



Office for
Nuclear Regulation

Licensing Nuclear Installations

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This guide provides an overview of the nuclear regulatory regime and the processes for licensing and delicensing nuclear sites. It is published on the Office for Nuclear Regulation's website at www.onr.org.uk

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List of abbreviations

ALARP	As low as reasonably practicable
AWE	Atomic Weapons Establishment
CDG 2009	The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (as amended)
CNS	Civil Nuclear Security
COMAH	Control of Major Accident Hazards Regulations 1999
DAC	Design Acceptance Confirmation
DECC	Department for Energy and Climate Change
DSEAR	Dangerous Substances and Explosive Atmospheres Regulations 2002
EA	The Environment Agency
EA13	The Energy Act 2013
EIADR	Environmental Impact Assessment Decommissioning Regulations
EU	European Union
Euratom	The European Atomic Energy Community
FDP	Funded Decommissioning Programme
GDA	Generic Design Assessment
GDF	Geological Disposal Facility
HSE	Health and Safety Executive
HSW Act	Health and Safety at Work etc Act 1974
IAEA	United Nations' International Atomic Energy Agency
LC	Licence Condition
MCA	Maritime and Coastguard Agency
MHSW	Management of Health and Safety at Work Regulations 1999
MoD	Ministry of Defence
NDA	Nuclear Decommissioning Authority
NEPDC	Nuclear Emergency Planning Delivery Committee

NEPLG	Nuclear Emergency Planning Liaison Group
NIA65	The Nuclear Installations Act 1965
NISR	Nuclear Industries Security Regulations 2003
NSL	Nuclear Site Licence
NORMS	National Objectives, Requirements and Model Standards
OECD	Organisation for Economic Co-operation and Development
ONR	Office for Nuclear Regulation
PBO	Parent body organisation
PCmSR	Pre-commissioning safety report
PCSR	Pre-construction safety report
POSR	Pre-operational safety report (i.e. installation safety report)
R2P2	Reducing risks, protecting people
REPIIR	Radiation (Emergency Preparedness and Public Information) Regulations 2001
RMT	Radioactive Materials Transport Team
RWMD	Radioactive Waste Management Directorate
SAPs	Safety Assessment Principles for Nuclear Facilities
SEPA	The Scottish Environment Protection Agency
SLC	Site licence company
SMP	Safety management prospectus
SoS	Secretary of State
TAGs	Technical Assessment Guides
WENRA	Western European Nuclear Regulators' Association

Foreword

Chief Executive's Foreword



The Office for Nuclear Regulation (ONR) is Great Britain's principal independent regulator for nuclear safety and security. We are committed to ensuring that the nuclear industry controls its hazards effectively, has a culture of continual improvement and sustains excellence across the nuclear estate. It is our duty to ensure that our processes and our regulatory judgements are open, transparent and robust. I believe that this is the only way to secure public trust and confidence in ONR as an effective regulator and I am delighted that ONR is now established as a Public Corporation.

Licensing Nuclear Installations sets out how and why we license sites that carry out prescribed activities. It covers the entire facility life cycle, from the licensing of new sites through the relicensing of existing sites to the final delicensing of sites where facilities have been decommissioned and there is no danger to the public. i.e. change activities to facilities. As such, it describes how we deliver our mission of providing efficient and effective regulation of the nuclear industry, holding it to account on behalf of the public and is therefore an important and fundamental part of our regulatory work.

I trust that this guidance will be of interest and value to organisations considering applying for a nuclear site licence as well as the public and other stakeholders who will be able to read about the rigorous process of review, assessment and challenge which ONR conducts as part of the licensing process.

John Jenkins
Chief Executive Officer,
Office for Nuclear Regulation.

Chief Nuclear Inspector's Foreword



Licensing Nuclear Installations provides guidance on the licensing process and the factors that ONR may take into account when reviewing a licence application. ONR is committed to being an effective regulator, and we seek to ensure that our processes and practices remain transparent and current. We have therefore revised this document to reflect recent legal changes arising from implementation of the Energy Act 2013 (EA13)

A prospective licensee should be aware that the granting of a nuclear site licence is a significant step but is not itself permission to start nuclear-related construction. That requires a regulatory permission under a licence condition, which is based on a substantial pre-construction safety case showing that the associated risks and hazards have been assessed, appropriate limits and conditions have been defined and adequate safety measures have been identified and put in place such that the facility can be operated safely. But before a licence is granted, ONR needs to be satisfied that the applicant's choice of site is suitable, that it understands the hazards and risks of the activities that it proposes to carry out, and that it has a suitable schedule of safety submissions leading through to the pre-construction safety case. We also emphasise the need to gain confidence that the applicant has the organisational capability to lead and manage for safety effectively. This means that we must be satisfied with the applicant's governance arrangements, resources, competencies and management processes before we will consider granting a licence.

