Office for Nuclear Regulation

Risk informed regulatory decision making

June 2017

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Foreword

The Office for Nuclear Regulation (ONR) is the independent regulator of nuclear safety and security across Great Britain. This document provides a re-statement of ONR's risk framework for nuclear installations and aims to further clarify the role of hazard and risk and their relationship with good practice in ONR's decision making. The intent is to give consolidated guidance on our risk and decision making approaches thereby supporting an enabling regulatory approach.

ONR's risk based decision making process is linked to the document 'Reducing risks, protecting people' (R2P2), published in 2001. R2P2 embraced and expanded on the document 'Tolerability of risk from nuclear power stations' (TOR), published in 1992, and extended the tolerability of risk framework to other types of installation and activity. This new guidance document does not replace or contradict R2P2, rather it: reinforces the TOR concept and its relationship to the law; describes application of TOR to the specific challenges presented by the nuclear industry; and clarifies how we take account of wider factors in reaching regulatory decisions. Essentially we have consolidated in one place our approaches and thinking on risk and decision making that are embedded in R2P2 and ONR's lower level guidance such as our Technical Assessment Guides. Neither TOR, nor R2P2 have been superseded or replaced by this new guidance; they remain key parts of ONR's regulatory framework.

I am pleased to publish this new ONR specific document that concisely sets out our risk informed framework and its use as part of our regulatory decision making. I hope that bringing the information together in one place will improve the transparency and understanding of the processes we use to make risk informed decisions.

The Health and Safety Executive (HSE), the Environment Agency (EA), and the Defence Nuclear Safety Regulator (DNSR) have supported ONR in development of this guidance and their contribution is gratefully acknowledged.

Dr Richard Savage

Chief Nuclear Inspector

Office for Nuclear Regulation

June 2017

1. Introduction

1.1 Purpose

1. The overall purpose of this document is to set out the Office for Nuclear Regulation's (ONR) risk-based framework for making regulatory decisions. It discusses the tolerability of risk concept, which is at the heart of our framework, and its relationship to the law. This document is new, but does **not** replace or contradict existing documents such as the Health and Safety Executive's (HSE) 'Reducing risks, protecting people' (R2P2)[1]. It is intended to reinforce the tolerability of risk (TOR) concept[2] and its relationship to the law, describe application of TOR to the specific challenges presented by the nuclear industry and, finally, clarify how we take account of wider factors in reaching our overall regulatory decisions. It consolidates into one document our approaches already embedded within our other publications.

2. This document is aimed primarily at stakeholders who want to know more about our risk based framework for making regulatory decisions. The framework contributes to securing the health, safety and welfare of persons at work and for protecting others against risks to health and safety arising from work activities in the nuclear industry. It sets out the framework and criteria by which we, in complying with our functions, make regulatory decisions. It considers how scientific evidence and uncertainties are taken into account and how we strike the balance between the benefits and disadvantages of adopting a measure, to avoid or control the risks.

3. In setting out our risk based framework, this document aims to:

   - set out our approach to the regulation of risk and the philosophy underpinning it;
   - set out the factors that inform our regulatory decisions;
   - provide reassurance to the public that risks to people are properly addressed, taking due account of the benefits of the activities giving rise to the risk; and
   - inform other regulators, whose responsibilities include regulating nuclear sites for matters other than safety and security, about the basis for the management of health and safety risks from work activities, thereby helping to promote consistency of decision making amongst regulators.

4. The central purpose throughout is to make our regulatory decision making process transparent rather than providing guidance to dutyholders. The difference in emphasis is important. For example, as we point out in paragraph 38, the factors that we consider in reaching a regulatory decision may be broader than those we would expect dutyholders to take into account in complying with the law.

5. The main part of the document sets out our risk informed framework and its role in our regulatory decision making. This is supported by Appendix 1 which outlines the context of the framework in relation to different elements of the life-cycle of a nuclear facility.

1.2 Scope of the risk informed framework

6. We regulate health, safety and security at licensed nuclear sites in Great Britain. In addition, we regulate the design and construction of new nuclear facilities and the civil transport of nuclear and radioactive materials. We also work with the international inspectorates to ensure that safeguards obligations for the United Kingdom (UK) are met.

7. Although regulatory decision making is relevant across all our areas of responsibility, this framework is mainly focused on the regulation of health and safety on nuclear licensed sites, new nuclear build (construction) sites, authorised defence sites, nuclear warship sites and our activities associated with assessing new reactor designs through our Generic Design Assessment (GDA) programme, which is a joint process with the Environment Agency. Regarding GDA of new nuclear facilities, although there is no nuclear hazard at this stage, our activities in this area are important in order to ensure future safe and secure operation; it is at this time that any necessary changes can be most easily made to the design.

8. For security, the threat comes from an 'intelligent adversary' who acts in a deliberate, planned fashion that is not amenable to numerical risk estimation in the way that many safety concerns are. Hence the risk informed framework described in this document is not used in making regulatory decisions on security matters, instead a qualitative approach is used, based on:

   - the State's current assessment of the nuclear security threats, both internal and external;
   - the relative attractiveness and vulnerability of identified targets to nuclear security threats;
   - characteristics of the nuclear material, other radioactive material, associated facilities and associated activities; and
   - potential harmful consequences from criminal or intentional unauthorised acts. Specifically, these acts include those involving or directed at nuclear material, other radioactive material, associated facilities, associated activities, sensitive information or sensitive information assets, and other acts determined by the State to have an adverse impact on nuclear security.

9. For transport, the vast majority of regulatory decisions are based on compliance with defined standards and requirements and a risk informed approach is not current practice. However, in unusual circumstances where compliance with the established standards is not on its own sufficient to come to an overall regulatory decision, the risk informed approach described here may be used to inform regulatory decisions.

10. Conventional and fire safety at nuclear installations is captured by the framework, which is applicable to all types of safety risk.

11. This document is not intended to cover all of our regulatory decisions – see Section 2. Instead it focuses on those based on the legal requirement to ensure health and safety so far as is reasonably practicable, where our regulatory decisions are informed by the tolerability of risk framework.

1.3 Legal background

12. On 1 April 2014 the Energy Act 2013[3] came into force which created ONR as a stand-alone regulator for nuclear safety and security and with a number of defined purposes:

   - protecting persons against risks of harm arising from ionising radiations from Great Britain's nuclear sites;
   - protecting people from risks to health and safety from work activities on Great Britain's nuclear sites, including risks from the storage of dangerous substances;

- ensuring the security of civil nuclear premises, the equipment used there, and sensitive information;
- ensuring compliance by the United Kingdom with the safeguards obligations, and ensuring the security of sensitive nuclear information; and
- protecting against risks relating to the civil transport of radioactive material in Great Britain by road, rail, or inland waterways.

13. To achieve these purposes we appoint inspectors who are suitably qualified to carry out the statutory functions of ONR. Inspectors are given a range of powers and authorities to regulate the nuclear industry, and may bring (or recommend in Scotland) prosecutions for a failure to comply with the requirements of the law. The authorities flow from the changes created by the Energy Act 2013, but equally from the Health and Safety at Work etc Act 1974[4]. The authority that flows from the Health and Safety at Work etc Act 1974 is important, as it provides the statutory basis for the term 'so far as is reasonably practicable' (SFAIRP).

14. SFAIRP is the description of the "*computation which must be made in which the quantum of risk is placed in one scale and the sacrifice, whether in money, time or trouble, involved in the measures necessary to avert the risk is placed in the other. Only if it can be shown that there is a gross disproportion between them – the risk being insignificant in relation to the sacrifice – can the person upon whom a duty is laid demonstrate that they had taken all reasonably practicable steps*"[5]. The nuclear industry commonly uses the terms as low as reasonably practicable (ALARP) or as low as reasonably achievable (ALARA), both of which are synonymous to SFAIRP and subject to the same test.

15. It is SFAIRP that creates a non-prescriptive regulatory framework, which puts the responsibility for safety and onus on dutyholders to demonstrate that the level of risk has been reduced ALARP. It is this non-prescriptive regulatory framework that drives the need for individual ALARP assessments. Alternatively, regulation by, for example, design rule setting takes some of that responsibility away from the dutyholder.

16. There is no precise legal factor or ONR algorithm that defines gross disproportion between the cost associated with the measures to reduce risk and the benefit in terms of risk reduction, and indeed numerical calculations are rare. Our policy of using a disproportion factor, that is the costs are greater than the benefits, up to approximately 10, before gross disproportion is demonstrated is based on evidence given to the Sizewell B Public Inquiry[6]. Although this evidence was produced some time ago, no subsequent legal proceedings or public inquiries have countered these views or provided alternatives.

17. Over time, guidance has developed which describes what is considered reasonably practicable in particular circumstances. This guidance is known as 'relevant good practice' and is discussed further in Section 3.3.

18. Nuclear Installations Act 1965[7] is another important piece of legislation which is linked to the Energy Act 2013. Whilst the vast majority of the Act addresses civil liability and compensation in the event of a nuclear incident, which is not the concern of ONR, certain provisions are relevant to the licensing regime that applies to nuclear installations. Those installations may be for the purposes of installing or operating a nuclear reactor or any other installation of a kind prescribed within the Nuclear Installations Act, and supporting legislation (the Nuclear Installations Regulations 1971[8]).

19. In order to install or operate such an installation the dutyholder must have a nuclear site licence, which can only be held by a corporate body. There is a period of responsibility attached to holding a site licence. Our policy is that the licensee is responsible for the site where the installation is located, until the risk of death to the most exposed individual from the residual radioactivity (above the average natural background radioactivity) is less than one in a million per year[9].

20. The nuclear site licence has 36 licence conditions attached to it, which are necessary or desirable in the interests of safety. Failure to comply with the licence conditions is an offence which, if the matter is put in front of the courts may attract an unlimited fine and can also result in a prison sentence.

