is important that inspectors in whatever role are aware of the need to ensure that licensees meet this requirement where it applies. In simple terms it is a requirement to take all measures to reduce risk where doing so is reasonable. In most cases this is not done through an explicit comparison of costs and benefits, but rather by applying established 'Relevant Good Practice' (RGP) and standards. The development of RGP and standards includes ALARP considerations so in many cases meeting them is sufficient. In other cases, either where standards and RGP are less evident or not fully applicable, the onus is on the licensee to implement measures to the point where the costs 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 (the safety benefit).
- 1.4 To aid use of this TAG in regulatory activities, a checklist is provided in [Annex 1](#) which references back to the appropriate text in the main body of the TAG. It is recognised that it is unlikely that all of the check points in Annex 1 will apply in any single case – inspectors will need to select those that are appropriate to the specific circumstances.
- 1.5 This TAG provides links to a number of other documents, in addition to R2P2 and the series of ALARP Guides referred to above. Two further key references are the ONR Guide to So Far As Is Reasonably Practicable [29], which provides more detail on the case law that has shaped the legal interpretation of SFAIRP, and the ONR Risk Informed Regulatory Decision Making [28] publication, which explains the role of SFAIRP/ALARP within the overall framework by which ONR makes regulatory decisions.

## 2. PURPOSE AND SCOPE

- 2.1 The purpose of this Technical Assessment Guide (TAG) is to provide advice to ONR inspectors to help them judge whether a licensee has met the requirement to reduce risks to ALARP. As such, the TAG is intended to be used for all ONR regulatory functions relating to nuclear safety falling within the remit of the HSWA.

## 3. RELATIONSHIP TO LICENCE CONDITIONS AND OTHER RELEVANT LEGISLATION

- 3.1 HSWA provides the basic legislation for health and safety related to work activities. HSWA places duties on employers to ensure the health, safety and welfare of their employees (Section 2) and to conduct their operations so that persons not in their

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<sup>1</sup> Hereafter, in the interests of brevity, 'licensee' should be interpreted as meaning licensee, requesting party or dutyholder as appropriate to the circumstances

employment are not exposed to risks to their health and safety (Section 3). The employer is required to ensure that these duties are met 'so far as is reasonably practicable'. This principle, abbreviated to SFAIRP, is therefore the basic legal requirement to which an employer needs to conform. ALARP (the term used in HSE and ONR guidance) and SFAIRP require the same tests to be applied and are effectively the same thing, though the terms are not interchangeable in legal proceedings (which must employ the wording in the legislation). ALARP is also equivalent to the term 'as low as reasonably achievable' (ALARA) as used internationally in relation to reducing ionising radiation exposure.

- 3.2 The parts of the Nuclear Installations Act 1965 (NIA) we are concerned with became Relevant Statutory Provisions of the Energy Act 2013 (TEA), rather than HSWA, on 1 April 2014; the impacts of this and related changes do not affect the guidance in this TAG.
- 3.3 It is important to recognise that not all the legal duties licensees need to meet are qualified by SFAIRP – so ONR's ALARP guidance should only be applied where this qualification is in place. For example, the duties in various Licence Conditions (LC), which are now Applicable Provisions of TEA, to make and implement adequate arrangements are not qualified by SFAIRP.
- 3.4 Nevertheless, the demonstration of ALARP will normally be made within the licensee's safety case required under Licence Condition 23. The need to demonstrate ALARP also arises in other legislation. For instance, specific legal requirements in relation to radiation protection are contained in the Ionising Radiations Regulations 2017 (IRR), which put into GB law the relevant elements of the EU Basic Safety Standards Directive 2013 (BSSD). IRR Regulation 9 requires that exposure should be restricted SFAIRP. Other relevant legislation is contained in the Management of Health and Safety at Work Regulations 1999, which requires a suitable and sufficient risk assessment, and in the Control of Major Accident Hazards Regulations 2015 (COMAH).
- 3.5 This TAG is written against the background of R2P2 [1] and the supporting documents published on the Internet which give guidance to health and safety inspectors on ALARP. This TAG extends the wider guidance to specific aspects of how ONR operates, the use of a licensing regime and other ONR guidance on inspection and assessment. Thus R2P2, the Internet guides (listed below) and this TAG taken together represent ONR guidance to our inspectors on ALARP.
- 3.6 This document assists in implementing EU Council Directive 2014/87/Euratom of 8 July 2014 amending Directive 2009/71/Euratom, by highlighting ONR's regulatory expectations regarding the achievement of nuclear safety and as reference for the timely implementation of reasonably practicable safety improvements (see Articles below) by nuclear site licence holders and, in particular, demonstrating that the International Atomic Energy Agency (IAEA) and Western European Nuclear Regulators' Association (WENRA) Safety Objectives and Safety Reference Levels underpin the UK's regulatory oversight of nuclear safety (See Section 4 and paragraph 4.6.)

**Article 8a Nuclear safety objective** for nuclear installations

8a (1) Member States shall ensure that the national nuclear safety framework requires that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with the objective of preventing accidents and, should an accident occur, mitigating its consequences and avoiding:

- (a) early radioactive releases that would require off-site emergency measures but with insufficient time to implement them;

(b) large radioactive releases that would require protective measures that could not be limited in area or time.

8a (2) Member States shall ensure that the national framework requires that the objective set out in paragraph 1:

(a) applies to nuclear installations for which a construction licence is granted for the first time after 14 August 2014;

(b) is used as a **reference for the timely implementation of reasonably practicable safety improvements** to existing nuclear installations, including in the framework of the periodic safety reviews as defined in Article 8c(b).

- 3.7 R2P2 sets out HSE's overall framework for decision-making to aid consistency and coherence across the full range of risks falling within the scope of the HSWA. This framework represents our risk management policy and is based on 'The Tolerability of Risks from Nuclear Power Stations' (TOR) published in 1992 [2]. TOR defines risks which are so high they are unacceptable unless there are exceptional circumstances, and risks which are so low that they may be considered broadly acceptable so that in most cases it would be disproportionate to apply regulatory time to reduce them further. Between these levels inspectors should consider whether risks have been reduced to ALARP, while recognising that the legal duty for risks to be ALARP is not limited to this range.
- 3.8 R2P2 explains our decision making process rather than providing guidance to individual dutyholders. The approach is essentially risk-based and R2P2 addresses the qualitative and quantitative role of risk assessment and the key role of good practice in determining control measures. Based on legal precedent [29], R2P2 considers risk to include the 'possibility of danger', though the terminology used in our guidance calls things that present the possibility of danger 'a hazard'.
- 3.9 The HSE ALARP guides published on the Internet (colloquially known as 'the ALARP six-pack') are:
- 3.10 [PRINCIPLES AND GUIDELINES TO ASSIST HSE IN ITS JUDGEMENTS THAT DUTYHOLDERS HAVE REDUCED RISK AS LOW AS REASONABLY PRACTICABLE](#) [3]. This paper defines ALARP and SFAIRP and sets out in plain terms what HSE believes the law requires.
- 3.11 [ASSESSING COMPLIANCE WITH THE LAW IN INDIVIDUAL CASES AND THE USE OF GOOD PRACTICE](#) [4]. This paper defines what HSE means by good practice and lists the responsibilities of Operating Directorates (which includes ONR) in respect of identifying and maintaining records of good practice.
- 3.12 [POLICY AND GUIDANCE ON REDUCING RISKS AS LOW AS REASONABLY PRACTICABLE IN DESIGN](#) [5]. This paper recognises the importance of taking account of health and safety in design and sets out HSE's intervention policy with respect to design. At licensed sites, intervention in the design is controlled by licence conditions attached under the powers of the NIA, and is a well established process (see NS-TAST-GD-051 [25] and Licensing Nuclear Installations [6]). For Authorised Sites, HSWA Section 6 and the Construction (Design and Management) Regulations 2015 (CDM) should be used.
- 3.13 [HSE PRINCIPLES FOR COST BENEFIT ANALYSIS IN SUPPORT OF ALARP DECISIONS](#) [7]. This paper explains the uses and limitations of Cost-Benefit Analysis (CBA) and is particularly concerned with the correct use of CBA as part of ALARP decisions.