Operators of nuclear sites have an obligation to protect their workforce and the public from risk so far as is reasonably practicable. The licensing process is an important stage in confirming that they are ready and able to meet these obligations, and in so doing provides assurance to employees, local communities and the wider public. It also, importantly, provides stringent tools and powers which enable ONR to ensure that future operations are supported by adequate safety cases and are subject to appropriate regulatory permission and oversight.

Andrew Hall

Chief Nuclear Inspector
Office for Nuclear Regulation

Preface

The safety of nuclear installations in Great Britain (GB) is assured by a system of regulatory control based on a licensing process by which a corporate body is granted a licence to use a defined site for specified activities. This document describes how the ONR regulates the design, construction and operation of any nuclear installation in GB for which a nuclear site licence is required under the Nuclear Installations Act 1965 (NIA65). Such installations include nuclear power stations, nuclear fuel manufacturing facilities, nuclear defence facilities for weapons manufacturing and fuelling/maintenance of nuclear submarines, reprocessing facilities and facilities for the storage of bulk quantities of radioactive matter which has been produced or irradiated in the course of the production or use of nuclear fuel.

ONR was established by the Energy Act 2013 (EA13). ONR's principal function is to take such action as it considers appropriate for the purposes for which it was established. These purposes relate to nuclear safety; conventional health and safety on nuclear sites; nuclear security; nuclear safeguards and the transport of radioactive materials. The activities that ONR carries out include proposing new law and standards, assessing and inspecting to judge compliance and encourage adoption of good practice, enforcing legislation, investigating work-related accidents and incidents, conducting research, and providing information, guidance and advice on matters relevant to its purposes. ONR reports to the Secretary of State for Work and Pensions, though it may report on specific matters to other Secretaries of State as appropriate. ONR is the licensing authority for nuclear installations in GB and advises the Secretary of State for Energy and Climate Change and the Secretary of State for Defence on nuclear matters.

ONR's mission is to provide efficient and effective regulation of the nuclear industry, holding it to account on behalf of the public. ONR brings together the regulatory functions for nuclear safety, nuclear security, nuclear safeguards, radioactive materials transport and conventional health and safety at nuclear sites.

Section 1: The law and the regulatory regime

The Health and Safety at Work etc Act 1974

- 1 Operators of nuclear facilities in Great Britain, like their counterparts in other industries and places of work in general, are required to comply with the HSW Act and its relevant statutory provisions^a. The HSW Act places a fundamental duty on employers to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all their employees. It also imposes a duty on employers to ensure, so far as is reasonably practicable, that persons not in their employment are not exposed to risks to their health or safety as a result of the activities undertaken.

Reducing risk and the ALARP principle

- 2 The requirement for risks to be reduced as low as is reasonably practicable (ALARP) is fundamental and applies to all activities within the scope of the HSW Act. In simple terms it is a requirement to take all measures to reduce risk where doing so is reasonable. In most cases this is not done through an explicit comparison of costs and benefits, but rather by applying established relevant good practice and standards. The development of relevant good practice and standards includes ALARP considerations so in many cases meeting them is sufficient. In other cases, either where standards and relevant good practice are less evident or not fully applicable, the onus is on the licensee to implement measures to the point where the costs of any additional measures (in terms of money, time or trouble – the sacrifice) would be *grossly disproportionate* to the further risk reduction that would be achieved (the safety benefit). This concept and the general approach to the regulation of safety risks in Great Britain is explained in HSE's publication *Reducing risks, protecting people*,³ also known as R2P2, which is based on the earlier HSE publication *The tolerability of risks from nuclear power stations*.⁴ It is further developed in HSE's ALARP suite of guidance⁵ and supplemented by ONR's guidance to its inspectors.⁶

a Part 1 of the Act (sections 1-54); Regulations made under section 15 and the existing statutory provisions, principally provisions of the Acts in schedule 1

The Energy Act 2013

- 3 Part 3 of The Energy Act 2013 deals with Nuclear Regulation. It establishes ONR as a statutory corporation. Amongst other things, it makes the ONR responsible for the enforcement of statutory provisions which are 'relevant statutory provisions' for the purposes of that Act. These provisions include sections 1; 3-6; 22 and 24A of NIA65 as well as the Nuclear Industries Security Regulations 2003 (NISR) and the Carriage of Dangerous Goods (CDG) 2009 as they apply to the carriage of radioactive material for civil purposes. It refers throughout to the 'appropriate national authority' which in England, Wales and Scotland is the ONR. In relation to Northern Ireland, it is the Secretary of State.