1.4 Hazards and risk

21. The difference between what constitutes a hazard, as opposed to something which represents a risk, is fundamental to understanding our decision making framework.

22. The terms ‘hazard’ and ‘risk’ are often used interchangeably in everyday vocabulary. Nevertheless, it is important to make a clear distinction between the two:

- A hazard is something that has the potential to cause harm.
- A risk is the chance or likelihood of the harm arising.

The primary hazards associated with the nuclear industry arise from radiation released by radioactive materials. The risk represents the likelihood that people are harmed by exposure to that radiation.

23. The term ‘hazard’ is absent in the Health and Safety at Work etc Act 1974. However, the courts have ruled[10] that, as far as the Act is concerned, ‘risk’ means the ‘possibility of danger’ rather than ‘actual danger’. For practical purposes in this document, we refer to the definitions in paragraph 22.

24. In regulating and assessing risks, we consider both individual risks and societal concerns, including societal risks:

- Individual risk considers the likelihood of a hazard affecting a given type of individual, for example a worker, or the most exposed member of the public. We would normally consider a hypothetical person, for example a member of the public most exposed to the hazards, which could be someone assumed to live on the site boundary of a nuclear facility and/or whose lifestyle would result in the highest exposure to radiation from normal operation, including from any discharges of radioactive waste, and accidents.
- Societal concerns relates to events that could cause widespread or large scale detriment such as multiple fatalities in a single nuclear accident, widespread contamination off-site and within the facility or site, and safety-related detriments such as evacuation, relocation, land interdiction and food bans.

25. As a measure of the societal concerns that would result from a major nuclear accident, risk targets have been defined in our Safety Assessment Principles (SAPs)[11] based on accidents that could potentially lead to an immediate or eventual 100 or more fatalities. Internationally, the concepts of ‘large early release frequency’ and ‘large release frequency’ are commonly used as societal concerns criteria[12]. For our purpose, we

equate large early release frequency and large release frequency with the societal risk target in our SAPs[1].

- 'Large release frequency' is the frequency of accidents leading to a radioactive release in excess of a defined amount (size of release and types of radioactive materials). This defined release has the potential to lead to harm to a large number of members of the public.

- 'Large early release frequency' is the frequency of accidents leading to a large release, but where there is insufficient time to initiate and perform off-site counter-measures such as evacuation.

1.5 Nature of nuclear risks

26. Not only does our regulatory decision making span numerous areas, the nature of the hazard we deal with varies widely and has implications for the decisions we make. It covers low nuclear hazards on decommissioning sites where the nuclear fuel has been removed to high nuclear hazards on operating nuclear facilities. This leads to risks that can be categorised at two extremes as either high consequence – low frequency or low consequence – high frequency.

27. Although the level of numerical risk can be similar in both situations, the characteristics can be very different:

- One characteristic of high consequence – low frequency risks is that there is usually limited historical experience and therefore a greater level of uncertainty. It can be very difficult to quantify precisely the risks they may give rise to, particularly when scientific knowledge is pushed to the limit. Our focus here is usually on the risk to members of the public and societal concerns. Section 5 outlines how we deal with uncertainty in our decision making framework.

- The characteristics of low consequence – high frequency risks tend to differ in that they usually have better defined historical experience; the uncertainty is usually much lower. Our focus here is usually on risks to workers, as consequences are generally confined to the site.

2. Regulatory decision making background

28. Regulatory decision making refers to the decisions that we make using our statutory powers in relation to enforcement of dutyholders or our agreements with requesting parties subject to our GDA process. Although requesting parties are not legally bound, we engage with them in a similar manner and our 'decisions' are commensurate with this. Section 7.2 provides further discussion on GDA.

29. The term 'enforcement' is used in its widest sense and covers all activities falling within the scope of the ONR Enforcement Policy Statement[13]. It includes all dealings with dutyholders which result in service of notices, issue of licence instruments or prosecution. It also extends to the provision of information and advice either verbally or in writing.

[1] We also have individual risk targets in our SAPs, which are discussed in Section 3.2.

30. Regulatory decisions result from a range of our activities, including:

- permissioning activities on nuclear sites;
- assuring ourselves that licensees comply with licence conditions and relevant statutory provisions through planned inspections;
- enforcement activities, from the provision of advice through to prosecution, in accordance with the ONR Enforcement Policy Statement and the Regulators' Compliance Code14; and
- activities associated with GDA.

31. These activities result in the following broad categories of regulatory decisions:

- decisions concerning the granting or otherwise of a nuclear site licence;
- decisions relating to the use of powers contained within the licence conditions (directions, approvals, specifications, consents, notifications and agreements);
- decisions relating to application of dutyholders' administrative arrangements to comply with the licence conditions;
- decisions concerning enforcement action, such as the issue of improvement or prohibition notices or taking a prosecution (or recommending a prosecution in Scotland); and
- accepting the generic safety implications of a new reactor design as part of a GDA.

32. As stated in paragraph 11, this document is not intended to cover all of the regulatory decisions made by ONR. Instead it focuses on those based on the legal requirement to ensure health and safety so far as is reasonably practicable and where our regulatory decisions are informed by the tolerability of risk framework.

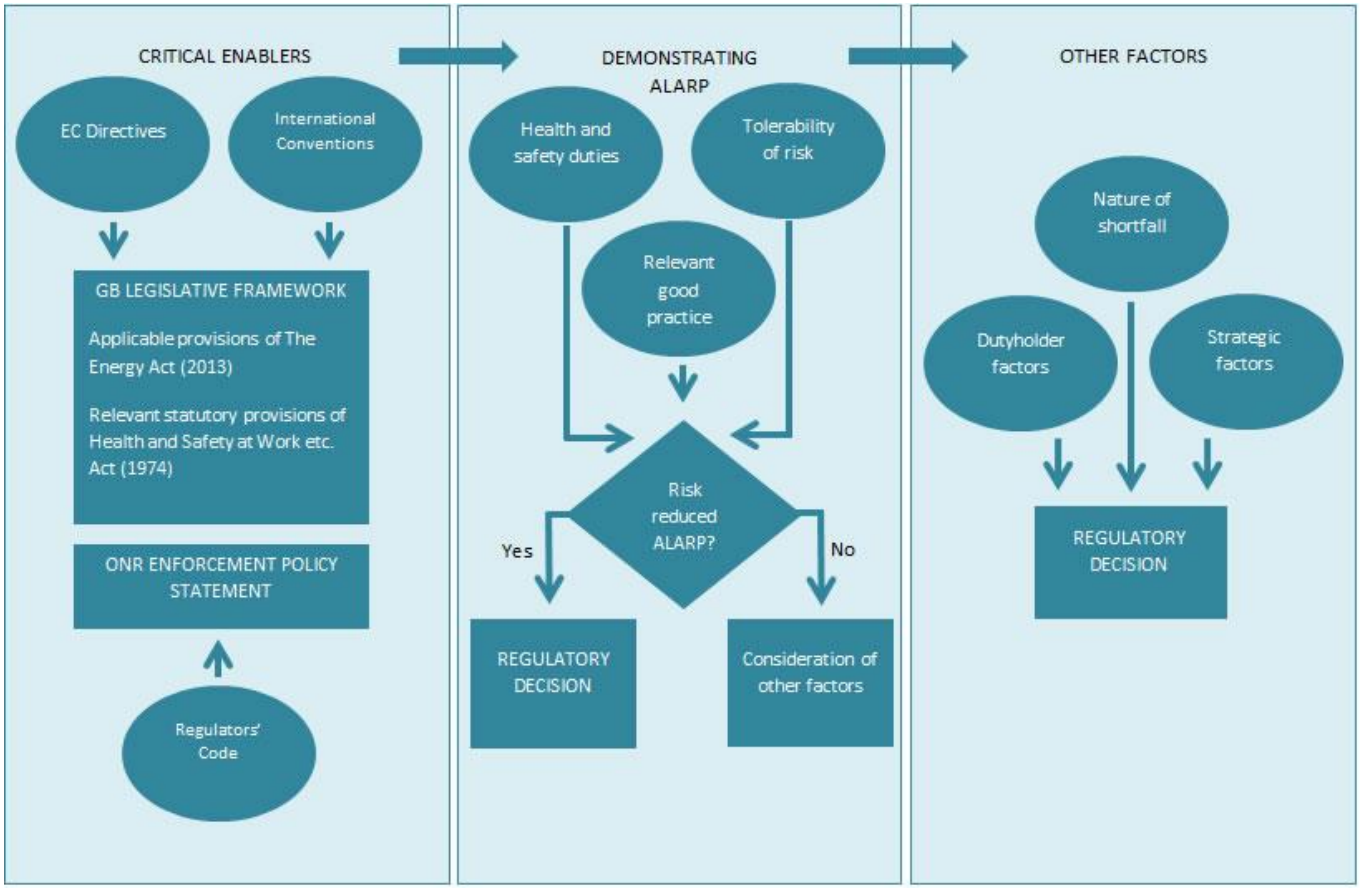

FIGURE 1: Overview of regulatory decision making

33. Figure 1 illustrates the key elements of our regulatory decision making. This incorporates relevant law and policy:

- the legislative framework, which is informed by European Commission (EC) Directives and international conventions; and
- the ONR Enforcement Policy Statement, which is in accordance with the Regulators' Code and regulatory principles required under the Legislative and Regulatory Reform Act 200615.

34. The ONR Enforcement Policy Statement sets out the following principles that underpin our regulatory decisions:

- proportionality in applying the law and securing compliance;
- consistency of approach when we exercise regulatory judgement;
- targeting of enforcement action on the areas of greatest risk or where the hazards are least well controlled;

- transparency about how we operate and ensure dutyholders understand regulatory expectations, both in terms of what is, and what is not, expected of them; and

- accountability for our actions.