- 3.14 [HSE - RISK MANAGEMENT: ALARP AT A GLANCE](#) [8]. This document summarises many of the key terms and concepts.
- 3.15 [HSE - RISK MANAGEMENT: COST BENEFIT ANALYSIS \(CBA\) CHECKLIST](#) [9]. This document summarises HSE's view of what should and should not be considered in a dutyholder's CBA for health and safety ALARP determinations.
- 3.16 NIA provides for ONR to attach Licence Conditions to a site licence in the interests of safety and with respect to the handling, treatment, and disposal of nuclear matter. Licence Condition 14 requires arrangements to “produce and assess safety cases ... to justify safety” and Licence Condition 23 requires an adequate safety case be produced and that the facility is then operated in accordance with that safety case. These safety cases still need to address the duty to reduce risks to ALARP from HSWA.
- 3.17 Under the IRRs, the licensee has to carry out a risk assessment prior to commencing work with ionising radiation, review progress during the job (for example tracking a dose budget) and consider plant, procedures and training aspects. A prime aim of these prior risk assessments, along with demonstrating legal limits on exposure etc. will be complied with, should be to ensure the risks, particularly those due to expected radiological exposures from the planned activities, will be reduced to ALARP.
- 3.18 Many decisions on what is needed to meet ALARP for conventional (i.e. non-radiological) safety are made at the time regulations are being written and judgements of acceptability can therefore often be made directly against the requirements of those regulations (although the legal duty to reduce risks SFAIRP still remains).

#### **4. RELATIONSHIP TO SAPS, WENRA REFERENCE LEVELS AND IAEA SAFETY STANDARDS ADDRESSED**

- 4.1 The SAPs [10] were developed against the background of the legal requirements and the TOR philosophy, and have been benchmarked against the IAEA Safety Standards. They contain engineering and operational principles, safety analysis requirements and numerical targets and legal limits. The need to demonstrate risks are ALARP is an overriding and all-embracing requirement. Paragraph 16 of the SAPs emphasises that “the principles are used in helping to judge whether reducing risks to ALARP is achieved ... This has not been stated in each case to avoid excessive repetition ...”. Furthermore, it is also a requirement of SAPs that “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 expectation from SAPs is that a safety case (see NS-TAST-GD-051 [25]) should provide an analysis of normal operation, potential faults and accidents, and of the engineering design and operations, and demonstrate the risks from all these perspectives have been reduced to ALARP.
- 4.2 The TOR philosophy has been translated into nine Numerical Targets in the form of Basic Safety Levels (BSLs) and Basic Safety Objectives (BSOs) (see SAPs para 695ff). It is however, essential that these are applied against a background of good engineering and operational practice. The BSOs represent broadly acceptable levels below which regulatory resources will generally not be used to seek further improvements, and where assessors should confine themselves to considering the validity of the arguments presented (SAPs para 701). This is a pragmatic approach to enable targeted and proportionate use of our resources; it is not a green light for licensees to forego ALARP considerations at such levels.
- 4.3 It is ONR policy that a new facility or activity should at least meet the BSLs (note that in a few cases the BSLs are legal limits derived from IRRs – these are designated as BSL(LL) in the SAPs). All the other Targets are policy guidance for inspectors and are not mandatory. Older facilities may have been designed and constructed to different safety standards and deterioration over time now means that BSLs are exceeded. In

these cases, provided the BSL is not a legal limit, it may be reasonable for operation to continue if:

- i) it has been shown that no reasonably practicable options are available to reduce risks further in the short term; and
- ii) a clear longer-term plan to manage and reduce risks within as short a period as reasonably practicable is in place.

- 4.4 The criteria for determining whether an explicit ALARP demonstration is required in relation to the Engineering SAPs, which represent ONR's views of RGP, are not set out in numerical terms. Instead, if the relevant SAP is evidently well satisfied, then the facility should be considered to be meeting the equivalent of the TOR broadly acceptable criterion on that particular point and therefore there is unlikely to be a need for further assessment against ALARP. Conversely, any non-conformance with RGP should be explicitly highlighted and then justified as reducing risks to ALARP within the safety case.
- 4.5 The hierarchy of safety measures set out in the Engineering Key Principles (EKP.1 to 5) and supporting guidance, particularly SAPs para 155 will usually be a key part of the ALARP analysis. Essentially the SAPs approach is to seek solutions as near to the top of the following list as possible: avoid the hazard; design to achieve fault tolerance; maintain safe conditions by passive means rather than active systems; initiate protection automatically in preference to manually; and mitigate fault consequences. This philosophy is also embodied in paragraph 8 of HSE's ALARP in Design paper [5].
- 4.6 In addition to SAPs, the IAEA Safety Standards and the Safety Reference Levels developed by WENRA for reactors, decommissioning, and the storage of radioactive waste and spent fuel [21] should be considered to be UK RGP. IAEA Safety Standards are developed by international consensus and were used to benchmark the SAPs [10]. The WENRA Reference Levels for reactors are much more specific and only apply to existing civil nuclear reactors. However, the decommissioning safety reference levels are RGP for all types of nuclear facilities and cover all stages in the lifecycle. The storage reference levels apply to facilities where radioactive waste or spent fuel is stored for a significant period of time. The UK, as a member of WENRA, has formally signed on to the Reference Levels and, in line with ONR's enforcement policy [22] in relation to RGP, we expect them to be followed. WENRA's safety objectives for new nuclear power plants [26] and guidance on timely implementation of reasonably practicable improvements to existing nuclear power plants [27] are also considered to be UK RGP.

## 5. ADVICE TO INSPECTORS – GENERAL POINTS

- 5.1 To aid use of this TAG in regulatory activities, a checklist is provided in [Annex 1](#) which references back to the appropriate text in the main body of the TAG. It is recognised that it is unlikely that all of the check points in Annex 1 will apply in any single case – inspectors will need to select those that are appropriate to the specific circumstances.
- 5.2 Our current advice [3] is that the essence of a demonstration that risks have been reduced ALARP is to show that the 'costs' (sacrifice) of improving safety any further would be grossly disproportionate to the safety benefits that would accrue from implementing any identified improvement compared to the status quo. This does not mean that a detailed analysis is necessary: the emphasis must be on an analysis which is fit-for-purpose. Neither does it mean that a quantitative argument based on risk estimates is always necessary, as qualitative features such as applying deterministic engineering principles may be sufficient in making a case. However, ONR inspectors should seek suitable and sufficient Probabilistic Safety Analysis (PSA) in addition to deterministic analysis for systems where there are significant hazards and

complexity. Assessing an ALARP demonstration is essentially a consideration of whether an adequate argument has been made that a further reduction in risk would not be feasible at a reasonable cost, given the magnitude of the risk. However where there are several risks which interact, whether arising from a single hazard or from different connected hazards, there may be a need for balancing to achieve the best overall solution.

- 5.3 Demonstration of ALARP requires the licensee to evaluate the risks and to consider whether it would be reasonably practicable to implement further safety measures beyond the initial proposals or what is currently in place. This ought to include the consideration of a number of options to identify which is the reasonably practicable option or collection of options that give the best safety benefit, and making this consideration transparent. In reality there may only be a limited number of options for dealing with a particular health and safety issue. However, features such as: good practice that HSE may have accepted as RGP; an option adopted elsewhere in similar circumstances; and the extent to which this option has worked in practice, often provide strong indications of what the ALARP solution might be.
- 5.4 The following represent principles which are likely to need addressing in most cases:
- 1 The application of ALARP can only be to risks which the licensee controls (e.g. it is not a requirement for nuclear power plant operators to consider other forms of electrical generation).
  - 2 Affordability, i.e. whether a company is in a position to fund improvements, is not a legitimate factor in the ALARP argument, though the cost of implementing the improvement is.
  - 3 ALARP cannot be used to argue against fulfilling statutory duties.
  - 4 The ALARP argument needs to consider all the types of risk that are relevant, not just the nuclear / radiological ones, and where these conflict with one another, ensure that an appropriate overall balance is achieved in regard to their management.
  - 5 ALARP demonstrations ought to consider all the various options which could realistically improve safety, and then implement the option or combination of options which achieves the lowest level of residual risk provided this is reasonably practicable ([HSE ALARP Principles](#) [3]). It is not adequate to start with the cheapest option first.

Similarly, inspectors should be alert to disproportionate consideration of 'deluxe' options that involve excessive cost being used to argue that there are no reasonably practicable improvements. The timescale for implementation may be a factor in the choice of the ALARP option, so due consideration should be given to less effective options that might be implemented with shorter lead times, especially where the risks are high or the resultant hazard reduction is significant.

In more complex situations, licensees will have to select an option taking cognisance of all relevant legislation such as safety, environmental and security. Paragraphs 6.36 to 6.40 provides guidance on developing an optimised solution where there are both safety and environmental duties to be met.

- 6 Existing facilities should be compared against relevant modern standards, including those not in force when they were designed / constructed. The safety case should consider the importance of any shortfalls and what options exist for improvement, again starting with the safest, and then consider the reasonable practicability of implementing them. Older facilities may meet the ALARP requirement at higher risks than new ones ([HSE ALARP Principles](#) [3]).