ONR's approach to Enforcement under the HSW Act and EA13

- 4 ONR's approach to enforcement of both the EA13's and the HSW Act's requirements is governed by the principles of **proportionality** in applying the law and securing compliance; consistency of approach; **targeting** of enforcement action; **transparency** about how the enforcing authorities operate and what those regulated may expect; and **accountability** for its actions. These principles apply both to enforcement in particular cases and to the management of enforcement activities as a whole: further details of ONR's policy are provided in ONR's *Enforcement Policy Statement*.¹ In addition, ONR must also have regard for the provisions of the Regulators' Compliance Code.² This code applies when regulators determine their general policies or principles about how they exercise their regulatory functions and when they set standards or give general guidance. It does not apply to individual enforcement decisions.
- 5 ONR has a range of tools at its disposal to help secure compliance with health and safety law and the provisions of and made under the EA13, enabling it to take a proportionate approach in each case. Inspections and investigations are undertaken to gather information, and inspectors may offer dutyholders guidance and advice, both face-to-face and in writing. This could include warning a dutyholder that, in the opinion of the ONR inspector, it is failing to comply with the law. Where appropriate, ONR inspectors may serve Improvement and Prohibition Notices, withdraw approvals, take action under the conditions attached to certain types of licences, or prosecute. Whilst the Crown is not bound by certain parts of HSW Act, there are agreed processes which have equal weight as enforcement notices and prosecution.

The Nuclear Installations Act 1965

- 6 Relevant parts of the nuclear industry must also comply with NIA65 which has three key purposes:
- It requires the licensing of sites which are to be used for the installation or operation of nuclear reactors (except reactors forming part of a means of transport) and certain other classes of nuclear installations which have been prescribed. Currently the latter are prescribed by the Nuclear Installations Regulations 1971 (SI 1971/381). In this guide references to “nuclear installations” relate to those installations for which a licence is required under NIA65 to install or operate them.
 - It provides for control, via permit, of processes for the enrichment of uranium and the extraction of plutonium or uranium from irradiated matter and the application of associated security measures.
 - it provides a special legal regime to govern the liability of nuclear site licensees towards third parties for certain kinds of damage caused by nuclear matter on, or coming from, their sites.
- 7 The licensing function is administered in Great Britain by ONR and in Northern Ireland by the Secretary of State. The other two functions are the responsibility of the Secretary of State for Energy and Climate Change for sites in England and Wales, and Scottish Ministers for Scotland.
- 8 Taking each function in turn:

Licensing: No site may be used in GB for the purpose of installing or operating a nuclear reactor or prescribed nuclear installation unless a licence has been granted by ONR and is in force. The sections of NIA65 relating to the licensing and inspection of sites (sections 1, 3 to 6, 22 and 24A) are “relevant statutory provisions” for the purposes of the EA 13. Thus, these sections are subject to EA13 arrangements for regulation and enforcement.

Control of certain processes: The enrichment of uranium (to increase the proportion of the isotope 235) and the extraction of plutonium or uranium from irradiated matter are controlled under section 2 of NIA65. The use of any licensed site for such activities requires a permit granted by the Secretary of State for Energy and Climate Change, or Scottish Ministers for sites in Scotland.

Third party liability: NIA65 places an absolute liability upon the licensee as regards injury to persons or damage to property arising from a nuclear occurrence without proof of fault on the licensee’s part. Under section 19 of NIA65 a licensee must ensure that sufficient funds are available, by insurance or other approved means, to meet third party claims within the limits prescribed in the Act.

The nuclear site licence

- 9 The safety of nuclear installations in Great Britain is secured primarily through the nuclear site licence and the conditions attached to it (see below). Any organisation wanting to install or operate a prescribed nuclear installation will need a nuclear site licence. A nuclear site licence is granted for an indefinite period and, providing there are no material changes to the basis on which the licence was granted, it can cover the entire lifecycle of a site from installation and commissioning through operation and decommissioning to site clearance and remediation.
- 10 NIA65 provides for a nuclear site licence to be granted to a named corporate body to install or operate specified nuclear installations in a defined location. Therefore, the three key themes ONR addresses in assessing a licence application are:
- the capability, organisation and resources of the applicant corporate body;
 - the nature of the prescribed activities and the relevant safety case;
 - the nature and location of the site.