35. A determination of whether a dutyholder has demonstrated that it has reduced or will reduce risk to a level that is ALARP forms a key part of our regulatory decisions. If a dutyholder has not demonstrated this, a key factor is an understanding of the size and significance of the shortfall. Consistent with the Health and Safety at Work etc Act 1974, in making this 'ALARP' judgement, we only consider those factors within a dutyholder's control. If there are other impacts on risk, for example across different dutyholders, we need to consider these aspects under strategic factors (discussed in paragraph 39).

36. Our decisions are informed by the health and safety duties arising from the legislative framework, the level of risk and whether relevant good practice has been implemented. The tolerability of the risk also informs our regulatory decisions, in determining where we focus our resources and how we respond to any shortfall against the requirement to reduce risk ALARP. Tolerability of risk and relevant good practice are discussed in some detail in Section 3 of this document.

37. If we determine that a dutyholder has reduced the level of risk ALARP this would lead us directly to our regulatory decision, for example, to grant permission or take no other enforcement action.

38. Where it is our judgement that the level of risk has not been reduced ALARP, in other words where there is a shortfall identified, we will consider the nature of the shortfall, for example, the size of the shortfall, the level of risk from the activity or the control of the risk, and any dutyholder and strategic factors in reaching our regulatory decision. In line with ONR's Enforcement Policy Statement, we will consider whether the size of the shortfall is small, such that it would be disproportionate to take further regulatory action or not permission an activity.

    - Dutyholder factors are specific to the dutyholder and its activities. The factors include any relevant incidents and its enforcement and inspection history; where harm has occurred, the level of that harm; its general performance regarding compliance with the law; and our confidence that the dutyholder will comply with the law.

    - Strategic factors may include relevant government policies, consideration of vulnerable groups, the effect of the decision on other dutyholders and the balance of risk between different sites, including across different dutyholders. Preventing or delaying an activity on one site could lead to an increase in risk elsewhere, which is outside an individual dutyholder's control.

39. The dutyholder and strategic factors, which are consistent with ONR's Enforcement Management Model[16], do not form part of our judgement on whether or not a dutyholder has reduced the level of risk ALARP (in order to meet its duty under the Health and Safety at Work etc Act 1974). They are however taken into account in our overall regulatory decision. These factors are those for which we have sufficient authority and knowledge, supplemented by consultation with others as necessary, to take into account in our decision making. 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.

40. Figure 2 illustrates the different elements in coming to a regulatory decision, as discussed in this section.

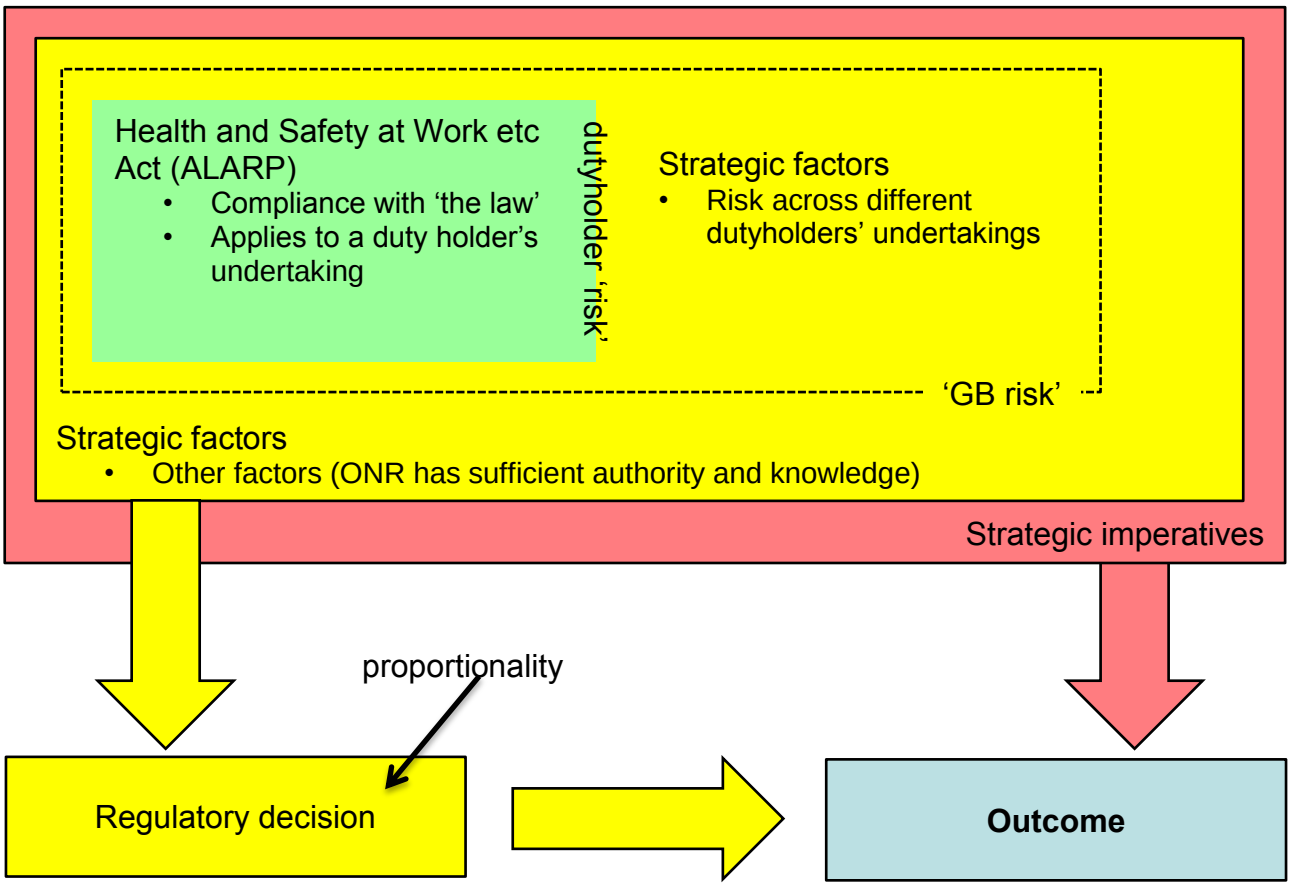

FIGURE 2: Decision making factors

3. Risk informed framework

41. In this section we outline our risk-based framework for informing our regulatory decisions. This includes the criteria and philosophy adopted for deciding what risks are unacceptable, tolerable or broadly acceptable. This 'tolerability of risk' concept is at the heart of our framework. It is based on 'The Tolerability of Risks from Nuclear Power Stations' published in 1992[2], which was the basis of HSE's overall framework for decision making, as outlined in 'Reducing Risks, Protecting People' published in 2001[1]

3.1 Tolerability of risk framework

42. Tolerability does not mean acceptability. It refers to a willingness to live with a risk in order to secure certain benefits, with the confidence that it is being properly controlled. To tolerate a risk means that we do not regard it as negligible or something we might ignore, but rather as something we need to keep under review and reduce further if and

when we can. For a risk to be ‘acceptable’ on the other hand means that for the purposes of life or work, we are prepared to accept it as it stands.

43. The tolerability of risk framework is illustrated in Figure 3. The triangle represents increasing level of risk as we move from the bottom of the triangle to the top. We use this framework to inform our regulatory attention. There are three regions shown in this triangle:

- The dark zone at the top (unacceptable region) represents risks which are so high we consider them to be unacceptable unless there are exceptional circumstances.
- The middle zone (tolerable region) is where we focus our attention on considering whether the dutyholder has reduced the level of risk ALARP.
- The light zone at the bottom (broadly acceptable region) represents the risks that are so low we consider them broadly acceptable. In most cases we focus on whether the claims are justified, and if so consider it disproportionate to apply regulatory resource to reduce them further.

The legal duty for dutyholders to reduce risks SFAIRP (or the level of risk to ALARP) applies to all levels of risk described in the bullet points above.