- 7 The ALARP case should be fit-for-purpose. If the risks are high then the demonstration of ALARP needs to be more rigorous than if the risks are low. The degree of rigour should also depend on the consequence level. For higher consequence situations the consequences should weigh more heavily than the frequency estimates. Furthermore, thought should be given to the robustness of the conclusions with respect to uncertainties and to any assumptions employed in the demonstration.
- 8 If the ALARP demonstration employs a comparison of costs and risk reduction benefits to rule out an improvement, then based on our current guidance [3], it must be shown that the costs (sacrifice) of the improvement would be ‘grossly disproportionate’ (see [Cost Benefit Analysis Principles](#) [7]). The law does not recognise an acceptable region other than when ALARP has been met so there is unlikely to be any sympathy in the courts for parity of costs and benefits, even at the TOR Broadly Acceptable level. Advice from HSE lawyers is that, provided the risk is more than fanciful, the courts would still seek ‘gross disproportion’. It is also true that, depending on circumstances, future health and safety court cases may lead to a change in interpretation of SFAIRP [29] and subsequently HSE and ONR guidance on this matter. However until such time we will continue to follow our existing guidance.
- i) There is however, no precise legal factor or HSE algorithm for gross disproportion. 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 3 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 2 was suggested, whereas for higher risks the factor should be about 10.
  - ii) Public Health England (PHE) (formerly the Health Protection Agency (HPA)) produced guidance relating to the dose saved resulting from routine exposure or minor accidents i.e. stochastic effects, up to about 100 mSv. This recommends that an increasing multiplier is used as the dose increases and comparison of licensees’ submissions with this approach may be valuable as part of our assessments [11].
  - iii) In view of these precedents, it is suggested that a factor of less than 10 in the vicinity of a BSL is unlikely to be acceptable and, for hazards that can cause large consequences, the factor may need to be larger still.

## 6. ADVICE TO INSPECTORS – DETAILED REQUIREMENTS

### RGP

- 6.1 ALARP demonstrations should consider first and foremost factors relating to engineering, operations and the management of safety. These expectations are often referred to by the general term ‘Relevant Good Practice’. Based on HSE guidance [4], RGP is “... those standards for controlling risk which have been judged and recognised by HSE as satisfying the law when applied to a particular relevant case in an appropriate manner.” In nuclear safety applications, where the potential consequences of accidents can be very serious, the latest RGP identified as appropriate to the application would normally be required for new designs. [Annex 2](#) contains further guidance on the application of ALARP for new civil nuclear reactors in the context of

Generic Design Assessment [20]. [Annex 3](#) contains responses to a number of frequently asked questions in relation to RGP.

- 6.2 For an existing facility, RGP is established by using the standards that would be applied to a new design as a benchmark and then subjecting any shortfalls to the test of reasonable practicability. Unless the sacrifice entailed in moving towards the benchmark is grossly disproportionate to the safety benefit, the licensee should make that move.
- 6.3 What is accepted as RGP may change over time because of technological innovation which improves the degree of control, cost impact of improvements or knowledge about the hazard. For existing facilities in Periodic Safety Reviews (PSRs), the facility should be compared with the benchmark of modern standards (see NS-TAST-GD-050 [23] on PSRs for more information). Due account should then be taken when considering compliance and the reasonable practicability of improvements, of aspects such as the age of the facility, its future lifetime, future operations and the degree and importance of any shortfall.
- 6.4 In terms of specific sources of RGP for the nuclear industry there are several legal requirements which must be met and in some cases ACoPs (Approved Codes of Practice) and Guidance have been issued (e.g. the ACoP to the IRRs [12]) to assist the licensee in achieving compliance.
- 6.5 Standards exist for many engineering and operational features and it is a feature of new designs that licensee proposals may be based on non-UK standards. Such standards should be subject to assessment to ensure they represent appropriate RGP in a UK context. There are also several international bodies which produce standards or guidance documents: where the UK is tied by international agreements, e.g. EU, the standards have the same status as UK ones; where such agreements do not exist, the guidance may be considered as authoritative, but subsidiary to UK requirements. In a nuclear context, IAEA Safety Standards and the Safety Reference Levels developed by WENRA for reactors, decommissioning, and the storage of radioactive waste and spent fuel [21] should be considered to be RGP.
- 6.6 ONR inspectors should use the SAPs together with the associated TAGs to judge whether licensees' claims for RGP are justified. As the TAGs are revised they will be updated in line with the SAPs and will also include explicitly the WENRA Reference Levels that are relevant to the TAG in question. Similarly, ONR guidance on inspection (TIGs) provides the means by which many day-to-day RGP decisions are made, e.g. in regard to operational safety.
- 6.7 Another important source of RGP in the nuclear industry is what is done on similar facilities. Many licensees have established their own standards reflecting good practice that are acceptable to ONR. However in invoking past practice it is important to be clear whether the practice remains relevant and whether it was implemented for safety reasons. In reaching a decision to implement measures to reduce risks, licensees sometimes take into account additional factors that are not directly safety related (e.g. lower insurance premiums, enhanced commercial reputation etc). It is important that inspectors do not take such factors into account when considering whether licensee precedents represent RGP (see para 19 of R2P2 appendix 3 [1]).
- 6.8 In many cases licensees will claim that the implementation of a particular RGP or standards is sufficient to demonstrate ALARP. In assessing such claims inspectors should apply SAPs ECS.3 to ECS.5 and EQU.1 (paras 169 to 177) and in particular may consider:
- the good practice or standard should be relevant to the specific application, plant, facility or industry in question.

- the good practice or standard should be up-to-date, taking account of the current state-of-the-art: any practice or standard more than a few years old, or not subject to active ongoing monitoring and review or not written by acknowledged experts may be suspect.
- the good practice or standard should not be in the form of a minimum requirement.
- where a good practice or standard allows for more than one option, these should be tested to determine those which are reasonably practicable.
- the good practice or standard should include explicitly all relevant factors, particularly relating to assumptions on the standards of contingent systems or inputs/outputs. Standards and good practice may relate to single Systems, Structures and Components and further consideration may need to be given to possible interactions.
- there should be no doubt about the applicability of the good practice or standard to the case in point.

### Explicit Comparisons

- 6.9 Deciding what is reasonably practicable involves the exercise of judgement and enforcing authorities will generally expect RGP to be followed. Where RGP in particular cases is not clearly established, health and safety law effectively requires dutyholders to establish explicitly the significance of the risks to determine what action needs to be taken. Where it is not possible to demonstrate ALARP by good practice features and risk estimates alone, the benefits of risk reducing measures should be compared with their costs. Sometimes it is helpful to use a common unit, which is generally money, so that the analysis may become a form of CBA. The degree of quantification is case dependent, but must be sufficient to make the case fit for purpose. In particular, a CBA is unlikely to be considered an adequate argument on its own that a situation is ALARP [14]. The following paragraphs give further brief guidance on quantitative approaches, on numerical estimation of risks, and on the application of CBA and other quantitative approaches. Further guidance to inspectors is provided in HSE's generic Principles for CBA [7]; the CBA Checklist [9]; HSE's policy in regard to CBA which is summarised in Appendix 3 of R2P2 [1] and paragraphs 101-108 of its main text.

### Risk Estimation

- 6.10 The outline of a quantitative case is relatively straightforward. The benefit requires two estimates of risk: one before the implementation of the improvement and one after. The safety benefit of the improvement is the incremental difference in risk between the two estimates in terms of the detriments (i.e. all the adverse consequences) and their likelihoods, summed over the remaining life of the facility. It is anticipated that a broad comparison of these benefits and the costs of the improvement can in many cases lead to a decision without needing to translate the risk reduction into monetary terms. In other cases the detriments may need to be expressed in terms of money to compare with the costs of the improvement.
- 6.11 The level of risk without the improvement sets the starting point on the risk scale and so influences the gross disproportion factor (see para 5.4 (8) and [9]). The selection of an appropriate gross disproportion factor will also depend on the robustness of the analysis and so should be one of the parameters varied in sensitivity studies.
- 6.12 Where a CBA is employed, inspectors should verify that the scope of the CBA is sufficient and comprehensive. In particular, there should be a process of systematic

identification and assessment of benefits and detriments, supported by a suitable sensitivity analysis.

