

ONR GUIDE			
Fundamental Principles			
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### TABLE OF CONTENTS

1. INTRODUCTION .....	2
2. PURPOSE AND SCOPE .....	2
3. RELATION TO LICENCE AND OTHER RELEVANT LEGISLATION .....	2
4. RELATION TO SAPS, WENRA REFERENCE LEVELS AND IAEA SAFETY STANDARDS.....	4
5. ADVICE TO ASSESSORS .....	6
6. REFERENCES .....	8

## 1. INTRODUCTION

- 1.1 ONR has established its Safety Assessment Principles (SAPs) which apply to the assessment by ONR specialist inspectors of safety cases for nuclear facilities that may be operated by potential licensees, existing licensees, or other duty-holders. The principles presented in the SAPs are supported by a suite of guides to further assist ONR's inspectors in their technical assessment work in support of making regulatory judgements and decisions. This technical assessment guide is one of these guides.

## 2. PURPOSE AND SCOPE

- 2.1 This Guide gives guidance to ONR inspectors on ONR's use of its eight fundamental safety assessment principles, in the assessment of licensees' safety cases, as set out in [ONR Safety Assessment Principles for Nuclear facilities \(SAPs\)](#) FP.1-FP.8 <sup>[1]</sup>. These are high-level principles, and the demonstration that they have been met can be shown by meeting the more detailed SAPs. This Guide does not itself aim to summarise or reproduce material in the Guides relating to the more detailed SAPs, but it indicates the broad intentions of the fundamental principles and some background considerations. Assessors should also take account of the general guidance in the Introduction to SAPs.
- 2.2 As with all guidance, inspectors should use their discretion in the depth and scope to which they apply this guidance in the exercise of their professional judgement in reaching regulatory decisions.

## 3. RELATION TO LICENCE AND OTHER RELEVANT LEGISLATION

### 3.1 Site licence conditions

As the Fundamental Principles are overarching principles to be applied throughout the SAPs then the 36 conditions attached to the standard site licence will be relevant. However, seven are of particular relevance to the SAPs covered in this guide. These are:

1. LC 10 (Training),
2. LC 11 (Emergency Arrangements),
3. LC 12 (Duly Authorised and other Suitably Qualified and Experienced Persons),
4. LC 14 (Safety Documentation),
5. LC 23 (Operating rules),
6. LC 26 (Control and supervision of Operations),
7. LC 36 (Control and Organizational Change).

### 3.2 The Health and Safety at Work etc. Act 1974 (HSWA)

The Health and Safety at Work etc. Act 1974 (HSWA) <sup>[2]</sup> sets out fundamental legal requirements concerning health and safety related to work activities in the UK. 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 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 with which employers must comply. ALARP (As Low As Reasonably Practicable) 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.

### 3.3 Ionising Radiations Regulations 2017 and Approved Code of Practice (ACoP)

The Ionising Radiations Regulations 2017 <sup>[3]</sup> (IRR17) specify the statutory requirements for the protection of persons against ionising radiation and are supported by an ACoP and guidance <sup>[4]</sup>. A facility must be designed, operated and decommissioned in compliance with these legal provisions. Aspects of particular relevance to the Fundamental Principles are highlighted in the following regulations and associated ACoP & Guidance in L121.

- **Reg 8 – Radiation risk assessments** – before work is undertaken every employer must carry out a risk assessment to identify the hazards and evaluate the risks to the workforce and to others. It should be noted that regulation 3 of the [Management of Health and Safety at Work Regulations 1999](#) <sup>[5]</sup> (MHSWR) requires the risk assessment to be reviewed and kept up-to-date.
- **Reg. 9 - Restriction of exposure** – this requires every employer, in relation to any work with ionising radiation that he undertakes, to take all necessary steps to restrict so far as is reasonably practicable the extent to which his employees and other persons are exposed to ionising radiation. The means of achieving this is the primary objective of the safety submission on radiological protection and all SAPs are relevant to judging the extent to which exposures are restricted by the licensee.
- **Reg. 13 – Contingency Plans** – this requires the employer, where an assessment made in accordance with regulation 8 shows that a radiation accident is reasonably foreseeable, to prepare a contingency plan designed to secure, so far as is reasonably practicable, the restriction of exposure to ionising radiation and the health and safety of persons who may be affected by such accident.

### 3.4 Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR) and its Guide <sup>[6]</sup>.

REPPIR 2001 establishes a framework for the protection of the public by means of emergency preparedness for radiation accidents with the potential to affect members of the public at premises and during specified transport operations. It also specifies requirements for the provision of information to the public: in advance in situations where a (REPPIR 2001) radiation emergency might arise; and in the event of any kind of radiation emergency (however it may arise).

Note that REPPIR 2019 is expected to come into force during 2019.