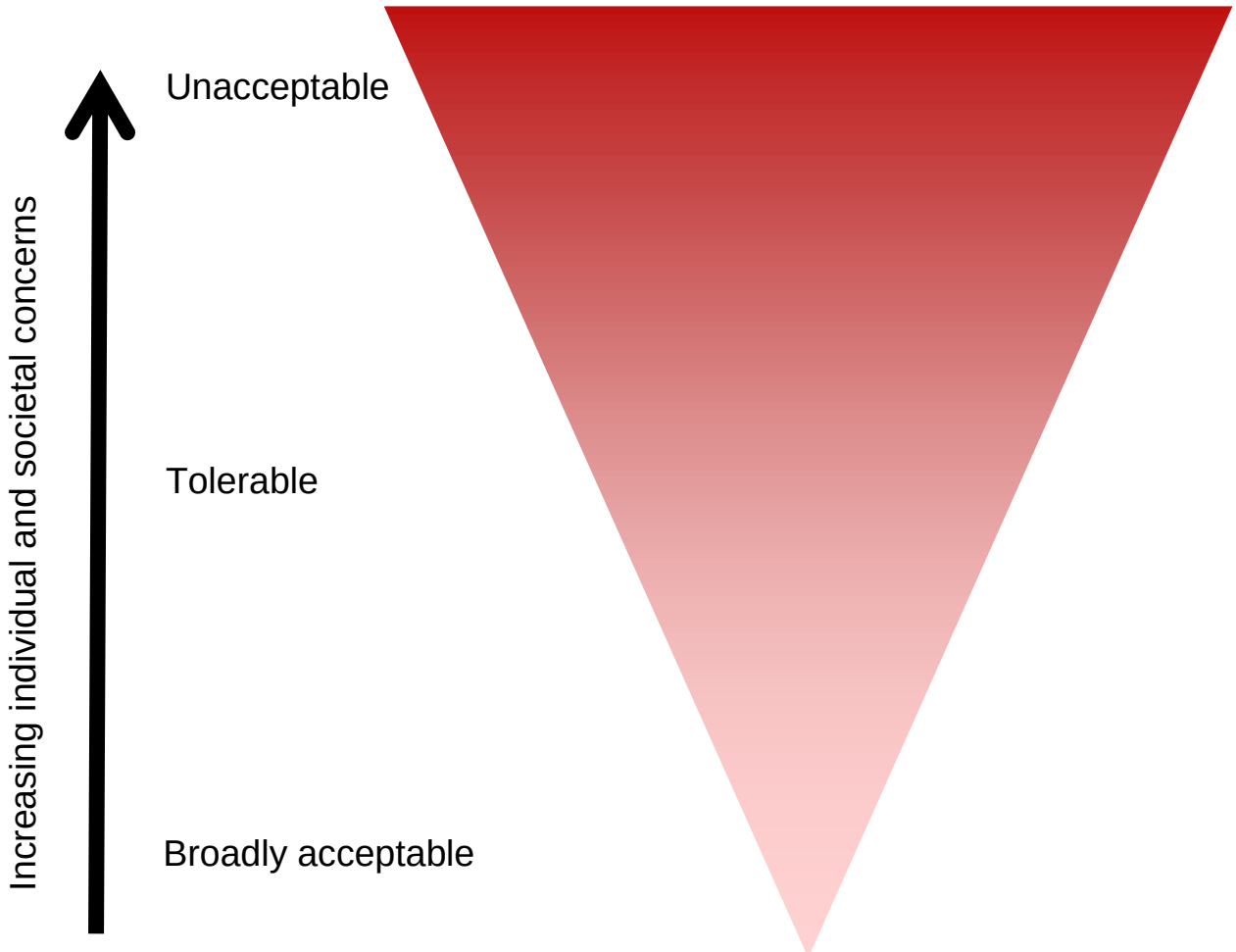

FIGURE 3: Tolerability of risk framework

44. Some health and safety duties, that are not specific or absolute, require action to be taken SFAIRP. There are no duties that require risks to be tolerable or broadly acceptable. Tolerability is our policy to inform our regulatory decisions and focus our regulatory attention, whereas the term 'reasonably practicable' refers to a legal duty.

45. Deciding what is reasonably practicable to control risks involves judgement. When considering the need for further measures to be implemented by dutyholders, we take account of the degree risk would be reduced against "*the sacrifice, whether in money, time or trouble involved in the measures necessary to avert the risk*". Unless the dutyholder can demonstrate gross disproportion between these factors and that the risk averted is insignificant in relation to the sacrifice, they must take measures to reduce the risk.

46. The balance between risk and sacrifice does not always mean that a detailed analysis is necessary. The emphasis must be on an analysis which is fit for purpose. Equally, it does not mean that a quantitative argument based on risk estimates is always necessary, for example when determining a disproportion factor. This is due to the fact that qualitative features such as applying deterministic engineering principles may be sufficient in making a case. However, we will seek suitable and sufficient probabilistic safety analysis (PSA) in addition to deterministic analysis for situations where there are significant hazards and complexity.

47. In all cases, as outlined in our SAPs, the dutyholder needs to demonstrate that all reasonably practicable measures have been implemented. As part of this demonstration, dutyholders must consider all relevant factors relating to engineering, operations and management of safety. These expectations are often referred to as 'relevant good practice' and include an option adopted elsewhere in similar circumstances and the extent to which this option has worked in practice. This can often provide strong indications of what the ALARP solution might be.

48. The starting point for determining whether the level of risk has been reduced ALARP should be the present situation and consideration of what more could be done to reduce the risk.

49. In practice, the vast majority of activities in the nuclear sector give rise to risks in the tolerable region. A key input into our regulatory decision making is therefore the acceptability of a dutyholder's ALARP demonstration.

50. 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. Guidance is given to our inspectors on assessing an ALARP demonstration in our Technical Assessment Guide (TAG) on ALARP[17].

3.2 Tolerability targets

51. The tolerability of risk framework has been translated into nine numerical targets in our SAPs. These are in the form of Basic Safety Levels (BSLs) and Basic Safety Objectives (BSOs). It is, however, essential that these are applied against a background of good engineering and operational practice. The BSOs represent the boundary between the broadly acceptable and tolerable regions within our tolerability of risk framework. Regulatory resources will generally not be used to seek further improvements below the BSOs where we will confine ourselves to considering the validity of the arguments presented. This is a pragmatic approach to enable targeted and proportionate use of our resources; it is not a green light for dutyholders to forego ALARP considerations at

such levels. The BSLs represent the boundary between the unacceptable and tolerable regions within our tolerability of risk framework.

52. With the exception of the BSLs derived from the Ionising Radiation Regulations[18], which are legal limits, all other targets are policy guidance for ONR inspectors and are not mandatory. Nevertheless, failing to meet risk targets (BSLs) is a strong indicator that the level of risks may not be ALARP.

53. Appendix 2 provides an overview of our numerical targets against the tolerability of risk framework.

3.3 Relevant good practice

54. We expect ALARP demonstrations to consider first and foremost the factors relating to engineering, operations and the management of safety, that is 'relevant good practice'. That is, we expect relevant good practice to form the starting point of a dutyholder's ALARP justification; we also expect them to consider whether it is reasonably practicable to go further. A key input into our regulatory decision making is whether relevant good practice has been implemented.

55. We consider relevant good practice is those standards for controlling risk which have been judged and recognised by us as satisfying the law, when applied to a particular relevant case in an appropriate manner. Good practice can be distinguished from best practice, where best practice usually means a standard of risk control above the legal minimum.

56. For an existing facility, relevant good practice 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 dutyholder should make that move.

57. Sources of good practice include:

- guidance within Approved Codes of Practice (ACoP), for example the Ionising Radiation Regulations 1999;
- HSE / ONR guidance including ONR's SAPs and TAGs / Technical Inspection Guides;
- standards produced by standards making organisations, for example British Standards Institution (BSI), International Organisation for Standardisation (ISO), International Atomic Energy Agency (IAEA) and Western European Nuclear Regulators' Association (WENRA);
- guidance agreed by a body representing an industrial / occupational sector; and
- well defined and established standard practice adopted by an industrial / operational sector.

58. In some cases ACoPs and guidance have been issued to assist the dutyholder in achieving compliance with the law. Where ACoPs are not followed by dutyholders, they have to demonstrate that the alternative methods employed are equal to or better than the ACoP recommendations.

59. The SAPs also inform our view of relevant good practice. The hierarchy of safety measures set out in the SAPs will usually form a key part of the ALARP analysis, seeking solutions as near to the top of the following list as possible:

- avoid the hazard or minimise if not avoidable;
- 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.

The criteria for determining whether an explicit ALARP demonstration is required in relation to the engineering SAPs, which represent ONR's views of relevant good practice, are not set out in numerical terms. Instead, if the relevant SAP is evidently well satisfied, we consider the facility to be engineered in a manner which is likely to present risks equivalent of the tolerability of risk broadly acceptable region on that particular point. In such a case it is unlikely that further assessment would be required. Conversely, we expect any non-conformance with relevant good practice to be explicitly highlighted and justified as reducing the level of risk ALARP within the safety case.

60. In addition to the SAPs, we consider the IAEA Safety Standards and the Safety Reference Levels developed by WENRA for reactors[19], decommissioning[20], and the storage of radioactive waste and spent fuel[21] as UK relevant good practice. IAEA Safety Standards are developed by international consensus and were used to benchmark the 2006 SAPs. 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 considered relevant good practice for all types of nuclear facilities and cover all stages in the lifecycle. The storage Safety 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 up to the Reference Levels and, in line with our enforcement policy in relation to relevant good practice, we expect dutyholders to follow them. In general, the IAEA Safety Standards and WENRA Reference Levels are included in our relevant TAGs.

61. Another important source of relevant good practice in the nuclear industry is what other facilities (including non-nuclear, for example the major hazards industry) have done. Many dutyholders have established their own standards reflecting good practice that are acceptable to us. However, in accepting the past practice we will seek evidence that the practice remains relevant and consider if it was implemented for safety reasons.

62. What is accepted as relevant good practice is subject to change over time. This is due to technological innovation which improves the degree of control, cost impact of improvements, knowledge about the hazard or operational experience, for example incidents and accidents. For existing facilities undergoing Periodic Safety Reviews (PSRs), the facility should be compared with the benchmark of modern standards. When considering compliance and the reasonable practicability of improvements, the dutyholder should take account of aspects such as the age of the facility, its future lifetime, future operations and the degree and importance of any shortfall.

63. Where relevant good practice is clearly established for the situation and fully implemented, for example, for day-to-day hazards, we consider the dutyholder has reduced risks to broadly acceptable levels and we generally will not expect an explicit comparison of costs

and benefits. The development of relevant good practice and standards includes ALARP considerations, so in many cases meeting them is sufficient when the circumstances in which they are applied are sufficiently close to those in which they were developed. This is particularly the case where the hazard leads to low consequences if realised.

64. In other cases, either where standards and relevant good practice are less evident or not fully applicable, or where the consequence of the hazard is high, the onus is on the dutyholder 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).

4. Judging whether risk has been reduced ALARP

65. Figure 4 illustrates how we use the tolerability of risk framework and relevant good practice conceptually within our regulatory decision making. It helps us to make a judgement on whether the legal duty to reduce the level of risk ALARP has been met and/or the level of risk is so small that it would not be good use of our regulatory resource to consider the matter further. This is relevant to all our regulatory decisions, including whether to focus our resources on an issue, permission a dutyholder's activity, direct operations to cease, take certain enforcement action following an inspection or investigation, or decisions regarding GDA.