- 6.13 The use of CBA for comparing the sacrifice from making improvements against the safety benefits gained is part of the regulatory process followed during the production of new regulations by HSE and other government departments. Less well developed is the use of CBA in decision making within the type of goal-setting regulation which ONR uses. TOR [2] Appendix 3 considers the application of CBA to nuclear safety assessment and concludes that whilst it may be useful in some circumstances (e.g. where quantification can be obtained without disproportionate effort or excessive uncertainty), it was not feasible, at the time of writing to develop a CBA 'rule book' approach that can be applied mechanistically. Principles for CBA [7] further acknowledges that HSE has no algorithm to determine this factor, which needs to be set on a case-by-case basis. Subsequent regulatory experience (since TOR) suggests there would be little benefit in ONR developing such a 'rule book' in view of the types of safety case arguments we normally see and the overriding need for licensees to consider RGP as the starting point for their risk assessments. Cost screening can be a useful aid to help decide if more needs to be done; justified risk estimates are used together with reasonable accident cost estimates, to provide an indication of the amount worth spending to remove the risk. If this amount is low, even taking account of potential uncertainties and gross disproportion, compared with the cost of any realistic risk reduction measures, then it can be a useful indicator that no further risk reduction is needed.
- 6.14 In calculating the accident risk it is important that all the changes in risks due to the potential modification are accounted for (see also para 17 of the HSE ALARP Principles [3]). It is important to be sure that licensees do not understate the value of the benefit from the improvement by limiting the analysis to only the most severe of risks. Assessors should therefore check that licensees have not masked potential improvements which would affect non-dominant risks by considering only changes to the overall risk: all possible risk reductions should be viewed on their own merits.
- 6.15 Some quantitative arguments may involve balancing risks, for example implementation of a modification to reduce risk to the public might lead to a dose uptake during the work, and hence a transfer of risk. Although TOR [2] gives the tolerable individual risk to a worker as ten times higher than that to the general public, this should not be interpreted to imply that risks to different groups should be valued differently for ALARP purposes (see HSE ALARP Principles [3]). The issue of balancing risks may also need to involve cooperation with other agencies (the Environment Agency (EA), Natural Resources Wales (NRW) and Scottish Environment Protection Agency (SEPA)) if some of the risks are associated with authorised discharges, protecting the environment or disposal of radioactive waste. The EA and NRW employ the concept of 'Best Available Techniques' (BAT) to establish the appropriate levels of protection and SEPA use 'Best Practicable Means' (BPM). In reality BAT and BPM require dutyholders to follow a very similar process of balancing to that used in ALARP determinations. This is discussed further in para 6.36.

### **Valuation of Detriments**

- 6.16 Valuation of detriments is still a subject of much discussion and research. HSE uses a figure [9] of £1.5million (2009) for the Value of Preventing a statistical Fatality (VPsF). In the case of death caused by cancer, HSE has taken the view that people are prepared to pay a premium and R2P2 says that a higher figure, twice the above should be used. It is suggested here that this premium is also appropriate for all radiation deaths. However, continuing research has questioned the validity of applying a premium, and so it is possible that the premium may be removed at some future date. Noting that in most cases a factor of 2 will not have any material effect on what is / is not reasonably practicable given the uncertainties generally prevalent in CBA, this

aspect will not normally be important. However, in the unlikely case that including this factor is the pivotal aspect in determining whether an improvement reduces risks to ALARP, inspectors should seek the advice of the relevant ONR Professional Lead as to the current status of the research into this area.

- 6.17 Accidental releases of radioactive material may lead to widespread contamination off and within the facility or site. Off-site it will lead to other safety-related detriments such as evacuation, relocation, land interdiction and food bans. Attempts to cost all of these have been made by licensees both for reactors and for chemical plant, based on the HPA (now Public Health England) model COCO-1 [15]. An updated model, COCO-2 [16], published in 2008, takes account of the current UK economic structure, considers some of the economic effects of an accident in more detail and includes some additional sources of loss. COCO-2 now represents the benchmark when the costing of detriments is part of the ALARP demonstration.

### **Costs of Implementation**

- 6.18 A more difficult area for assessment may well be estimating the costs (sacrifice) of the modification as these may require a knowledge of both the engineering design and the costs of components etc. It is likely that the full engineering details of the modifications will not be available so that accurate costings will be difficult.
- 6.19 In considering the sacrifice, it is important that only those costs relating to health and safety improvements are included. The costs considered should be only those necessary and sufficient for the purpose of reducing the risk and not be for 'deluxe' measures where cheaper 'standard' measures are available.
- 6.20 Of all the cost factors, the loss of revenue is particularly problematic as it can lead to a paradox: If a plant shutdown is required to implement an improvement, a high revenue earning plant may be able to show it is not reasonably practicable to implement an improvement which a lower revenue plant would otherwise have implemented. Nevertheless ONR accepts that shutdown costs constitute a legitimate part of the sacrifice and it is valid to include them. To avoid undue influence of this factor, licensees should have considered the phasing of the implementation. For example, it may be reasonable to delay implementation until a planned or other outage. Furthermore, in some circumstances it may be established RGP to shutdown to enable implementation of the improvement, and in such cases these costs will have already been implicitly accounted for. Where this is the case, a CBA-based argument against implementing established good practice is unlikely to be acceptable.
- 6.21 Any discounting of costs and benefits into the future should follow standard Treasury rules, with due allowance made for up-rating benefits to take into account predicted future improvement in living standards. For further information relating to the application of discount rates, inspectors are referred to 'The Treasury Green Book' [18], which describes the appraisal and evaluation of Government funded projects.
- 6.22 When reviewing proposals to reduce the risks posed by an existing facility, there will often be a delay before implementing improvements, for example arising from the need to design/manufacture equipment. This raises questions regarding how to take this intervening period into account. In such cases, the extent of the original shortfall against ALARP should be based on the future life of the facility etc. at the time the safety case is made, and not the (shorter) remaining life following implementation. However, the evaluation of the benefits arising from the improvement may take account of the time to implement. In addition, consideration of the risks during the period prior to implementation should apply the Time at Risk guidance discussed below.

### Difficult Areas

- 6.23 The purpose of this part of the TAG is to consider some of the applications of the ALARP principle which can lead to contentious situations and/or difficult decisions.

### Uncertainties

- 6.24 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, sensitivity studies to test the robustness of the arguments should always be provided. Paragraphs 89 to 93 of R2P2 [1] and appendix 1 of R2P2 recommend the use of a precautionary approach in the face of uncertainty, i.e. assume that precautions should be taken unless there is a good reason to think that the risk is insignificant (see also SAPs para 30).

### Time at Risk Situations

- 6.25 The Numerical Targets set out in SAPs are (mostly) given as frequencies based on annual averages. Circumstances will arise where a higher risk will exist for shorter periods of time that make the use of annualised frequency targets inappropriate.
- 6.26 There are three principal situations in which licensees may argue the acceptability of increased risk for a short period to justify not spending resources to improve safety to a level that would be reasonably practicable for continuous, long-term operation:

Through Life – Where a short-term increased risk is needed for continued normal operation of the facility. Examples here 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 production.

Residual Facility Life – As a facility ages, its safety margins may be eroded, for example due to ageing effects, or its risks may appear high when compared to newer facilities designed to more modern standards. Licensees may however invoke arguments that these risks are acceptable because the short remaining operating life of the facility means that significant investment is unreasonable.

End of Life Legacy – Clean-out and decommissioning may necessitate short periods of increased levels of risk compared to those from previous normal operations. Licensees may argue this is unavoidable if remediation of the facility is to be completed.

### Through Life Risk – Specific Considerations

- 6.27 The guidance below is intended to provide an overall policy against which to assess whether a licensee has made an adequate demonstration that all reasonably practicable measures to control any short-term elevated risk have been taken. Due to the large number of possible reasons for elevated short-term risk, judging whether these requirements have been met for a specific situation however needs to be done on a case to case basis:
1. SAPs Principle NT.2 states that there should be sufficient control of radiological hazards at all times. Any period in which the risk is elevated, whatever the situation, must be subject to a specific demonstration that risks are controlled ALARP. The period of this elevated risk should be as short as reasonably practicable (SAPs para 762).

2. In considering NT.2, the demonstration of 'sufficient control of radiological hazards' should include explicit consideration of defence-in-depth levels 1 to 4 (SAPs Principle EKP.3), and the hierarchy of such measures (SAPs Principle EKP.5).
3. The short-term risk, when annualised, should not exceed BSLs except in exceptional circumstances. Any case made for carrying out any operation which requires the risk to be in the intolerable region, however briefly, needs to be made very rigorously to show that nothing more can reasonably be done. Such circumstances should be regulated consistent with the guidance set out in SAPs paras 699-700. Exceptional circumstances may include, for instance, situations not originally foreseen in the design of the facility. It is expected that the licensee will put arrangements in place to prevent a recurrence of the unforeseen situation.
4. The extent of the time for which the risk is increased should not be the sole argument for acceptability that a situation reduces risks to ALARP. The safety case should, drawing from appropriate RGP, consider whether or not additional measures are necessary. As in any consideration of ALARP, the magnitude of the potential consequences should also be a factor, as well as the likelihood of the risk being realised.
5. During operations which impose a planned short-term risk, additional monitoring of the actual plant state should be undertaken to ensure that the mode of operation and the time during which it persists meet the assumptions in the ALARP case.
6. Unexpected failures of plant and equipment may lead to an increase in risk that is so high that BSLs are exceeded and the risks thus judged 'intolerable' (see TOR [2]). In such cases the licensee should be actively managing and prioritising the situation to reduce the risks back to ALARP as quickly as possible. It certainly should not be the case that a facility is allowed to operate at this level of risk unless there is no alternative (see paras 699-700 of the SAPs).