### 3.5 The Energy Act 2013 (TEA13). <sup>[7]</sup>

The Energy Act 2013 (TEA13), <http://services.parliament.uk/bills/2012-13/energy.html>, which established the Office for Nuclear Regulation and specified its functions, came into force on 1<sup>st</sup> April 2014. The Nuclear Installations Act 1965 (as amended) (NIA) <sup>[8]</sup> is a Relevant Statutory Provision (RSP) under TEA13.

### 3.6 The Nuclear Installations Act 1965 (as amended) (NIA) <sup>[8]</sup>

The NIA prohibits the operation of certain facilities unless such facilities are licensed under the terms of the Act. It allows for the attachment of Licence Conditions that may be necessary or desirable in the interests of safety. The standard Nuclear Site Licence has 36 conditions; under TEA13 these are now applicable provisions. The duties in various Licence Conditions to make and implement adequate arrangements are absolute and not qualified by SFAIRP.

#### 4. RELATION TO SAPS, WENRA REFERENCE LEVELS AND IAEA SAFETY STANDARDS

##### Relevant SAPs

- 4.1 The SAPs covered by this TAG are FP.1 to FP.8 and the supporting paragraphs 47-52.
- 4.2 FP.1, 'Responsibility for safety' - The prime responsibility for safety must rest with the person or organisation responsible for the facilities and activities that give rise to radiation risks. This principle reflects the need for there to be a clear responsibility for safety in any workplace. For nuclear installations the main responsibility rests with the licensee, as defined in the Nuclear Installations Act 1965 (as amended) (NIA65). It should however be borne in mind that other persons in relation to nuclear licensed sites, tenants or the owners of sites, may have responsibilities for safety under the provisions of HSWA. For facilities not on nuclear licensed sites, it rests with the employer/dutyholder.
- 4.3 FP.2, 'Leadership and management for safety' - Effective leadership and management for safety must be established and sustained in organisations concerned with, and facilities and activities that give rise to, radiation risks. This principle is further developed in the SAPs section with that title and in corresponding ONR guidance. It follows from FP.1 and recognises the crucial importance of leadership and management, including safety management systems, in achieving and maintaining a safety culture for positive safety outcomes.
- 4.4 FP.3, 'Optimisation of protection' - Protection must be optimised to provide the highest level of safety that is reasonably practicable. This principle is directly related to the fundamental requirement of HSWA that risks must be controlled and reduced SFAIRP. 'Protection' in the present context means measures to reduce the exposure of persons (workers and public) to ionising radiation, from both normal operation of facilities and accidents, including consideration of future generations. The principles in the SAPs are always subject to ALARP considerations.
- 4.5 FP.4, 'Safety assessment' - Dutyholders must demonstrate effective understanding and control of the hazards posed by a site or facility by means of a comprehensive and systematic approach to safety assessment. This relates to the dutyholder's processes for the generation of safety cases. These are the means by which dutyholders demonstrate an understanding of the hazards associated with their facilities and the means by which they are to be controlled. The principles for safety cases are developed in the SAPs section on 'the regulatory assessment of safety cases'.
- 4.6 FP.5, 'Limitation of risk to individuals' - Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm. This reflects the basic aim of those parts of IRR17 which set statutory limits on the exposure of individuals to ionising radiation. In addition, there are non-statutory limits targeted at limiting the risk to people. See for example SAPs paragraphs 698-700 and 706-709.
- 4.7 FP.6, 'Prevention of accidents' - All reasonably practicable steps must be taken to prevent and mitigate nuclear or radiation accidents. This is assessed against the SAPs relating to design and operation, and demonstrated in safety cases on system robustness and accident analysis. Many of the SAPs, for example EKP.3 'Defence in depth', are aimed at this objective. Mitigation covers both the on-site response to make safe any plant involved in an accident, and measures taken to protect individuals on and off-site.
- 4.8 FP.7, 'Emergency preparedness and response' - Arrangements must be made for emergency preparedness and response in case of nuclear or radiation incidents. This

relates to the requirements of the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPiR01) for the protection of people on and off-site in the event of an emergency with the potential to give rise to radiation doses above a certain threshold. It also considers responses made under IRR17 regulation 13.

- 4.9 FP.8, 'Protection of present and future generations' - People, present and future, must be adequately protected against radiation risks. This principle recognises that the hazard from radioactivity may be long-lived and widespread. This means that the possible consequences, now and in the future, of current actions have to be taken into account in judging the adequacy of measures taken to control radiation risks. In addition it recognises that there may be risks of genetic detriment to future generations, as well as somatic detriment to exposed individuals.
- 4.10 Satisfying the fundamental principles is the main aim of all other principles in the SAP. These fundamental principles should therefore be kept in mind when assessing all safety submissions because they establish the overall framework and underlying philosophy for safety that should be used in ONR safety assessment.