A register of extant nuclear site licences is available on ONR's website.⁷

- 11 A licence is not transferable, but a replacement licence may be granted to another corporate body if that body demonstrates it is fit to hold a licence. Other circumstances which may lead to the need to relicence a site include changes to the site boundary and changes to the types of prescribed activity for which the site is licensed. In considering an application for a replacement licence ONR would take a proportionate approach and focus particularly on those aspects of the licensing basis which are the subject of the change.
- 12 Each nuclear site licence is unique to its site. It may be varied by ONR to exclude any part of the site which the licensee no longer needs for licensable activities. Before granting such a variation, ONR is required by NIA65, section 3(12)(b), to be satisfied that there is no danger from ionising radiations from anything on that part of the site (see Section 4 of this guidance).
- 13 A licence may be revoked by ONR or surrendered by the licensee. However, depending upon the circumstances, the licensee may be required to retain certain responsibilities for the site. This "period of responsibility" is ended only when a new licence has been granted for the site, the site is used by the Crown and does not require a licence, or ONR has given written notice that in its opinion there has ceased to be any danger from ionising radiations from anything on the site. Before such a notice is issued ONR needs to be satisfied that the site has been decommissioned and adequately decontaminated (see Section 4 of this guide).

Licensable activities (prescribed activities)

14 NIA65 requires that a nuclear site licence is in force before a site may be used for the purpose of installing or operating any nuclear reactor (excluding a reactor comprised in a means of transport) or any other installation which may be prescribed. The installations currently prescribed by the Nuclear Installations Regulations 1971 (SI 1971/381) are those designed or adapted for:

- the carrying out of any process involved in manufacturing fuel elements from enriched uranium or plutonium;
- the carrying out of any process involved in producing alloys or chemical compounds from enriched uranium or plutonium;
- manufacturing rigs incorporating enriched uranium or plutonium for subsequent irradiation in a reactor;
- installing a sub-critical nuclear assembly in which a neutron chain reaction can be maintained;
- processing irradiated nuclear fuel except where this is for assay or similar purposes;
- the storage of:
 - fuel elements containing enriched uranium or plutonium;
 - Irradiated nuclear fuel;
 - bulk quantities^b of radioactive material which has been produced or irradiated in the course of the production or use of nuclear fuel;
- the extraction of plutonium or uranium from irradiated materials, or for enriching uranium;
- the production of isotopes from irradiated material for industrial, chemical and other purposes.

Consequently, the licensing regime encompasses nuclear power stations, research reactors, fuel manufacturing and isotope production facilities, fuel reprocessing, refuelling & maintenance of nuclear submarines; manufacture of nuclear weapons and the bulk storage of certain types of radioactive materials.

15 Other types of installation may be prescribed from time to time. For example, the Government has declared an expectation that any future geological disposal facility would be licensed. Prospective nuclear operators should familiarise themselves with the provisions of the NIA65 and the Nuclear Installations Regulations 1971 but enquiries

^b ONR has published an [interim position statement](#) on the interpretation of 'bulk quantities' in relation to the storage of radioactive matter

regarding the prescribed status of a proposed installation or activity can be made to the Chief Nuclear Inspector at Redgrave Court, Merton Road, Bootle, Merseyside L20 7HS.

Licence conditions

- 16 NIA65 requires ONR to attach to each nuclear site licence such conditions⁸ as it considers necessary or desirable in the interests of safety and ONR may attach conditions with respect to the handling, treatment and disposal of nuclear matter. The licence and licence conditions apply at all times throughout the life of a licensed nuclear site and therefore cover design, construction, commissioning, operation, maintenance, modifications, decommissioning etc. NIA65 empowers ONR to add, vary or revoke conditions at any time allowing ONR the flexibility, if it considers it necessary, to tailor the requirements placed on the licensee to specific circumstances and the phase of the installation's life.
- 17 In the main, the licence conditions require the licensee to make and implement adequate arrangements to address the matters identified. Each licensee can develop licence condition compliance arrangements which best suit its business whilst demonstrating that safety is being managed properly. Similarly, the arrangements made to comply with them may change as the plant progresses through its life from initial design to final decommissioning.
- 18 The licence conditions provide the main basis for regulation by ONR. They do not relieve the licensee of the responsibility for safety. They are generally non-prescriptive and set goals which the licensee is responsible for meeting, amongst other things by applying detailed safety standards and safe procedures. The licensee's management system will incorporate arrangements which it has developed to meet the requirements of the licence conditions. ONR reviews the licensee's licence condition compliance arrangements to ensure they are clear and unambiguous and address the main safety issues adequately. Procedures which comply with nuclear site licence conditions are likely to satisfy the requirements of other health and safety legislation under the HSW Act which relate to nuclear hazards, for example the Management of Health and Safety at Work Regulations 1999 (MHSW). However, compliance with these other requirements must still be demonstrated.

Operational methods

- 19 ONR is responsible for granting licences for sites in Great Britain and attaching appropriate conditions to those licences. ONR makes judgements on the acceptability of licensees' responses to the requirements of those conditions i.e. their licence condition compliance arrangements and their implementation.