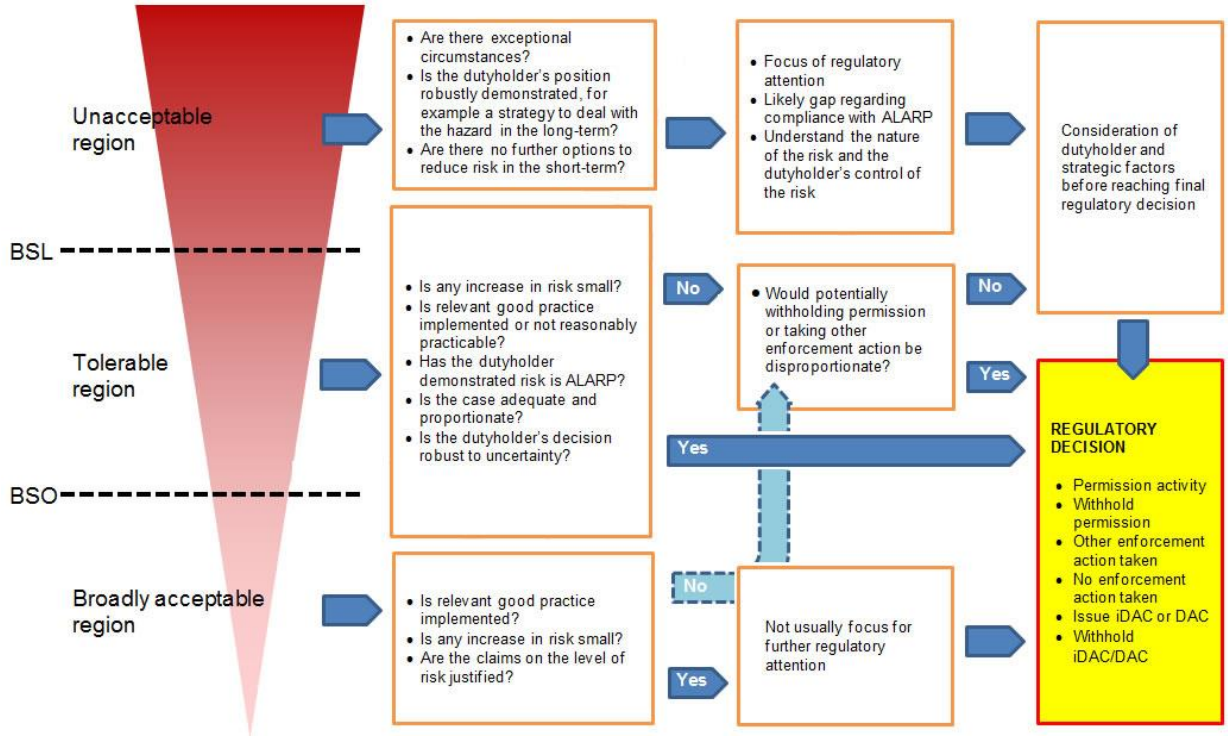

FIGURE 4: Tolerability of risk framework in informing regulatory decisions

66. If the level of risk is broadly acceptable (meets the BSOs in our SAPs), the activity is not new, novel or complex, and we are satisfied that the dutyholder has implemented relevant good practice and has control of the risk (or any increase in risk is small), these activities will not normally be the focus of further regulatory attention. There will be greater benefit from applying our resources to areas of higher risk. We will, however, satisfy ourselves that the dutyholder's claimed level of risk is justified and its arguments

are valid. This does not remove the requirement for the dutyholder to seek or implement further reasonably practicable improvements.

67. If we judge that an activity leads to a level of risk that is so high that it falls into the unacceptable region (exceeds the BSLs in our SAPs), this will be a priority for our regulatory attention. In such cases it is our expectation that the dutyholder should be actively managing and prioritising the situation to reduce the level of risk 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. We recognise that for some facilities, for example storage facilities with a large hazard, it is not possible to shutdown the plant to reduce risk.

68. If the BSL is a legal limit, for example the dose limits to workers outlined in the Ionising Radiation Regulations, it is our expectation that the dutyholder must take measures to restore compliance and we will consider appropriate enforcement if necessary. For other BSLs, our policy is that the level of gross disproportion in ALARP considerations should be very high and we assume that it is highly likely that additional improvements to safety will prove reasonably practicable. We require dutyholders to demonstrate that they have undertaken a robust optioneering process to control the radiological hazard. ONR will only permit continuing to operate while failing to meet a BSL if the dutyholder can demonstrate that there are no reasonably practicable options to reduce risks further in the short-term. Moreover, if operation is to continue, we will seek a clear longer-term plan to manage and reduce the risks within the shortest reasonably practicable period. Where a BSL is exceeded, we will consider regulatory action to shutdown the facility or prohibit or curtail the activity.

69. If we judge that an activity falls into the tolerable region, which is the case for the vast majority of activities in the nuclear industry, we will focus on whether the dutyholder has demonstrated that the level of risk has been reduced ALARP, whether relevant good practice has been implemented, the effect of uncertainty and the robustness of a dutyholder's arguments. Where it is not possible to demonstrate ALARP by good practice features and risk estimates alone, dutyholders need to explicitly compare the benefits of other risk reducing measures with the costs of their implementation, demonstrating that the costs relating to implementation would be 'grossly disproportionate' to the benefit provided (risk reduction).

70. Where there are significant hazards and/or the operation is complex, we expect dutyholders to produce adequate risk analyses and/or PSAs that are related to and underpinned by engineering substantiation and operational measures. It is important to note that we expect such analyses to highlight potential weaknesses in the engineering and operation of the facility and not solely to compare against numerical risk targets.

71. We expect dutyholders will implement the safest option that is reasonably practicable taking appropriate consideration of the impact of all risks to all those affected in making its balanced decision. Where there are several linked risks, whether arising from a single hazard or from different connected hazards, balance may be needed to achieve an appropriate overall solution. This may include balancing risks from potential accidents with those from normal operation (e.g. from radioactive discharges). We recognise that regarding the safest option, the implementation of the option giving the lowest risk is not always the most appropriate with respect to ALARP. The time taken to implement an option to reduce risk is a key input into our judgement on whether a dutyholder has demonstrated it is doing all that is reasonably practicable. **A reduction in risk implemented in a short time can provide a better, overall safer solution over a period of time than a larger reduction in risk not implemented for a number of years.**

72. Where there are long timescales involved and/or where risk may need to increase in the short-term to reach a much lower risk in the long term, we will take a holistic view to make a judgement on whether a dutyholder is doing enough to reduce risks ALARP. We will not consider the level of risk for a short period of time in isolation, but take account of the context of the change in risk. However, we will always expect a dutyholder to demonstrate it is in control of the hazard at all times. Relevant good practice and consideration of uncertainty are key in such circumstances. We will also examine carefully any short-term increases in risk that are *'unacceptable'* when assessed against our tolerability of risk framework.

73. Nuclear dutyholders have generally embraced the tolerability of risk framework and often embedded it within their own internal procedures and guidance. Similarly they have long recognised the need to demonstrate that risks are ALARP, that 'good practices' are the starting point of their demonstration and the fundamental question they address is 'what more could we do?' Dutyholders identify potential further measures and subject them to the reasonable practicability test. The measures are then adopted if appropriate. We scrutinise these considerations as part of our assessment of dutyholder submissions.

74. The application of the process outlined above can often be more complicated in real life. Although we do not accept affordability in isolation as a legitimate factor in an ALARP argument, we recognise resource pressures and the impact of trying to implement too many measures at one time, or during particular operational situations could be counterproductive in terms of safety. Therefore, some form of prioritisation or scheduling is both sensible and necessary, even if it may appear that some improvements are delayed. In such cases we are keen that the 'when' is considered in the same way as 'what' should be implemented and where implementation is deferred, the dutyholder provides a sound rationale for it.

75. The output of considering whether a dutyholder has demonstrated that it has reduced or will reduce risk to a level that is ALARP will generally fall into one of the following areas:

- The level of risk is so small that it would not be a good use of our resource to consider it further.
- The level of risk is ALARP or there is a negligible shortfall. In this case, we would permission an activity and take no enforcement action.
- The level of risk is not ALARP, and the level of risk or change in risk is not small. In this case, where the legal duty to reduce the level of risk ALARP has not been met and relevant good practice not implemented, we would consider enforcement action and/or whether to grant permission, taking dutyholder and strategic factors into account. This aspect is considered in the discussion on regulatory decision making in Section 6.

5. Handling / treatment of uncertainty

76. In many cases there is a degree of uncertainty in the information considered in our regulatory decisions. Our decision making takes account of uncertainty by, where possible, understanding its origin, magnitude, what can be done to reduce it and how it may affect our decisions. To help make such decisions we engage with the dutyholders and a wide range of technical disciplines within ONR and where necessary seek the advice of external specialists. We expect dutyholders to produce a multi-faceted safety case, based on independent and diverse arguments, so that no undue reliance is placed on any single facet of the argument in the safety case.

77. In most situations where there is uncertainty, our standard approach is to take some confidence from the use of a multi-faceted safety case and to expect dutyholders to use conservative data and assumptions and safety factors – where they demonstrably err on the side of safety. This approach provides a degree of confidence in the results of the dutyholder's safety or engineering analysis, which are used for comparison with acceptance criteria and therefore in our regulatory decision.