### **Residual Facility Life – Specific Considerations**

- 6.28 The SAPs (para 35) note that as a facility ages, its safety margins may be eroded, for example due to the incidence of, or vulnerability to, faults increasing due to wear etc. Reducing the risk level may not be possible, so a judgement then has to be made whether the continued operation of the facility is acceptable at the higher risk. The future planned lifetime of the facility may be a factor in making such judgements. This sort of situation can be difficult where the ageing is gradual and there is no obvious transition from 'safe' to 'not safe'. In such cases, careful monitoring and regular review, as required of licensees through compliance with their LC15 arrangements (particularly short-term reviews – see NS-TAST-GD-050 [23]), is likely to be needed.
- 6.29 The guidance presented here relates to periods that are short in comparison to the total design or operational life of the facility. It also relates to assessment of safety cases either resulting from a Periodic Safety Review or at any time when a significant ageing phenomenon is being considered.
- 6.30 The following points should be considered by inspectors in this context:
- i. The safety case should be updated promptly 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.

- ii. The revised risk assessment must show that the facility is tolerable for future operations. For example the numerical risk estimates should not be greater than BSLs. If the risk is deemed to be intolerable then the guidance in SAPs paras 699-700 should be followed.
- iii. Proposed limits on remaining lifetime may be invoked in making the ALARP demonstration, but this cannot be used to justify a facility operating in the intolerable region. A case not to make an improvement based largely on limited future lifetime would only be acceptable 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) should be considered for the purposes of the ALARP demonstration (see SAPs para 35).

### **End of Life Legacy – Specific Considerations**

- 6.31 There may be situations, particularly during cleanout and decommissioning, where the risks need to be increased temporarily so that the long-term risks can then be reduced or eliminated (SAPs paras 759-767). Such increased risks need to be balanced against the continuing risks from doing nothing and with due consideration of the alternatives available to address the hazard. Cases arguing for extensive delays to hazard reduction by invoking CBA with significantly discounted future costs need to be guarded against. Concentration on removal of the hazard, or on decreasing its propensity to cause harm should instead be paramount. Arguments based simply on time at risk will not generally be sufficient.
- 6.32 During the course of hazard reduction, which may be for a significant time, it is expected that suitable engineering and/or operational arrangements will be made to minimise, so far as is reasonably practicable, both the magnitude and time of the higher risk, balancing e.g. operational doses and the potential for accidental releases. Further details on these aspects are addressed in NS-TAST-GD-026 on Decommissioning [24]).

### **Arguments for allowing an increase in risk**

- 6.33 Licensees may argue that moving to a less protected situation meets the ALARP criteria e.g. by suggesting that increases in risk are more than balanced by the gains in reduced operational costs or increased operating profit. Other factors, particularly those relating to good practice and previous experience, would militate against this argument and, in general, ONR would require previous good practice to be upheld.
- 6.34 To succeed in an approach where risks appear to increase, the licensee would have to show 'changed circumstances', as noted in para 39 of the HSE ALARP Principles [3], or that the existing situation went well beyond what was required by ALARP. In addition, any case for reducing safety would also have to show that additional safety measures are not reasonably practicable in the new situation. However, where the level of risk is low, and the increase in risk is small and forms part of a package which overall improves health and safety, the licensee's proposals should be considered in this wider context.
- 6.35 Other grounds which may be acceptable are where the risks are low and the measures in place can be shown to be unduly conservative as a result of new knowledge. In other cases a change may be forced due to it being impossible to replace like-for-like components due to obsolescence. Another possibility is where the safety case contains generous margins which can be relaxed without any diminution in the

required level of safety. Many people feel uncomfortable about accepting increased risks, which is often referred to as 'reverse' or 'negative' ALARP, but in the past ONR has accepted cases which meet the above criteria and HSE's ALARP Principles anticipate the need to deal with such situations.

### Regulatory Application of ALARP and BAT/BPM

- 6.36 Another area where an increase in risks (on and/or off-site) can occur is where additional measures need to be taken on the site to reduce the quantity of radioactive material permitted to be discharged to the environment in normal operations. This usually results from activities regulated by the EA, NRW and SEPA to reduce discharges to comply with BAT (BPM in Scotland). Possible consequences of these additional measures are that on-site accumulation of radioactive waste will increase (unless a disposal route exists), or safety risks to workers will rise (e.g. from implementing and/or operating the new measures).
- 6.37 Concerns were historically expressed by the nuclear industry that different regulatory application of ALARP and BAT in nuclear safety and environmental protection gave a propensity for conflict. This was a factor that prompted a review of the working relationship between HSE and EA in respect to nuclear sites and development of a Statement of Intent<sup>2</sup> between HSE and EA in 2001. A separate Statement of Intent was also developed for HSE interactions with SEPA.
- 6.38 Given the different terminology used in different legislation and the requirement for licensees to meet all their duties, the term 'optimisation' is used in NS-TAST-GD-026 Decommissioning Technical Assessment Guide [24] to refer to the level of protection that meets all the legal requirements of ALARP, BAT, BPM etc. Optimisation is also the term used in the IAEA Safety Fundamentals [17] where Principle 5 states "Protection must be optimised to provide the highest level of safety that can reasonably be achieved."
- 6.39 Consequently it is important that, during optioneering studies carried out by the licensee to establish the BAT or BPM option, adequate weighting is given to health and safety aspects so that an overall ALARP solution that balances health, safety and environmental aspects is reached in an optimised manner. Such a balance should consider:
- The number of people (workers and the public) who may be exposed to radiation;
  - The likelihood of their incurring exposures;
  - The magnitude and distribution of radiation doses received;
  - Radiation risks arising from foreseeable events;
  - Economic, social and environmental factors.
  - Using good practices and common sense to avoid radiation risks as far as is practical in day to day activities.
- 6.40 More guidance on how to achieve ALARP in a decommissioning context is set out in NS-TAST-GD-026 [24].

### Risk Trade-offs

- 6.41 If a change to the design or operation of a facility is implemented to reduce a particular risk, it is highly likely that there will be other effects which could alter the risk profile of the facility. HSE's ALARP Principles [3] refers to this as 'risk transfer' and confirm the

<sup>2</sup> Memorandum of understandings are now in place between ONR and relevant organisations.

importance of considering all of the risks within the licensee's control as part of a balanced decision on how to reduce overall risks to ALARP. It has already been emphasised that the full effect of the implementation needs to be considered in terms of the reduction in risks, but it should be borne in mind that risks may also be increased in other areas. For example, risks from radiological hazards may be from accident or normal operational risks; these could affect the public and/or persons on-site; there may be conventional (non-radiological) risks arising from the changes. It is important therefore, when considering implementation of a modification, to consider whether the licensee has analysed all relevant types of risk and that any increase in risk in other areas is not greater than the decrease in the area being analysed.

### **Dose/Risk Sharing**

- 6.42 When considering doses that are received in normal operation, a certain degree of dose sharing is acceptable to reduce doses to individual workers and hence their risks. The IRR ACoP [12] says that if a choice between restricting doses to individuals and groups has to be made, priority should be given to keeping individual doses as far below dose limits as reasonably practicable. Dose sharing might reduce individual doses further but should not be used as a primary means of complying with dose limits. Priority should instead be given to changing methods of work, improving engineering controls and adopting other means of restricting exposure. In the case of doses received due to accidental releases, the concept of risk sharing for workers by use of occupancy factors may be questionable; individual risk cannot be made acceptable by using many people for short periods so each only gets a small portion of the total risk.

### **Occupancy Factors**

- 6.43 In the analysis of an individual fault scenario, the risks and protection measures should be assessed with respect to the potential dose to a worker who is exposed to the consequences of identified faults/events. The likelihood of a particular fault/event should not be judged acceptable on one facility, and not on another, merely because there are more people working within the first facility to 'share' the risk. When summing risks to an individual worker on a facility from all faults (e.g. for comparison against SAPs Target 5), it is acceptable to consider justified 'occupancy' factors as not all persons on-site will be exposed to all the risks from the facility.
- 6.44 Occupancy claims need to be considered carefully as the occupancy under consideration can mean different things:
- the fraction of time a specific individual is on-site. If the risk being estimated is to a specific individual this factor is valid.
  - the fraction of risks on a particular facility or site that a specific individual may be exposed to. Again if calculating specific individual risk is the aim, including this factor is valid.
  - the likelihood of a worker being in the vicinity of an accident. Where a worker may be present for part of the time and the fault is random, there are two situations to consider: in assessing the risk in cases where the occupancy is controlled it is valid to consider the occupancy factor, but where the occupancy is uncontrolled (e.g. in a corridor) the dose should be assessed assuming a person is present.
- 6.45 In considering SAPs Target 6, which addresses doses from single accidents on site, it is expected that estimates will be made assuming someone is present unless adequate control measures are in force to ensure their absence (see SAPs Annex 2). Should the summed risk to any worker be high however, then justified occupancy claims can be considered, along with any proposals to control exposure etc.