- 20 Nuclear safety, security, transport and safeguards inspectors are appointed by the ONR under the Energy Act. They have powers to enforce the relevant requirements of EA13 and its relevant statutory provisions including sections 1, 3-6, 22 and 24A of NIA65 (as relevant statutory provisions of EA13) and the licence conditions (as ‘applicable provisions’ under EA13). Inspectors are also appointed by the ONR under the HSW Act to enforce health and safety legislation relevant to nuclear safety and conventional safety at licensed nuclear sites. Inspectors’ activities include prior assessment of the safety of proposed nuclear facility designs and operational regimes; assessment of the competence and capability of the licensee’s organisation; inspection of the implementation of the licensee’s licence condition compliance arrangements; and investigation of incidents and complaints.

Assessment

- 21 Under the licence conditions, arrangements and actions by the licensee having significance for nuclear safety are subject to expert assessment by ONR and may require prior regulatory permission before work commences or changes are implemented. The nuclear regulatory regime is therefore described as a permissioning regime. HSE’s policy statement ‘*Our approach to permissioning regimes*’, which is available on HSE’s website⁹ explains the regulatory philosophy within which the nuclear licensing regime is operated.
- 22 Assessment is the process by which ONR’s assessors, who are inspectors and technical experts in specific fields, establish whether a licensee has demonstrated that it understands the hazards associated with its activities and how to control them adequately. This is based, amongst other things, on the licensee’s safety case. The technical principles which ONR uses to judge a licensee’s safety case are expressed in ONR’s Safety Assessment Principles for Nuclear Facilities (SAPs). They are developed further in a series of internal guides to inspectors - Technical Assessment Guides (TAGs). The SAPs and TAGs are available on ONR’s website.^{10,11}

The safety case

- 23 A safety case is the totality of documented information and arguments developed by the licensee that substantiates the safety of the plant, activity, operation or modification in question. It provides a written demonstration that relevant standards have been met and that risks have been reduced to a level which is ALARP. The safety case is not a one-off series of documents prepared to obtain a nuclear site licence but a living framework which underpins all safety-related decisions made by the licensee. The safety case must be updated regularly and the implications of proposed facility modifications and other

safety-related changes need to be examined against it and, when necessary, additional demonstrations of safety provided. Accordingly, the requirements to produce and maintain safety cases are embodied in the conditions attached to all nuclear site licences. Guidance on ONR's expectations of the scope and content of safety cases is available on the ONR website.¹²

- 24 Each licensee is required, by Licence Condition 15, to make and implement adequate arrangements for the periodic and systematic review of safety cases. ONR assesses the major periodic safety reviews and, in order to permit continued operation, needs to be satisfied that the facility continues to meet its original design standards; that the licensee has implemented all reasonably practicable modifications to close any gaps between those standards and modern standards; that findings arising from operational experience have been addressed and that there are robust measures in place to manage any safety-related ageing mechanisms. If ONR is satisfied on all these aspects, the facility may continue to operate, providing that the required continuing monitoring activities do not reveal any new information that undermines the safety case.

Inspection

- 25 Nuclear licensed sites are subject to a rigorous inspection regime with one or more ONR site inspectors being allocated to major sites. Typically, around 30% of a site inspector's available time is spent at site, the balance of time being committed to reviewing the licensee's justifications of safety with other site inspectors and with technical assessors, and administering the nuclear site licence for the site. Inspectors also seek to advise and encourage licensees to enhance nuclear safety where this is consistent with the ALARP principle.
- 26 The scope of inspections at site and at the licensee's corporate headquarters and elsewhere includes:
- reviewing implementation of the licensee's arrangements for managing nuclear safety, covering:
 - corporate governance and organisational structures;
 - the maintenance of a capable organisation with suitable staffing resources and competences to deliver nuclear safety;
 - in-house nuclear safety assurance, including access to expert advice, internal inspection and a "challenge" culture;
 - evidence of learning from events and experience, both from within and outside the organisation;
 - effective implementation of appropriate change management arrangements;

- monitoring compliance with the conditions attached to the nuclear site licence;
- observing the condition of the plant and verifying that it is being operated within the limits set by the safety case.

The site inspection programme enables ONR to check compliance with licence conditions, safety cases and other legal requirements. It provides a basis for enforcement and informs other regulatory decisions.

- 27 Additionally, ONR undertakes team inspections on particular topics. These may be regular events, such as witnessing the annual demonstration emergency exercise for a site, or special inspections on a selected aspect of safety. Team inspections typically involve a mixture of site inspectors and technical assessors.
- 28 All inspection and assessment is done on a sampling basis. The size and scope of the sample is determined by factors such as the potential hazard of the activity being considered, the findings from initial examinations, the novelty and complexity of proposed changes, the maturity of the organisation and ONR's knowledge of the licensee's safety performance history. This reflects the normal regulatory practice of targeting and proportionality, whilst retaining the basic principle that safety is the responsibility of the licensee. It depends for its success on an independent, suitably qualified and experienced inspectorate; on the quality of information supplied by the licensee; and on the readiness of the licensee to report to ONR matters which have safety significance.