78. We recognise that dutyholders need to take care if they use a conservative analysis, risk assessment or PSA to identify potential safety improvements; the outcome of the conservative bias may be worse than the outcome of a more realistic analysis. A good example of this is in severe accidents, where overly conservative assumptions may lead to an incorrect conclusion that no further reasonably practicable measures can be implemented. In such circumstances best estimate analysis can lead to a safer outcome. Similarly where long and short-term risks are being balanced, for example during decommissioning of a nuclear facility, best estimates are recommended, supported by sensitivity analyses. However, conversely we also recognise that best estimate analysis can miss cliff-edge effects, where a small change in assumptions leads to a disproportionate increase in radiological consequences, which need to be addressed through sensitivity studies.

79. Subject to reasonable practicability, consideration should be given by dutyholders to reducing uncertainty by, for example, research to address incompleteness and modelling uncertainty or by seeking better data.

6. Regulatory decision making

80. Regulatory decisions within ONR are made in accordance with ONR's Enforcement Policy Statement, 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 permission for an activity, issuing improvement or prohibition notices, through to prosecution in the most serious cases.

81. In reaching a regulatory decision, as illustrated in Figure 2, we take into account a number of factors:

- firstly, whether a dutyholder has demonstrated that it has reduced or will reduce risk to a level that is ALARP and the nature of any shortfall, taking a holistic view of the risk;
- the proportionality of withholding permission, taking other enforcement action, or not accepting an aspect of a proposed reactor design in GDA; and
- finally, wider factors including dutyholder and strategic factors where we have sufficient authority and knowledge.

82. Within the scope of this document, our decisions usually fall into two broad categories: those relating to compliance and those relating to permissioning.

83. Regarding the first category, compliance, the Enforcement Management Model[16] was developed to guide us in making consistent and proportionate enforcement decisions. In applying the model to the outcome of ALARP considerations, we establish the seriousness of shortfalls with reference to where the dutyholder is and where it ought to be when complying with the law. This is then used to inform our decision on appropriate enforcement action. It is at this point in the enforcement process that wider factors are taken in to account, and not when determining compliance.

84. Where the dutyholder's ALARP justification is part of a request to grant permission required under a nuclear site licence condition, we distinguish between wider arguments related to dutyholder and strategic factors and the judgement as to whether the level of risk is reduced ALARP. Ultimately, consideration of an ALARP shortfall in the context of those wider factors where we have sufficient authority and knowledge may lead us to grant permission for the activity.

85. It must also be recognised that, in accordance with our regulatory philosophy there may be situations where the dutyholder has not adequately demonstrated that the level of risk has been reduced ALARP, but where the gap is such that it would be disproportionate not to grant permission. In these cases, we would work with the dutyholder to reach a position where risks are ALARP, but this process should not necessarily mean that our permission is withheld.

86. We also recognise that dutyholders may need to conduct their undertakings in a particular 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'.

87. Furthermore, we recognise that dutyholders do not have unlimited resource, and some form of work prioritisation is necessary. Claims related to these factors can sometimes appear in safety cases under the banner of 'group / global ALARP', 'programme ALARP', 'holistic ALARP' or 'dynamic ALARP'. Dutyholders use these terms to try and capture prioritisation, strategic factors and/or wider national factors. Whilst this is understandable, it can lead to a lack of clarity as many of these factors normally lie outside the scope of the Health and Safety at Work etc Act 1974 (and dutyholders' undertakings) and therefore ought not to feature in an ALARP case.

88. Instead dutyholder and strategic factors normally inform our regulatory decisions and it is helpful if dutyholders, where relevant, identify them explicitly and separately from their ALARP considerations, providing arguments of their relevance. If the level of risk has not been reduced ALARP, relevant dutyholder and strategic factors can and should be taken into account by us in our regulatory decisions. However, wider national factors would not normally influence our regulatory decisions, as we would not have the authority or sufficient knowledge of the considerations involved to judge the significance of such factors.

89. We term these wider national factors 'strategic imperatives'. An example of such a strategic imperative is where a dutyholder makes a case not to reduce risks SFAIRP because of overriding strategic defence needs, thereby invoking the so-called 'defence imperative'. In such circumstances the government would specify that the nature of the defence needs to be so important that they override any obligations on the dutyholder to reduce the level of risk further. Strategic imperatives should not be confused with strategic factors, which are considered in reaching our regulatory decisions. Where strategic imperatives are invoked by wider government, this will not normally change our regulatory decision. Such situations are expected to be very uncommon and would involve detailed discussions between our senior management, other relevant regulators, the dutyholder and UK Government to ensure all parties understand the implications of the course of action. We would work collaboratively within the constraint of the imperative to achieve the best safety outcome.

90. In conclusion, we separate out the legal duties and wider factors in our regulatory decision making and make this clear in our records. Firstly we judge whether risks have been reduced SFAIRP (or the level of risk reduced ALARP) independently of any considerations of dutyholder or strategic factors. If this judgement concludes that risks have not been reduced SFAIRP, then dutyholder and strategic factors are taken into

account in forming an appropriate and proportionate regulatory decision. This approach is consistent with our enforcement policy and procedures, which includes management review and approval of decisions by persons with the necessary delegated authority. Strategic imperatives are considerations outside our regulatory decisions, but we will nonetheless work collaboratively with others to achieve the best safety outcome.

Appendix 1

7. Framework in context of different areas we regulate

7.1 Introduction

91. In the main part of this document we set out our risk based framework and regulatory decision making for managing nuclear safety and site conventional health and safety risks. This framework is applied to all our nuclear safety regulatory decision making where the tolerability of risk framework and/or the legal requirement to ensure health and safety SFAIRP are at the heart of our regulatory decisions. This includes, for example, making decisions in the following broad areas: GDA, licensing of and permissioning the construction and operation of new facilities, and operational, legacy and decommissioning facilities. Each of these areas are quite diverse in terms of the nature of the nuclear hazard, the level of risk, how the level of risk changes over time to reach a reasonably practicable position, and the environment in which they exist. Given this diversity, and often unique challenges, the following paragraphs set out how we apply our risk based framework across the broad areas we regulate that are within scope of this document.

7.2 Generic Design Assessment of new commercial reactor designs

92. GDA is the process that we use, jointly with the environment agencies (Environment Agency / Natural Resources Wales), to assess safety, security and environmental implications of proposed new reactor designs separately from applications to build them at specific sites. If we are fully content with the generic safety aspects of the design we issue a Design Acceptance Confirmation (DAC). The Environment Agency / Natural Resources Wales will issue a Statement of Design Acceptability (SoDA) if they are content with the generic environmental aspects. This would mark the end of GDA for that generic design. Provision of a DAC and a SoDA means that the generic reactor design is capable of being built and operated in Great Britain, on a site bounded by the generic site envelope, in a way that is acceptably safe, but subject to a further site specific assessment including the licensing process for new facilities. The issue, or non-issue, of a DAC is ONR's key regulatory decision resulting from the GDA process.

93. GDA is a voluntary process and a DAC is not a legal requirement of Great Britain's nuclear licensing regime for new nuclear power stations. However, the UK Government recognises that the approach is more efficient and therefore expects reactor designers to follow the GDA process.

94. Important aspects we take into account in our decision to issue a DAC include the following:

- For all new nuclear reactor designs we will concentrate our attention on those faults and hazards which, if inadequately controlled, could give rise to societal consequences and serious radiological health effects to workers and the public.
- The overriding legal requirement for new reactor designs is that the level of risk is demonstrated to be ALARP when the facility starts operation and over its lifetime.
- It is our policy that the level of risk from a new facility or activity should at least meet our BSLs. However, the application of relevant good practice in the nuclear

industry should lead to risks that fall in the broadly acceptable region of our tolerability of risk framework, that is, it should meet our BSOs.

- It is also our policy for GDA that the level of safety must be no less than a comparable facility already working or being constructed in Great Britain or somewhere else in the world.
- We will consider the design holistically so that improvements to particular features of the plant will be considered for reasonable practicability in the context of the overall impact on risks.
- We will also judge the safety of new reactor designs on their own merits and not compare them.
- We will assess the ability to meet the requirements of relevant statutory provisions for site conventional health and safety, and fire safety.

95. For the overall demonstration that the level of risk is ALARP within GDA, we expect four main areas to be addressed:

- There is a clear conclusion that there are no further reasonably practicable improvements that could be implemented, and therefore the level of risk has been reduced ALARP.
- Relevant good practice has been incorporated into the design. This is the basic requirement for meeting the law and we would expect this demonstration to include comparisons with national and international standards.
- The requesting parties present rationale for the evolution of the proposed design from its forerunners. This should examine why certain features were selected and others rejected to result in a safer design.
- Risk assessment is used to identify potential engineering and/or operational improvements in addition to confirming the numerical levels of safety achieved.

7.3 The construction of new facilities

96. The construction of new facilities primarily includes new reactor designs progressing through GDA and into the site licensing, construction and operations phase, or the design, construction and operation of a new facility on an existing licensed site.

97. For new reactor designs progressing into the licensing phase, the Nuclear Installations Act 1965 describes the legal requirement to obtain a nuclear site licence from ONR before installing a nuclear reactor on a site. In addition, the legal requirement for all new nuclear facilities is underpinned by the more general Health and Safety at Work etc Act 1974, which places a fundamental responsibility on the dutyholder to reduce risks SFAIRP both during the construction phase and during the plant's operational lifetime.

98. It is our policy that the level of risk from a new facility or activity should at least meet our BSLs in addition to being demonstrated ALARP. However, meeting our BSLs is a minimum expectation and for new facilities we expect the application of relevant good practice to result in a level of risk which can be demonstrated to meet our BSOs, in addition to being demonstrated ALARP.

99. The demonstration that the level of risk is being reduced ALARP during the development of new facilities also requires the application of our licensing, licence

condition inspection and permissioning processes. These need to be established for a new operator and/or a new site, although a new facility on an existing nuclear licensed site will already be subject to our licence condition inspection and permissioning activities.

100. For new reactor designs we consider that there are advantages in granting a nuclear site licence as early as possible as this enables regulatory control and influence under our licence conditions.