## Long-Term Risk Assessment

- 6.46 There is a growing perception that risks that are imposed, that are unevenly distributed, or that affect future generations should be scrutinised and seen to be justified (R2P2 [1], paras 47 & 48). Some projects in the nuclear industry, and particularly those associated with radioactive waste management and decommissioning, run over many years, and the risks that result may affect future generations of workers and the public as well as the present generation. For such cases the risks should be assessed in a holistic manner and not restricted to part of the overall time period or part of a process.
- 6.47 In general, we should seek to protect future generations at least as well as we seek to protect the present one. Although it could be argued that the next few generations may gain some indirect benefit, the uncertainty of how they will view the risks left to them (and indeed the uncertainty of any benefits further into the future) argues for a precautionary approach (R2P2 [1], paras 89-93) and hence a particularly stringent demonstration that risks are indeed ALARP. We would therefore expect to see particular efforts made to demonstrate that risks to future generations are at least consistent with the levels of risk that would be accepted as adequate protection for the present generation.
- 6.48 Given the uncertainties in estimating long-term future risks, good practice and the application of the Engineering Key Principles hierarchy with the emphasis on control of hazard (see SAPs EKP.1-4) are likely to be much more important than numerical risk estimates and CBA in establishing the way forward. In this context it is worth bearing in mind that a  $1 \times 10^{-4}$  pa risk for one year implies a low likelihood of someone being hurt, whereas  $1 \times 10^{-4}$  pa for 10 000 years implies a high likelihood of an adverse consequence.

## SFAIRP and the Requirement for Risk Assessment

- 6.49 The requirement to carry out a risk assessment and produce a safety case is absolute and cannot be argued against on the grounds that the costs are grossly disproportionate to the risks. Instead, the scope, depth and effort put into the risk assessment / safety case should be proportionate to the level of risk and hazard.

## 7. ALARP AND REGULATORY DECISIONS

- 7.1 Licensees 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 strategic factors/imperatives can sometimes appear in safety cases in the context of 'time', or 'trouble' aspects, on the sacrifice side of the ALARP balance. Inspectors should however, make their judgements on whether the legal duty to reduce risks to ALARP has been met independently of such considerations, as these normally lie beyond the scope of HSWA. Instead these will normally be a factor informing ONR's enforcement and permissioning decisions. For instance, if risks have not been reduced to ALARP, relevant strategic factors can and should be taken into account by those with delegated authority when determining proportionate enforcement action, or in decisions whether to grant a permission. Guidance on what to do when dealing with Strategic Imperatives is provided in the following two sections, and should be read in conjunction with ONR's guidance on Risk Informed Regulatory Decision Making [28].

## Enforcement Decisions

- 7.2 Enforcement decisions within ONR are made in accordance with ONR's Enforcement Policy Statement (EPS) [22], which sets out the principles, purpose and methods of enforcement. A spectrum of enforcement options is available depending on the circumstances. These range from providing verbal or written advice, delaying or refusing to grant a permission for a given activity, issuing Improvement Notices (IN) or Prohibition Notices (PN), through to prosecution in the most serious cases. Reflecting this, HSE has developed the Enforcement Management Model (EMM) to guide regulators in making consistent and proportionate enforcement decisions.
- 7.3 ONR guidance on applying the EPS within the framework of the Nuclear Licencing regime is provided in the ONR Enforcement Management Model (EMM), ONR-ENF-GD-006 [19]. In applying the EMM to ALARP decisions, inspectors should establish the seriousness of shortfalls with reference to the risk gap (i.e. between where the licensee is and where they ought to be when complying with the law). This should then be used to inform ONR's decision on appropriate enforcement action. It is at this point in the EMM process that 'Dutyholder Factors' and 'Strategic Factors' should be taken into account, and not when determining legal compliance.

## Permissioning Decisions

- 7.4 Similarly, where the licensee's ALARP justification is part of a request to grant a permission required under a nuclear site Licence Condition, ONR inspectors should distinguish between wider arguments related to Dutyholder and Strategic Factors and the judgement as to whether risks are reduced to ALARP. Ultimately, consideration of an ALARP shortfall in the context of these wider factors may lead ONR to nonetheless grant permission for the activity, e.g. where it is deemed in the public interest to do so. The supporting audit trail (i.e. the Project Assessment Report (PAR)) for such licence instruments should clearly define the rationale for the decisions made, and detail why the permission has been granted, despite the evident shortfall(s) in demonstrating ALARP.
- 7.5 It must also be recognised that, in accordance with ONR's regulatory philosophy and irrespective of any claims of Strategic Factors, there may be situations where the licensee has not adequately demonstrated that risks have been reduced to ALARP, but where the gap is such that it would be disproportionate not to grant a permission. In these cases, inspectors should work with the licensee to bring the situation back into legal compliance, but this process should not (depending on the EMM) necessarily mean that our permission is withheld.
- 7.6 ONR's published guide to Risk Informed Regulatory Decision Making [28] gives further information on the factors involved in decision making and notes that "there can also be other wider factors (beyond Dutyholder and Strategic Factors), such as 'in the interests of national security', that we term 'Strategic Imperatives', where we do not have the authority or sufficient knowledge of the considerations involved to judge the significance of such factors. Strategic Imperatives would not normally change our regulatory decision, but may require a different course of action. In such circumstances, we would work collaboratively with the dutyholder to ensure the best safety outcome within the constraints of the imperative, but also to ensure that all relevant stakeholders understand the implication of the chosen course of action. Such circumstances have been, and are likely to remain, extremely rare."

## 8. CHECKLIST

- 8.1 Attached at [Annex 1](#) is a checklist of the main assessment points which will help inspectors decide whether all the key points have been addressed by the licensee in its ALARP assessment.

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## 10. GLOSSARY AND ABBREVIATIONS

ACoP	Approved Code of Practice
ALARA	As Low As Reasonably Achievable
ALARP	As Low As Reasonably Practicable
BAT	Best Available Technique
BPM	Best Practicable Means
BSL	Basic Safety Level
BSL(LL)	Basic Safety Level (Legal Limit)
BSO	Basic Safety Objective
BSSD	Basic Safety Standards Directive(s)
COMAH	Control of Major Accident Hazards
CBA	Cost Benefit Analysis
CDM	Construction Design and Management Regulations 2015
EA	Environment Agency
EMM	Enforcement Management Model
EPS	Enforcement Policy Statement
EU	European Union
GDA	Generic Design Assessment
HPA	Health Protection Agency (now PHE)
HSE	Health and Safety Executive
HSWA	The Health and Safety at Work etc. Act 1974
IAEA	International Atomic Energy Agency
IN	Improvement Notice
IRR	Ionising Radiations Regulations 2017
LC	Licence Condition
NIA	Nuclear Installations Act 1965 (as amended)
NRPB	National Radiological Protection Board (now part of PHE)
NRW	Natural Resources Wales
ONR	Office for Nuclear Regulation
PAR	Project Assessment Report
PHE	Public Health England
PN	Prohibition Notice
PSA	Probabilistic Safety Analysis
PSR	Periodic Safety Review
R2P2	Reducing Risk Protecting People
RP	Requesting Party
SAP	Safety Assessment Principle(s)
SFAIRP	So Far As Is Reasonably Practicable
SEPA	Scottish Environment Protection Agency
TAG	Technical Assessment Guide
TEA	The Energy Act 2013
TIG	Technical Inspection Guide
TOR	Tolerability of Risk
VPsF	Value of Preventing a Statistical Fatality
WENRA	Western European Nuclear Regulators' Association

## 11. APPENDICES

### **Annex 1 - ALARP Checklist**

A1.1 The risks must be ALARP. If the engineering and operation of the facility gives no cause for concern, and the risks are adequately demonstrated to be 'broadly acceptable' (i.e. below all the BSOs) then this is sufficient for ONR assessment purposes. If the risks are above a BSO, then inspectors should consider specifically whether these are reduced to ALARP.

A1.2 If the risks exceed a BSL or fall significantly short of an accepted RGP, e.g. evidently poor engineering or sub-standard operations (procedures or implementation) then inspectors need to follow the advice set out in SAPs paras 699-700. This includes consideration of whether the facility should be shutdown or the activity curtailed.