Regulatory controls

- 29 ONR's regulatory powers are employed in accordance with its Enforcement Policy Statement.¹ In exercising its licensing function ONR makes use of a number of controls derived from NIA65 and the licence conditions. These enable ONR to:
- grant a licence to an applicant;
 - attach conditions to the licence, and to vary or revoke those conditions;
 - vary a licence, to reduce the area of the licensed site;
 - consent to particular actions, usually to the commencement of a given activity;
 - approve particular arrangements or documents, generally to "freeze" them so they cannot be changed without ONR agreement;
 - notify the licensee that it requires certain information to be submitted, for example a safety case;

- issue specifications to require the submission of particular documents for examination, or specify that something must be done in a particular way, for example the form in which radioactive waste is stored;
 - issue agreements to proceed with an agreed course of action;
 - direct the licensee to shut down particular operations;
 - revoke a nuclear site licence.
- 30 The first three of these are comparatively infrequent events, as are the last two. Most of the remainder are likely to be much more frequent, and generally reflect the rate of change on the site. They can result from requests from, or applications made by, a licensee (or prospective licensee). In general they will have been signalled to ONR in advance of the formal request, and will often be the subject of considerable discussion, during which the views of each side will be well aired, before ONR exercises its powers. Further information on Regulatory Powers available to ONR can be found in Appendix 1.
- 31 In addition, a licensee's licence condition compliance arrangements may provide a means for ONR to permission activities using powers derived from the arrangements themselves. Since licensees' arrangements can differ these "derived powers" may vary from licensee to licensee. Licence instruments issued under derived powers consist of agreements, acknowledgements and specifications.
- 32 ONR may from time to time refuse a licensee's formal application or reject a submission. Similarly, ONR may if necessary, call on its power to issue a Direction to shut down particular operations for safety reasons. In addition, ONR inspectors may use their enforcement powers under the EA13 or HSW Act to issue Prohibition and Improvement Notices and to prosecute for breaches of those Acts or their relevant statutory provisions. Breaches of the licence conditions are offences for which the licensee, as well as any other person with duties on the site who commits such a breach, may be prosecuted. ONR's enforcement powers are summarised in Annex 1.

Appeals

- 33 Nuclear site licensees, like all duty holders under the EA13, have the right of appeal to an employment tribunal in respect of Improvement and Prohibition Notices issued to them by ONR. In addition to this, a licensee or licence applicant who is dissatisfied with a particular regulatory decision may raise concerns with the relevant ONR inspector and senior management in ONR. Should issues not be resolved at this level they may request a 'decision review' to be undertaken by ONR's Chief Executive Officer. Details of the ONR's decision review process are available at www.hse.gov.uk/nuclear/operational/assessment/ns-per-in-006.pdf.

Regulatory costs

- 34 Section 24A of NIA65 enables ONR to recover costs from licensees and licence applicants for expenses associated with its nuclear site licensing and inspection work. Licensees and licence applicants are charged according to the amount of ONR staff time applied to their sites or applications. Charges may also cover the costs of research and of nuclear safety studies commissioned to assist ONR and ensure that it has access to independent technical advice and information. Such costs are allocated to licensees according to the nature of the work done under each contract.
- 35 The Health and Safety (Fees) Regulations 2012¹³ made under the HSW Act enable the ONR to recover the costs of pre-licensing assessments, including Generic Design Assessment (GDA) of new reactor designs, and the cost of advising prospective licence applicants during the pre-application phase.

Other legislation relevant to the safety of nuclear sites

- 36 In addition to the HSW Act itself, NIA65 and EA13 ONR has functions under and enforces other legislation which is particularly relevant to the safety of nuclear installations in Great Britain, including:

Ionising Radiations Regulations 1999 (IRR99): These regulations and their associated Approved Code of Practice¹⁴ cover the protection of workers and the public from work activities involving ionising radiations. They include a general duty to keep exposures ALARP and, among other requirements, set limits on such exposure. They implement, in part, the latest revision of the European Atomic Energy Community's (Euratom) Basic Safety Standards Directive.

Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999 (EIADR 99): Under EIADR 99 the dismantling or decommissioning of nuclear power stations and most nuclear reactors is subject to Environmental Impact Assessment and various procedural requirements.¹⁵ In carrying out the Environmental Impact Assessment, the licensee must submit an Environmental Statement to ONR, seeking consent for the work to commence. ONR consults on the Environmental Statement with expert bodies (for example, the environment agencies, nature conservation bodies, local authorities, and other relevant organisations) and considers submissions from members of the public and other stakeholders. ONR may attach conditions to any consent in the interests of limiting the impact of a project on the environment. No decommissioning work on any part of a nuclear reactor site, even non-nuclear work, can begin until ONR has granted consent.