101. Prior to granting a site licence we will assess the prospective licensee's organisation in the areas of management, leadership and safety culture. We will also assess the suitability of the site for the proposed activities, ensuring that the plant is adequately designed, constructed and operated, and that the level of risk is ALARP, or is capable of being so as the design develops. A full safety case is not necessary at this stage. However, the safety case must be developed with the prospective site licensee's legal duties in mind. In the site licensing phase, we will assess the degree to which the prospective site licensee understands and takes responsibility for the safety case and the management of risks ALARP.

102. New and existing nuclear licensed sites will be subject to our permissioning regime, which will be accompanied by ongoing inspection of the associated licence conditions; see the discussion on operating plant (Section 7.4) for further information. We will take confidence from the safety case and consider the outcome of licence condition and readiness inspections in order to permission the project at key stages. This approach ensures that robust arrangements are in place to manage construction, commissioning and, eventually, operational risks.

103. We apply our SAPs, TAGs and appropriate national and international standards during the assessment process for any new nuclear facility. This enables us to reach an independent and informed judgement on the adequacy of the nuclear safety case. Adequacy is based on:

- the legal requirement that the level of risk will be reduced ALARP;
- national and international relevant good practice is incorporated into the design;
- the evolution of previous designs has led to improved safety;
- risk assessment has been used to identify potential improvements; and
- risks achieve our BSOs if reasonably practicable.

7.4 Operating plant

104. Operating plant includes the existing fleet of operating reactors, fuel cycle facilities, waste management facilities and relevant defence facilities. The hazards and risks associated with these facilities vary widely and are regulated in a targeted and proportionate manner.

105. In reaching a judgement on whether an acceptable level of safety is being achieved and that the level of risk has been reduced ALARP, a significant amount of information is considered, including:

- assessment of safety cases;
- assessment of PSRs;
- results of on-site compliance inspections; and
- the findings from investigations of incidents and events.

106. In assessing safety cases for existing facilities comparison is made against relevant modern standards, including those not in force when the facilities were designed and constructed. The safety case should identify any important shortfalls against modern standards together with options for improvements. The reasonable practicability of implementing improvements should be considered, starting with improvements which offer the greatest benefit to safety. We recognise that older facilities may meet the ALARP requirement at higher risks than new ones.

107. As a facility ages, its safety margins may be eroded, for example due to the incidence of, or vulnerability to, faults increasing due to material changes in the plant. Reducing the risk level may not be possible, so a judgement has to be made as to 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, but where based largely on the remaining lifetime this would only be acceptable where the maximum lifetime was irrevocably fixed. Furthermore, we would not normally accept arguments relating to the remaining lifetime where the level of risk is in the unacceptable region of the tolerability of risk framework. Situations with eroding margins 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 Licence Condition 15 (see paragraph 109) is paramount.

108. Ageing of facilities could result in BSLs being exceeded. In these cases, provided the BSL is not a legal limit, it may be reasonable for operation to continue if:

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

109. Under Licence Condition 15 PSRs must be carried out by the licensee. The reviews are complementary to the day-to-day regulatory controls applied to operating facilities. They provide the opportunity to undertake a comprehensive study of plant safety, taking into account aspects such as its operational history, ageing factors which could lead to deterioration in safety, and the advances in safety standards since the time of construction or the previous review. From this, the safety of future operation of the plant can be evaluated.

110. Adequate PSRs are critical in ensuring that dutyholders implement timely changes to prevent risk increasing to an unacceptable level in the future, and therefore minimise future high-risk situations. PSRs should look forward over planned future operation for at least the next ten years, and systematically review the whole of the remaining life of the facility including decommissioning. PSRs should identify and make recommendations to address any reasonably foreseeable circumstances that could compromise the future safety of the facility or its operations.

111. Where a facility provides a safety function that cannot be provided by an alternative means, the forward review should address the longevity of the facility and the time required to design, construct and commission a replacement facility if required. This applies particularly to radioactive waste stores, and to other facilities in which the hazard cannot be simply removed by shutting them down.

112. Compliance inspection includes inspections against licence conditions and relevant statutory provisions, and systems based inspections. We perform systems based inspections of critical safety systems and structures to ensure that such systems comply with the requirements of the safety case. Compliance inspections support regulatory judgements on the safety performance of the facility and the dutyholder.

113. Nuclear facilities may experience unplanned events that can be described as anomalies, incidents or accidents depending on their severity. In order to prevent the recurrence of such events it is important that the lessons learnt are acted upon. This contributes to a culture of continuous improvement and to ensuring that the level of risk is ALARP.

114. There is no specific action required from us in order for a licensee to extend the lifetime of a facility. Instead, the ability of a facility to operate continues to be subject to the validity of the extant PSR, an adequate safety case, operation within that safety case, satisfactory maintenance, and our inspection of compliance with site licence conditions. If at any stage we are not satisfied that the facility can be operated safely, we will not allow it to continue.

7.5 Legacy facilities

115. The term ‘legacy facilities’ is used to describe nuclear installations that are a legacy from the UK’s early defence and civil nuclear development programmes. In the context of this framework, we consider that risks at a number of these facilities are either ‘*unacceptable*’ or are likely to become unacceptable against our tolerability of risk framework, if dutyholders do not take action (in the short-term) to remediate the facility, thereby reducing the risks in the long-term.

116. There are a number of nuclear facilities where the conditions for storing and managing waste are not suitable for the long-term. Moreover, meaningful interventions designed to remove and deal with the inventory will result in an inevitable additional increase in risks during those interventions. It is worth noting that the term ‘legacy facility’ has a wider, more general meaning when referring to facilities which may pose significant challenges in delivering post operation clean out and decommissioning strategies, however, here, we are specifically referring to high hazard legacy facilities.

117. Our decision making process recognises that the age and degradation of such legacy facilities, mean that long-term risk reduction is not achievable without removing and dealing with the inventory causing the risk. We also recognise that intrusive interventions on degraded facilities could give rise to an increase in short-term risk to workers and the public. However, undue delays in dealing with the hazard will also increase the level of risk, albeit at a slower rate, to a point where the likelihood of an undesired event could become unacceptably high. Furthermore, as these facilities continue to degrade, the options available to remove, treat and passivate the inventory become fewer and increasingly more complex.

118. Whilst taking regulatory decisions to allow intrusive modifications on legacy facilities, we consider the balance between the long-term consequences of taking ‘no action’ (i.e. leaving things as they are) against the potential consequences of ‘taking action’, whilst still treating the issue within the existing legal framework.

119. We recognise the difficulties that dutyholders face to acquire the necessary underpinning information to characterise the hazard and develop mitigation measures that meet relevant good practice. This could be due to a number of reasons: such as, gaps in inventory records, characterisation and behaviour of the hazard etc. Whilst developing the mitigation measures, we expect dutyholders to carefully consider whether delays in the development and deployment of safety measures, that in other circumstances would be considered relevant good practice, do not result in undue delays to the commencement of hazard reduction activities. Hence 'fit for purpose' engineered solutions that can be deployed quickly and effectively may in fact represent the optimum risk solution.

120. Furthermore, we recognise that there may need to be an increased reliance on administrative safety measures, where fully engineered measures are too complex, impracticable or take too long to deploy. The term 'fit for purpose' is used to describe those measures that achieve a careful balance between appropriate risk reduction and the time and resource that has to be deployed to achieve this safety benefit, recognising that delays may result in an overall increase in risk from the facility.

121. We further recognise that there may be instances where the measures proposed by dutyholders, to achieve timely hazard reduction, result in a short-term level of risk that cannot practicably be reduced to meet the BSOs, or perhaps even the BSLs (but not those that are legal limits). Such instances will always be considered on a case-by-case basis, taking into account a number of factors towards a balanced regulatory decision, such as:

- how far the residual level of risk exceeds the BSOs or the BSLs;
- the level of risk to society currently posed by the hazard in its current, unmitigated form;
- the nature and extent of shortfall of proposed engineering solutions against relevant good practice;
- the degree of uncertainty in the characterisation of risk posed by the legacy situation and how well proposed solutions mitigate this;
- the extent to which time at risk arguments contribute to the overall defence-in-depth;
- the balance of emphasis dutyholders place across the various engineering and administrative facets of a multi-faceted defence-in-depth hierarchy; and
- overall justification presented by the dutyholders, which demonstrates that the short-term increase in risk is balanced by the long-term risk reduction.

122. Our regulatory attention is often targeted at high hazard and high risk legacy facilities. Our regulatory intervention plans are developed taking account of the strategic need for dutyholders to prioritise hazard reduction and remediation over activities which, for example, address less significant compliance gaps. For regulatory intervention strategies, this may mean that plans are geared towards an approach that is designed to achieve a more stable platform, which supports more intrusive and challenging hazard reduction activities.

7.6 Decommissioning

123. Decommissioning is the set of actions taken at the end of a nuclear facility's operational life to take it permanently out of service, with adequate regard for health and safety. The ultimate aim of decommissioning is to make the site available for other purposes. However, this is not a mandatory requirement and other end states are possible in which some restriction on future use and continued legal responsibilities continue under nuclear legislation.

124. Our objective in regulating decommissioning is to secure a progressive reduction in hazards and for this to be done in a way that optimises the protection of individuals, society and the environment, by effective management of risks.

125. The timing of decommissioning is an important aspect of decommissioning strategies. Many factors can, however, influence this timing, not all of which will necessarily be within the control of the dutyholder (the availability of funding on sites owned by the Nuclear Decommissioning Authority (NDA)). Equally, prompt or early decommissioning may not be a viable option for technical or logistical reasons.