A1.3 The following checkpoints may be relevant in reviewing licensees' safety cases or arguments that the risks are ALARP:

1. Is there evidence of an adequate and fit-for-purpose evaluation of risks that underpins the ALARP case (para 5.2)
2. Does the ALARP argument refer only to those risks which the licensee controls ([para 5.4\(1\)](#))
3. Affordability is not a legitimate factor in the assessment of costs ([para 5.4\(2\)](#))
4. ALARP cannot be used to argue against statutory duties ([para 5.4\(3\)](#))
5. Does the ALARP argument take adequate account of all types of risks, including conventional (i.e. non-radiological) risks ([para 5.4\(4\)](#))
6. Have all relevant options been considered by the licensee and does the licensee's study of the options begin with the safest (as opposed to the cheapest) option [para 5.4\(5\)](#)
7. If measures are deemed not reasonably practicable, has partial implementation been considered? Inspectors need also to be wary of 'deluxe' measures unduly inflating the cost [para 5.4\(5\)](#)
8. Is the rigour of ALARP case made commensurate with the level of risk in the scenario under consideration ([para 5.4\(7\)](#))
9. For measures deemed not reasonably practicable, has the licensee demonstrated gross disproportion ([para 5.4\(8\)](#))
10. The ALARP arguments should include explicit consideration of qualitative features related to engineering and other types of RGP ([para 6.1 – 6.49](#)).
11. The ALARP argument should be based on comparisons with RGP, informed as necessary by CBA ([para 6.13](#)), rather than the other way around. A CBA on its own is not acceptable as an ALARP case.
12. Are all of the relevant engineering SAPs met? If not, has the licensee identified and considered any deficiencies from an ALARP perspective ([para 6.8](#))
13. ALARP applies at all times and arguments employing Time at Risk may need special consideration ([para 6.25 – 6.32](#)).
14. Reverse ALARP arguments for increased risk are only allowable in 'changed circumstances' or where the licensee can show that the existing situation goes well beyond what is required by ALARP ([para 6.35](#)).

15. Dose sharing: Has the licensee given adequate consideration to changing working methods, engineering controls or other means of dose restriction before proposing dose sharing ([para 6.42](#))
16. Have occupancy factors in assessments of worker risk been properly considered ([para 6.43](#))
17. Have safety and environmental factors been considered in an optimised manner during optioneering studies in order to meet all legislative requirements of ALARP and BAT ([para 6.36 – 6.39](#))
18. Have strategic factors, dutyholder factors or strategic imperatives been used as justification for the activity where risks are not actually reduced ALARP ([para 7.1](#))

## **Annex 2 – ALARP for proposed new civil nuclear reactors**

A2.1 In the context of the Generic Design Assessment (GDA) process for new reactor designs ONR has to judge whether the legal duty of controlling and reducing risks so far as is reasonably practicable (SFAIRP), usually referred to as ALARP (as low as reasonably practicable), will be met. In contrast to the majority of cases we normally deal with at existing licensed sites, the ALARP arguments presented for GDA will not relate to whether additional features should be implemented to an existing design, but will instead involve consideration of the facility's design as a whole. Thus the position when a new reactor design is presented to us goes beyond the situations considered in other HSE ALARP guidance.

A2.2 Although nominally at the design stage, all of the proposed designs are essentially complete in terms of the overall concept and major systems, and have reached that stage after many years of development and optimisation in non-UK regulatory environments. However, the essence of the UK system is goal-setting and the main objective is to see whether the reactor designs represent an ALARP outcome rather than to examine the route by which that end was achieved. Similarly, ONR needs to look at the design holistically and be guided by overall safety rather than focussing on incremental changes (e.g. the thickness of a concrete wall, or level of redundancy in a single system) to individual elements of the safety argument in isolation. Hence the intention is not to seek new, UK-specific design features, but to see that the law is met. Furthermore we recognise there are safety benefits in standardisation: a wider pool of experience will inevitably provide better feedback for future improvement in safety and this must be taken into account. It is also worth noting that the intent is to judge whether the individual designs meet the requirement to demonstrate ALARP on their own merits, not to compare them.

A2.3 For the overall ALARP demonstrations we expect the four main areas below to be addressed:

1 There is a clear conclusion that there are **no further reasonable practicable improvements** that could be implemented, and therefore the risk has been reduced to ALARP.

2 **RGP:** This is the basic requirement for demonstrating that designs meet the law. The Requesting Party (RP) must set out the standards and codes used and justify them to the extent that we can 'deem' them RGP when viewed against our SAPs. This justification is expected to include a comparison with other international/ national standards. Clearly the standards and codes adopted by the RP must be shown to have been met.

3 **Options:** This will comprise two stages: Firstly an examination of the RP's rationale for the evolution of the design, using its forerunners as a baseline, looking at why certain features were selected and others rejected and how this process has resulted in an improved design from a safety perspective. Secondly the RP needs to address the question "what more could be done?" and provide an argument of "why they can't do it" (i.e. why it is not reasonably practicable). This second element could be done by postulating further options for improvement (previously discarded options may be suitable candidates) and evaluating them. Clearly if an option is shown to be reasonably practicable then that option should have been taken, or where it is found not to be excessively expensive to improve safety, then further avenues for risk reduction should be explored.

4 **Risk Assessment:** The use of risk targets in isolation is not an acceptable means of demonstrating ALARP and we expect to see risk assessments used to identify potential engineering and/or operational improvements as well as confirming numerical levels of safety. The BSOs in the SAPs represent broadly acceptable levels below which we have said that we expect to confine ourselves to considering the validity of the arguments that the BSOs have actually been met. We have also made it clear that

the way in which we apply these numerical targets will depend heavily on the views we form on the engineering (and at a later stage operational practices) and that meeting the BSOs is not a green light for RPs to forego further ALARP considerations. Nevertheless, well-supported numerical risk figures that show BSOs to be met can be an important element of support to the overall ALARP demonstration

A2.4 In support of these four elements, ONR expects the following in respect of new commercial reactor designs:

- The level of safety must be no less than a comparable facility already working or being constructed in the UK or somewhere else in the world.
- As evolutionary designs, which have been designed taking account of experience of earlier ones, the RP must show how the evolution has maintained or improved the design from a safety perspective.
- The demonstration should set out how known problem areas (e.g. identified from Operational Experience Feedback (OEF), improved analysis, or improving standards) have been addressed and how and why the particular solution chosen was arrived at.
- The Engineering Key Principles (EKP) 1, 2 and 3 of SAPs should be seen as a hierarchy where, all else being equal, the higher up the list the better. Cases where this is not so will need specific justification.
- Likewise, the hierarchy within EKP 5 should be addressed in a similar manner.
- There should be clarity to the reasons for the choice of design standards and demonstration that the chosen ones lead to the safest reasonably practicable design.
- The RP must provide evidence that it has used processes for making design decisions in which safety is clearly considered and has been given the appropriate priority.
- Risk/CBA type arguments on their own must not be allowed to override established RGP where this results in degradation in safety.

A2.5 In addition we might reasonably expect the RP to provide evidence of the following:

- The RP should show how its process is compatible with UK law; specifically how the comparison of sacrifice and risk averted is considered within the design process and what approach is used for determining 'gross disproportion';
- Where risk-based CBA-type decision-making has been used, the costings should be appropriate to UK conditions, gross disproportion factors justified and adequate sensitivity studies should be included to demonstrate a robust conclusion;
- The design should be considered holistically so that whilst individual systems could be improved, the impact on the overall risks makes further improvement not reasonably practicable;
- There is a proper balancing of all risks, worker/public, normal operation/accident, radiological/conventional and the procedures used to ensure this should be clear and adequate;
- If any numerical targets for risks are used as cut-offs these must be justified either as a whole or in individual applications;
- In particular, where intermediate targets rather than the effects on people and the environment are used, the RP should: (a) explain why such a target is used; (b) explain how it is used during design and optioneering; (c) justify the specific target; and (d) justify the levels of 'gross disproportion' used.

## **Annex 3 RGP Common questions and answers**

### **Remind me! – What is ALARP?**

A3.1 ALARP stands for ‘as low as reasonably practicable’ and is used when referring to the steps necessary to reduce health and safety risks in order to meet legal duties. It is the term used by ONR, HSE and industry. For almost all purposes it has the same meaning as ‘so far as is reasonably practicable’ (SFAIRP) as used in health and safety legislation.

A3.2 A risk has been reduced ALARP when a dutyholder can show that further risk reduction is not justified because the sacrifice associated with doing so would be grossly disproportionate in terms of money, time or trouble. Sections 2 and 3 of the Health and Safety at Work etc. Act 1974 (HSWA) require dutyholders to reduce the risks to their employees and to others from their activities SFAIRP. Similar requirements are also reinforced in more specific applications through other health and safety legislation, such as the Ionising Radiations Regulations 2017 (IRR).