Radiation (Emergency Preparedness and Public Information)

Regulations 2001 (REPPIR): REPPIR¹⁶ establishes a framework of emergency preparedness measures to ensure that the population local to a licensed nuclear site is:

- informed and prepared, in advance, about what to do in the unlikely event of a radiation emergency occurring;
- provided with information if a radiation emergency actually occurs.

REPPIR places obligations on the licensee to produce an on-site emergency plan for dealing with any reasonably foreseeable radiation emergency, as well as providing prior information to the population around the site. The regulations also place duties on the local authority, to prepare (and if necessary, implement) an off-site emergency plan for dealing with the consequences of any reasonably foreseeable radiation emergency in an area surrounding the site that is determined by ONR. The local authority is also required to ensure that relevant information is supplied to the affected population in the event that a radiation emergency should occur.

Other health and safety legislation

- 37 Other relevant health and safety legislation includes the MHSW Regulations 1999 that require, among other things, a suitable and sufficient risk assessment and effective arrangements for planning, organising, controlling, monitoring and review of preventive and protective measures. Although the Control of Major Accident Hazards Regulations 1999 (COMAH) apply mainly to the chemical industry, some nuclear sites are also COMAH sites since threshold quantities of dangerous substances identified in the regulations are kept or used. The Dangerous Substances and Explosive Atmospheres Regulations 2002 (DSEAR) require employers to assess the risks of fires and explosions that may be caused by dangerous substances. The Provision and Use of Work Equipment Regulations 1998; the Lifting Operations and Lifting Equipment Regulations 1998; the Personal Protective Equipment at Work Regulations 1992; the Pressure Systems Safety Regulations 2000 are also relevant and nuclear operators must comply with these regulations in the same way as any other employer. Codes of practice associated with these regulations will often contain relevant good practice that can be used in safety cases when demonstrating what is reasonably practicable.

Fire safety

- 38 ONR also enforces fire safety legislation on licensed nuclear sites via the Regulatory Reform (Fire Safety) Order 2005 and the Fire (Scotland) Act 2005.

Security

- 39 ONR's security team has responsibility for regulating security for the civil nuclear industry and enforcing the Nuclear Industries Security Regulations 2003 (NISR). ONR's security team has issued the National Objectives, Requirements and Model Standards (NORMS) document that sets out a series of security objectives and model standards which provide a possible solution to meet these objectives. It approves and inspects against the duty holders' security arrangements. These are described in Nuclear Site Security Plans and/or Construction Site Security Plans.
- 40 ONR's security team's remit also includes management of sensitive nuclear information and the transport of nuclear material both within the UK and overseas on UK flagged vessels. In addition, ONR approves and inspects against the personnel security arrangements established by duty holders to meet Government requirements for vetting. Further information about ONR's security team is available on ONR's website.¹⁷

Transport

- 41 The transport of radioactive material is an international activity that operates within a well-established regulatory framework based upon the International Atomic Energy Agency (IAEA) Regulations for the Safe Transport of Radioactive Material. Although IAEA publications are not in themselves law, they provide the technical basis for the legal framework and much of the detailed legal requirements in the UK insofar as they relate to the transport of radioactive material. In this context, the regulatory body for the transport of radioactive material is known as the Competent Authority.
- 42 ONR is the GB Competent Authority for the inland civil carriage of (United Nations) Class 7 goods (radioactive material). ONR's Radioactive Materials Transport (RMT) team perform the legal functions conferred on the GB Competent Authority for the inland civil carriage of Class 7 goods.
- 43 Such functions include assessment of safety cases intended to underpin the issue of radioactive material transport package, material and design approvals; delivery of proactive and reactive inspections as part of a wider Compliance Assurance programme; and enforcement.
- 44 ONR is responsible for the enforcement of those provisions of The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG2009) which concern the transport and security of radioactive material (except for the security of material that falls within scope of the Nuclear Industries Security Regulations

2003), as well as other relevant statutory provisions of the Energy Act 2013; and relevant statutory provisions of the Health and Safety at Work etc. Act 1974 under certain circumstances.

- 45 The Maritime and Coastguard Agency (MCA) and the Civil Aviation Authority (CAA) are the UK Competent Authorities for the safe transport of radioactive material by sea and air respectively. ONR advises the MCA and CAA on all matters relating to the safe transport of radioactive materials by sea and air; and performs certain competent authority functions (excluding enforcement during carriage) on their behalf.
- 46 The Department of the Environment Northern Ireland (DoENI) is the Competent Authority for the safe transport of radioactive material by road in Northern Ireland. ONR advises (DoENI) on all matters relating to the road transport of radioactive materials in Northern Ireland; and performs certain competent authority functions (excluding enforcement during carriage) on its behalf.