126. As decommissioning proceeds the radiological hazards posed by a facility will eventually reduce, particularly once the bulk of the radioactive material is removed. There may, however, be a short-term increase in risk as a result of specific activities, such as those needed to retrieve radioactive material. There is therefore a need to balance short-term health and safety considerations with longer-term benefits. As radiological hazards reduce, there is a commensurate rise in the risks to workers from decommissioning activities, particularly with regard to significant conventional health and safety risks, such as exposure to asbestos and demolition activities.

127. Other important factors that we take into account in our regulatory decision making within decommissioning include the following:

- Decommissioning is a long-term process where the state of a plant is in continual change; these timescales also increase the level of uncertainty.
- Given the age of the facility and the long timescales, ageing facilities and the potential for safety to degrade is a key factor.
- Decisions on when to start decommissioning, how long to take and whether there are any periods of deferral have a significant impact on safety.
- The approach to decommissioning can have a large impact on the balance between nuclear safety, conventional health and safety, and environmental protection. We expect that an optimised approach is taken, with adequate weighting given to health and safety aspects.

128. The first phase of our decision making is to determine whether the proposed action reduces the level of risk ALARP, as outlined earlier, by consideration of the level of risk against the tolerability of risk framework and application of relevant good practice. This is independent of any wider factors. We consider the short-term position and also the longer-term position, especially if decommissioning has been deferred. A key consideration of the long-term position is having the test or surveillance criteria in place so that timely action can be taken to prevent the level of risk becoming unacceptable against our tolerability of risk framework, and the arrangements in place to ensure risk remains ALARP. We expect dutyholders to identify and justify such criteria and that the necessary action can be taken in time to prevent an '*unacceptable*' situation arising.

129. In the early phases of decommissioning where the hazard is removed, for example on reactor sites, the hazard and level of risk is significantly reduced. However, in order to meet Government policy, considered as part of strategic factors, to make the site available for other purposes, as for all nuclear installations at the end of life, decommissioning should be carried out as soon as reasonably practicable. Should decommissioning be deferred, it is our expectation that the safety case defines the period of deferment and demonstrates that the risks posed will be acceptable and properly controlled throughout. We recognise that decommissioning such facilities will increase risk in the short-term, particularly conventional health and safety risk to workers, and we expect those risks to be managed and reduced SFAIRP. We therefore consider ALARP during the different phases of decommissioning as well as over the whole period in coming to an overall judgement on whether risk has been reduced ALARP.

130. During the course of decommissioning, we expect dutyholders to continue to apply the principle of defence-in-depth to engineering solutions, providing a suitable number of barriers (as appropriate to the risks involved). We acknowledge that some levels of defence-in-depth will not be available in certain circumstances and that mitigation will have to be strengthened where protection is missing or rudimentary.

131. We further recognise that application of the engineering hierarchy and substantiation of safety measures to a level required for modern operating plants may not be practicable or desirable for aged facilities due to undergo decommissioning. Therefore, there is likely to be reliance on multi-faceted arguments and managerial safety measures, proportionate to the hazards being addressed.

132. For high hazard facilities, our focus is on situations where risks are high, where risks must rise in the short-term to achieve long-term hazard reduction, and where there is uncertainty in the way decommissioning will progress. In such cases, we balance such increased risks against the continuing risks from doing nothing and with due consideration of the alternatives available to address the hazard. During the course of hazard reduction, which may be for a significant period of 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, for example, operational doses and the potential for accidental releases.

133. If it is our judgement that the decommissioning programme does not reduce the level of risk ALARP, we will take account of relevant strategic factors in determining the appropriate and proportionate enforcement action, or a decision to grant permission. Examples of such strategic factors include:

- national policy on decommissioning; and
- prioritisation of funding by any relevant statutory body, for example the NDA.

134. Notwithstanding this, it is our expectation that a dutyholder's arrangements demonstrate that the safety of nuclear matter shall be secured and risks reduced SFAIRP:

- in the short-term by an adequate safety case, implemented through adequate arrangements; and
- in the longer-term by arrangements to ensure that either the period of validity of the short-term safety case can be safely extended or that the nuclear matter will have been retrieved and placed in another facility with an adequate safety case before the short-term safety case expires.

135. Regarding the timing of the decommissioning, we will only allow delays to decommissioning where there is an adequate safety case to justify that the situation will remain adequately safe in the interim.

Appendix 2

8. BSO and BSL numerical risk targets in the SAPs

Target	BSO	BSL
Individual risk of death to a person on site, from accidents at the site resulting in exposure to ionising radiation	1 in a million per annum	1 in 10 thousand per annum
Individual risk of death to a person off the site, from accidents at the site resulting in exposure to ionising radiation	1 in a million per annum	1 in 10 thousand per annum
Total risk of 100 or more fatalities, either immediate or eventual, from accidents at the site resulting in exposure to ionising radiation	1 in 10 million per annum	1 in 100 thousand per annum

9. Glossary

Approved Code of Practice	Gives practical advice on how to comply with the law. Such Codes have a special legal status. If you are prosecuted for a breach of health and safety law, and it is proved you did not follow the relevant provisions of a relevant Code, you will need to show that you have complied with the law in some other way or a Court will find you at fault.
Cliff-edge effect	A small change in assumptions leads to a disproportionate increase in radiological consequences.
Decommissioning	The set of actions taken at the end of a nuclear facility's operational life to take it permanently out of service. The ultimate aim of decommissioning is to make the site available for other purposes.
Design Acceptance Confirmation	Issued at the end of a *Generic Design Assessment* if we are fully content with the generic safety and security implications of a new reactor design.
Dutyholder factors	Factors specific to the dutyholder and its activities and include for example any relevant incidents, and its enforcement and inspection history; where harm has occurred, the level of that harm; its general performance regarding compliance with the law; and our confidence that the dutyholder will comply with the law.
Generic Design Assessment	Process for the safety and security assessment of nuclear power stations intended for construction and operation in Great Britain, in advance of an application for a nuclear site licence being made.
Hazard	Anything that has the potential to cause harm.
Individual risk	The likelihood of a *hazard* affecting a given type of individual, for example a worker, or the most exposed member of the public. Instead of an actual individual we would normally consider hypothetical persons. An example of a hypothetical person is a member of the public most exposed to the hazards, which could be someone assumed to live on the site boundary of a nuclear facility and/or whose lifestyle would result in the highest exposure to radiation from normal operation and accidents.

Interim Design Acceptance Confirmation	Issued at the end of the planned assessment of a *Generic Design Assessment* if there remain a number of issues, but we are satisfied with how the *Requesting Parties* intend to resolve the issues.
Large early release frequency	The frequency of accidents leading to a large release where there is insufficient time to initiate and perform off-site counter-measures.
Large release frequency	The frequency of accidents leading to a radioactive release in excess of a defined amount (size of release and isotope). This defined release is one with the potential to lead to harm to a large number of members of the public.
Legacy facility	Nuclear installations that are a legacy from the UK's early defence and civil nuclear development programmes.
Multi-faceted arguments	A safety case built up from independent and diverse arguments.
Relevant good practice	Those standards for controlling risk which have been judged and recognised by us as satisfying the law when applied to a particular relevant case in an appropriate manner.
Requesting Party	Those parties who request a *Generic Design Assessment* to be carried out.
Risk	The chance or likelihood of the specified harm arising.
Safety case	In this document 'safety case' refers to the totality of a dutyholder's documentation to demonstrate safety, and any sub-set of this documentation that is submitted to us.
Societal concerns	Events that could cause widespread or large scale detriment such as multiple fatalities in a single event, widespread contamination off-site and within the facility or site and safety-related detriments such as evacuation, relocation, land interdiction and food bans.
Strategic factors	Strategic factors include relevant Government policies, consideration of vulnerable groups, the effect of the decision on other dutyholders and the balance of risk between different sites including across different dutyholders. Preventing or delaying an activity on one site could lead to an increase in risk elsewhere, which is outside an individual dutyholder's

	control.
Strategic imperatives	Factors where we do not have the authority or sufficient knowledge of the considerations involved to judge the significance of such factors. Such factors may affect the outcome of our regulatory decisions.

10. List of abbreviations

ACoP	Approved Code of Practice
ALARA	As Low As Reasonably Achievable
ALARP	As Low As Reasonably Practicable
BSI	British Standards Institution
BSL	Basic Safety Level (in SAPs)
BSO	Basic Safety Objective (in SAPs)
DAC	Design Acceptance Confirmation
EC	European Commission
GDA	Generic Design Assessment
HSE	Health and Safety Executive
IAEA	International Atomic Energy Agency
iDAC	Interim Design Acceptance Confirmation
ISO	International Organisation for Standardisation
NDA	Nuclear Decommissioning Authority
ONR	Office for Nuclear Regulation
PSA	Probabilistic Safety Analysis
PSR	Periodic Safety Review
R2P2	Reducing Risks, Protecting People – HSE's decision making process
SAP	Safety Assessment Principle(s)
SoDA	Statement of Design Acceptability
SFAIRP	So Far As Is Reasonably Practicable
TOR	Tolerability of Risk
UK	United Kingdom
WENRA	Western European Nuclear Regulators' Association

11. References

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3 The Energy Act 2013 http://services.parliament.uk/bills/2012-13/energy.html

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7 Nuclear Installations Act 1965 www.legislation.gov.uk/ukpga/1965/57/contents

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12 Probabilistic Risk Criteria and Safety Goals, NEA/CSNI/R(2009)16 www.oecd-nea.org/nsd/docs/2009/csni-r2009-16.pdf

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http://www.hse.gov.uk/radiation/ionising/index.htm

19 WENRA Safety Reference Levels for Existing Reactors (2014)
www.wenra.org/publications

20 WENRA Decommissioning Safety Reference Levels
www.wenra.org/publications

21 WENRA Waste and Spent Fuel Storage Safety Reference Levels
www.wenra.org/publications