### **WENRA safety reference levels**

- 4.11 The objective of the Western European Nuclear Regulators Association (WENRA) is to develop a common approach to nuclear safety in Europe by comparing national approaches to the application of IAEA safety standards. Their Safety Reference Levels (SRL) <sup>[9]</sup> which are primarily based on the IAEA safety standards, represent good practices in the WENRA member states and also represent a consensus view of the main requirements to be applied to ensure nuclear safety in operating facilities. The SRL are not set at the fundamental principle level, so there is no one-to-one correspondence with them and this guide, however, this guidance is generally consistent with them.

### **IAEA safety standards**

- 4.12 The IAEA Safety Standards, Fundamental Safety Principles, Safety Fundamentals No. SF-1 <sup>[10]</sup> and supporting documents are relevant to the Fundamental Principles in the SAPs. The objective of SF-1 is to establish the fundamental safety objective, safety principles and concepts that provide the bases for the IAEA's safety standards and its safety-related programme. Related requirements are established in the General Safety Requirements publications. Guidance on meeting these requirements is provided in the related Safety Guides.
- 4.13 The IAEA have established 10 safety principles. Of these 7 are relevant to the SAPs Fundamental Principles. The relation between the Fundamental Principles in the SAPs and those in SF-1 are as follows:
  - FP.1 relates to IAEA Principle 1,
  - FP.2 relates to IAEA Principle 3,
  - FP.3 relates to IAEA Principle 5,
  - FP.4 relates to IAEA Principle 5,
  - FP.5 relates to IAEA Principle 6,
  - FP.6 relates to IAEA Principle 8,
  - FP.7 relates to IAEA Principle 9, and
  - FP.8 relates to IAEA Principle 7.
- 4.14 It should be noted that IAEA Fundamental Safety Principles 2 (legal framework), 4 (justification) and 10 (unregulated radiation risks) are outside the scope of the SAPs.

## 5. ADVICE TO ASSESSORS

- 5.1 Duties predicated on the ‘reasonably practicable’ test in HSWA and its relevant statutory provisions are open to interpretation by dutyholders and regulators alike. This is because it is a test that is not expressly defined in criminal law but rather a determination made in accordance with relevant case law when proceedings are brought before a court in this matter. In this regard, courts are strongly directed by a legal precedent established in 1949 in “Edwards V. The National Coal Board” which, on appeal, led to the following verdict on the meaning of ‘reasonably practicable’:

*“Reasonably practicable is a narrower term than ‘physically possible’ and implies that a computation must be made... in which the quantum of risk is placed in one scale and the sacrifice involved in the measures necessary for averting the risk (whether in time, trouble or money) is placed in the other and that, if it be shown that there is a great disproportion between them – the risk being insignificant in relation to the sacrifice – the person upon whom the obligation is imposed discharges the onus which is upon him.”*

It should be noted that the standard of proof that courts apply in such cases is the civil law test of ‘balance of probability’ rather than the test of ‘beyond all reasonable doubt’ and that the burden of proof rests with the defendant rather than the prosecution.

SAPs paragraphs 9-18 give general guidance on the philosophy of ‘reasonably practicable’, which underlies the HSWA phraseology SFAIRP and the effectively equivalent term ALARP. The term As Low As Reasonably Achievable (ALARA) is used internationally and is taken to be equivalent to ALARP allowing for social and economic factors. Assessors should be familiar with the SAPs general guidance and the documents referred to therein. Aspects specific to nuclear safety are developed further in [NS-TAST-GD-005](#) supported by; Reducing Risks, Protecting People: HSE’s decision making process (R2P2) <sup>[11]</sup> and the 6 ALARP guides published on the HSE website.

- 5.2 The FPs are drafted as requirements, using the word ‘must’, reflecting their relation to legal requirements. Most of the other SAPs use ‘should’ or similar (exceptions being those SAPs which contain statutory requirements). The use of ‘should’ reflects the flexible nature of health and safety law where ‘reasonably practicable’ takes account of the nature and scale of hazards and risks. This also allows the possibility of different equivalent or better alternatives to the safety provisions indicated in SAPs and guidance. See SAPs Introduction, paragraphs 14-18 and 27-30 regarding ALARP and proportionality.
- 5.3 Guidance on FP.1 regarding dutyholder responsibilities is given in the document [‘Licensing Nuclear Installations’](#).
- 5.4 In the application of FP.2, Leadership and management for safety, the assessor should take account of the Principles MS.1 to MS.4 and the guidance given in paragraphs 53-78 of the SAPs. Additional guidance can be found in the TAG related to Leadership and Management for safety [NS-TAST-GD-093 Revision 1 Guidance for undertaking Leadership and Management for Safety Reviews](#).
- 5.5 FP.4 emphasises the need for the dutyholder (i.e. licensee on nuclear licensed sites) to understand the hazards and their control, and to demonstrate such understanding. This includes evidence that the dutyholder is an ‘intelligent customer’ for any information supplied by another party which is relevant to a safety case. Guidance on ‘intelligent customer’ is given in [NS-TAST-GD-049 Licensee Core and Intelligent Customer Capabilities](#).