A3.3 SFAIRP, and by implication ALARP, are ‘goal-setting’ standards that provide an objective against which a dutyholder must select and then justify its approach to achieving it.

### **Who judges ALARP?**

A3.4 Ultimately, whether a dutyholder has complied with its legal duty to reduce risks ALARP in a particular case may be for a court of law or employment tribunal to decide.

A3.5 However, in regulating the industry, ONR (and other regulators) effectively make the required day-to-day judgements, e.g. as part of inspecting and assessing dutyholders against their obligations and in deciding whether to take enforcement action. We use a body of knowledgeable and experienced inspectors, assisted by comprehensive guidance, to make these judgements on the basis of the available evidence. ONR also considers ALARP during the assessment of a licensee’s safety case carried out as part of making a permissioning decision.

A3.6 Note that our regulatory decisions (including those relating to enforcement action or the granting of permission) also take into account broader factors in addition to whether or not legal standards, including that of ALARP, have been achieved. This is described in our Risk Informed Regulatory Decision Making guidance [28].

### **What is good practice?**

A3.7 ‘Good practice’ is a generic term referring to a wide range of control measures, policies, practices and other aspects pertaining to a particular health and safety issue.

A3.8 Good practice can refer to physical aspects, including the design of plant and equipment, the fitting of safety mechanisms, mitigating and emergency measures or to the use of particular items of personal protective equipment. It can equally refer to administrative control measures, including things like training practices, maintenance, inspection, testing, decision-making processes or operating instructions. It can also refer to fault, hazard or risk analysis methodologies, strategies, design principles, risk targets and other approaches to safety analysis, substantiation or design.

### **What are the sources of good practice?**

A3.9 While anyone can propose good practice, there is a hierarchy to its significance based on its formal status and pedigree, i.e. the weight it might carry in a potential court case:

- Approved Codes of Practice (ACoPs) carry the strongest weight and have a special legal status. If a dutyholder complies with the approach to a health and

safety issue set-out in an ACoP, then it is deemed to have complied with the law. A dutyholder may choose to follow a different approach, but then must be able to demonstrate why this is equivalent or it will be considered to be below minimum legal compliance. (Note that an ACoP is usually published as a single document to go with a set of regulations. This will provide the ACoP text together with accompanying non-statutory guidance. The accompanying guidance does not however carry the special legal status of the ACoP.)

- Published regulatory guidance is also a recognised source of good practice. For nuclear safety, our principal sources of good practice are the Safety Assessment Principles (SAPs) and the additional guidance provided in the Technical Assessment Guides (TAGs) and Technical Inspection Guides (TIGs). Several TIGs and TAGs also address conventional health and safety, where ONR would also make particular use of guidance published by HSE.
- Other written sources which may be recognised as good practice include guidance produced by:
  - other government departments;
  - national and international standard-setting bodies, e.g. the British Standards Institute (BSI), International Atomic Energy Agency (IAEA), International Standards Organisation (ISO), the European Committee for Standardisation (CEN) or Western European Nuclear Regulators' Association (WENRA);
  - industry bodies and professional institutes, e.g. the Safety Directors' Forum (SDF), Nuclear Engineering Directors' Forum (NEDF) or World Association of Nuclear Operators (WANO).
- There may be unwritten sources of good practice, for example through well-defined and well-established practices across a particular industrial sector.

A3.10 The mixing of different standards – 'pick and mix' – is discouraged where there is an applicable encompassing standard, particularly for standards 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 thing is to consider the overall outcome against the ALARP requirement. It is also important to ensure that we do not apply inappropriate regulatory pressure to 'gold-plate' the solution beyond what would be ALARP.

## What is RGP?

A3.11 RGP stands for 'Relevant Good Practice'. It refers to the body of good practice that is specifically relevant to the situation and that which, if implemented, would typically be considered to meet the requirement to reduce risks to ALARP for a particular situation.

A3.12 The concept of RGP is used because there is usually well-established good practice in addressing a particular issue and it is usually unnecessary for a dutyholder to revert to a detailed, first-principles ALARP demonstration in most circumstances. RGP is therefore helpful in avoiding unnecessary replicated effort where the standard that would be required by the courts and the regulator is well-recognised. This is often true in areas that are common across industry, including many aspects of conventional health and safety and the more widespread aspects of nuclear and radiological safety.

A3.13 The concept of RGP is less helpful for unique or unusual circumstances because typical standards and practices are often not fully relevant to the situation. In these cases RGP is only a starting point for a more detailed demonstration against the fundamental

ALARP requirement. This is often true for older nuclear facilities which fall short of modern standards developed since they were constructed. This can be exacerbated by age-related degradation, making decommissioning more challenging. Whilst what is RGP elsewhere 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 standard in the specific circumstances.

A3.14 Remember: for something to be RGP it must be 'relevant' in that it has been read-across for appropriately similar circumstances. It must also represent 'good practice' rather than 'best practice' (a practice beyond what the law requires).

A3.15 Note that ONR also uses the concept of RGP to underpin its judgment of compliance against other goal-setting requirements in addition to those based on ALARP/SFAIRP, such as 'suitable and sufficient' and 'adequate' as used in the licence conditions. The remaining questions and answers in this document are generally also applicable to these kinds of goal-setting requirements as well as ALARP.

### **What is the legal basis of RGP?**

A3.16 RGP does not have a legal basis and is not mentioned in legislation, although a regulator's view on what is considered to be RGP is likely to be persuasive in a court of law.

A3.17 RGP is based on regulatory policy and refers to the controls, standards and approaches that meet the ALARP requirement based on what has been accepted in similar circumstances. It is used to avoid the need for first-principles ALARP justifications being required for commonly encountered circumstances or to provide a starting point for determining the ALARP position in more complex or bespoke situations. Adherence to RGP is not a legal requirement: alternative approaches can be used.

### **Who determines RGP?**

A3.18 As part of demonstrating ALARP, a dutyholder will need to consider and judge what it considers to be RGP in order to be able to make an argument for the reasonable practicability of the approach it has taken. The arguments and evidence supporting ALARP justifications should be included within the safety case.

A3.19 The regulator also needs to consider and judge RGP, based on the sources listed above, to enable regulatory judgments. In doing so, it is important to bear in mind that RGP is only regulatory policy, and represents only an interpretation of what is considered to meet the legal requirement based on similar circumstances (although a regulator's view on what is RGP will be persuasive in a court of law).

### **Are alternatives to RGP acceptable?**

A3.20 Definitely! RGP is not the law: it is a regulatory concept that provides a practical mechanism for day-to-day judgments on what would usually be considered to meet the legal requirements based on what has been judged and accepted in similar circumstances. If the same standards of safety can be achieved through different means then this also complies with the law.

### **Can standards lower than RGP be acceptable?**

A3.21 Yes they can – because it is the overall outcome that matters and lower standards in some areas might be justifiable providing the overall result can be shown in the safety case to be ALARP. However, it can be challenging to argue for lower standards because the RGP (providing that it is relevant and constitutes 'good' practice) embodies the approach that has been previously judged to meet the legal standard in similar circumstances.

**What are the key things I should consider when making regulatory ALARP judgments?**

A3.22 If you are making an assessment of an ALARP position you should consider the following:

- Remember that the requirement is to reduce risks to be ALARP and this refers to the overall outcome rather than seeking to narrowly apply ALARP to each individual aspect.
- RGP refers to those good practices (be they safety measures, standards, etc.) that have been assessed and judged to meet the legal standard in similar circumstances and are applicable to the situation at hand. Only those good practices that are both relevant and 'good' (as opposed to 'best practice' or inadequate practice) are RGP: you must think carefully whether these are relevant to the situation and provide good practice (as opposed to inadequate practice or best practice).
- ALARP in relation to older facilities and in decommissioning requires especially careful consideration. RGP on modern design and operational standards is often not fully relevant and it is particularly important to consider the overall outcome, including the long-term safety benefits.
- Remember that RGP is not mandatory. It is most applicable to commonly-encountered circumstances but is only a starting point in situations that do not fall within the scope of the circumstances under which the RGP has been based. A dutyholder is free to take an alternative approach providing it can demonstrate that it has achieved an ALARP position.
- It is important to understand how and why a dutyholder considers its position to be ALARP. You must avoid making premature judgments until you have seen a dutyholder's ALARP case, even when you are confident in the authority of the RGP you have identified.
- It is important to properly document the sources of any RGP which we have identified and to properly record your reasoning, judgement and the application of our decision-making due process.
- It is important to ensure appropriate cross-discipline working within ONR to ensure we make balanced and proportionate judgements. You should seek appropriate specialist advice, including the appropriate engineering or human factors expectations and fault analysis.
- It is important that you make use of the ONR ALARP TAG and Risk Informed Regulatory Decision Making Guidance as appropriate, seeking assistance where necessary – such as from the ONR ALARP Working Group.