- 5.6 In order to demonstrate an effective understanding of the hazards of a facility and their control, and thus satisfy FP.4, the safety assessment in the safety case should include both deterministic and probabilistic analyses as complementary approaches to the demonstration of safety.
- 5.7 An apparent adherence to the quantitative risk criteria is not sufficient on its own to establish that a situation is acceptably safe. Similarly, cost/benefit analysis may help to support a case, but very careful scrutiny is needed if it is invoked to support non-adherence to well-established good practice. In general, probabilistic and cost/benefit arguments are easier to accept when the variation from current good practice is also evidently safer according to deterministic analysis. The Design Basis Analysis (DBA) would be used to guide the engineering requirements of the design. However, DBA may not be sufficient, on its own, to demonstrate the adequacy of the safety of a facility and should be complemented by suitable and sufficient Probabilistic Safety Analysis (PSA) and Severe Accident Analysis (SAA) to give a comprehensive demonstration of facility safety performance. Further information can be found in [NS-TAST-GD-051 The Purpose, Scope and Content of Nuclear Safety Cases](#).
- 5.8 In meeting FP5, IRR17 provides statutory limits on radiation doses that correspond to the upper limit in the three-zone approach to risk judgements as set out in The tolerability of risks from nuclear power stations (TOR) <sup>[12]</sup> and R2P2 <sup>[11]</sup> (see SAPs paragraphs 9-11). FP.3 on 'Optimisation of protection' should be applied to reduce potential dose levels below the dose limits and to demonstrate ALARP. The SAPs section on Radiation Protection, and associated guidance, indicate what is expected for such optimisation.
- 5.9 In relation to FP.5 and FP.8 it should be noted that off-site doses from authorised disposals of radioactive waste from nuclear sites, including discharges to air and to bodies of water, are regulated by the Environment Agency (England), Natural Resources Wales (Wales) and Scottish Environment Protection Agency (Scotland). Appropriate liaison should be done in accordance with HSE/ONR's memoranda of understanding with such bodies.
- 5.10 To satisfy FP.5, limitation of risks to individuals, the SAPs paragraphs 695-758 contain several types of numerical dose and risk criteria, mostly expressed as 'Basic Safety Levels' (BSL) and 'Basic safety Objectives' (BSO) and presented as Targets rather than Principles. Where the 'levels' are IRR17 statutory limits on doses to the workforce and the public they are designated 'Legal Limits' (LL). Dose limits and risk targets at the BSL/LL level represent an upper bound that ONR expects a new facility or activity to meet. However, they are insufficient in themselves to ensure the best reasonably practicable protection in any given circumstances. They therefore need to be complemented by optimisation of protection as required by FP.3. Thus both limitation of dose and optimisation of dose below that limit, for normal operations, are necessary to achieve the required level of safety.
- 5.11 Principle FP.6 addresses both accident prevention and mitigation. Mitigation is regarded as the last level of defence-in-depth, discussed in 'engineering principles: key principles Defence in depth, EKP.3' of the SAPs; but it should not be invoked to justify a relaxation or reduced benefit from earlier levels. The safety assessment (FP.4) should include analysis of potential accidents to indicate a basis for the planning of accident management and emergency response (FP.7).
- 5.12 In respect of FP.7, the assessor is referred to SAPs paragraphs 768ff and principle AM.1 together with its supporting paragraphs. Generally speaking the arrangements required by FP.7 are addressed through various licence conditions, especially LC11.

- 5.13 Relevant to FP.8 are the criteria in SAPs paragraphs 712-758 relating to accidents which includes in paragraph 756, that stochastic health effects from long-term doses should be integrated up to a time of 100 years and be restricted to the UK population. The SAPs on radioactive waste management, decommissioning and land quality management are also relevant to the long-term protection of people.
- 5.14 The other SAPs are aimed at ensuring that the fundamental principles are satisfied. If it is judged that the totality of SAPs relevant to a particular installation have been met, this should be sufficient to satisfy inspectors that the installation meets the fundamental principles. For example, if a plant is adequately robust (that is, the technical principles are satisfied SFAIRP, so giving suitable and sufficient defence in depth) and if the plant is operated safely (that is, in accordance with the FP.2 requirements plus the site licence requirements) then the 'accident prevention' part of FP.6 is deemed to have been satisfied.

## 6. REFERENCES

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