Environment

- 47 The Environment Agency (EA), the Scottish Environment Protection Agency (SEPA) and Natural Resources Wales are responsible for environmental protection matters, including authorising discharges of radioactive waste from nuclear licensed sites under the Environmental Permitting (England and Wales) Regulations 2010 or the Radioactive Substances Act 1993 (Scotland).¹⁸
- 48 NIA65 places a statutory obligation on ONR to consult the appropriate environment agency before:
 - granting or revoking a licence;
 - varying a licence or attaching, varying or revoking a condition attached to a licence, if the variation of the licence or, as the case may be, the condition itself relates to or affects the creation, accumulation or disposal of radioactive waste within the meaning of the Environmental Permitting (England and Wales) Regulations 2010 or the Radioactive Substances Act 1993.
- 49 In addition to these statutory requirements for consultation, ONR, the Environment Agency and SEPA are committed to working together to deliver effective and efficient regulation of the nuclear industry. The working arrangements between ONR and the environment agencies have been set out in a Statement of Intent with the Environment Agency¹⁹ and separate Memoranda of Understanding with the Environment Agency²⁰ and SEPA.²¹ ONR and the Environment Agency have also introduced supplementary arrangements to co-ordinate assessment work relating to new nuclear power station developments.

Regulation of sites operated on behalf of the Nuclear Decommissioning Authority

- 50 The Nuclear Decommissioning Authority (NDA) is a non-departmental public body established under the Energy Act 2004. Its purpose is to ensure that nuclear sites designated to it by the Secretary of State are decommissioned and cleaned up safely, securely, cost effectively, in ways that protect the environment and are made ready for their next planned use. The NDA is responsible for 18 designated civil public sector sites operated under 17 nuclear site licences - almost half of the licensed sites in Great Britain - including Sellafield, Dounreay, Harwell and the Magnox-class power stations. Each of the 18 sites is operated by a site licence company (SLC) under contract to the NDA. The SLC is responsible for day-to-day operations and the delivery of the site programme. A parent body organisation (PBO), selected through a competitive process bringing in private sector expertise, owns the SLC for the duration of their contract with the NDA, earning fees based on performance and efficiencies gained. It is therefore important to understand the NDA's role and duties in relation to the licensed nuclear sites within its estate and an overview is provided in Annex 2 to this guide. The NDA, via its Radioactive Waste Management Directorate (RWMD) is also responsible for planning and delivering a geological disposal facility for higher activity radioactive wastes.

Regulation of defence-related nuclear sites

- 51 Some defence-related licensed nuclear sites are operated for the Ministry of Defence (MoD) by contractors and it is the contracting companies that hold nuclear site licences granted by ONR. These include the privately-owned and operated Devonport and Rosyth dockyards and sites at Barrow and Derby. The Atomic Weapons Establishment (AWE plc) sites at Aldermaston and Burghfield remain in MoD ownership, but are occupied and operated by a contractor, AWE plc, which holds the nuclear site licences. MoD ministers account to Parliament on nuclear safety matters for these sites.
- 52 NIA65 licensing requirements do not apply to the Crown hence MoD nuclear sites operated directly by the MoD (such as the Clyde Naval Base and the Vulcan test site at Dounreay) are not licensed. NIA65 also specifically excludes any nuclear reactor comprised in a means of transport such as a submarine. MoD is not, however, exempt from the HSW Act, IRR99 or REPPPIR, and ONR regulates MoD nuclear sites under these regulations and other legislation.²² As a Crown body the MoD cannot be prosecuted; however, there are administrative arrangements in place whereby Crown bodies may be censured in respect of offences which would otherwise have led to prosecution.

- 53 Where exemptions and disapplications exist it is MoD policy to ensure, where reasonably practicable, that standards on defence-related sites are at least as good as those required by civil regulation. The MoD's internal regulator for its nuclear programme is the Defence Nuclear Safety Regulator, which maintains close and regular working liaison with ONR, and an agreement on the regulation of MoD sites (the "MoD / HSE Agreement") sets out how ONR's normal activities are modified to take account of legal and international obligations connected to MoD-related activity. A Letter of Understanding between ONR and MoD regulators amplifies and clarifies working-level arrangements made under the general provisions of the MoD / HSE agreement.

International obligations

Safeguards

- 54 ONR's Safeguards team oversees the application of nuclear safeguards to ensure that the UK complies with its international safeguards obligations.²³ Nuclear safeguards are measures to verify that states comply with their international obligations not to use nuclear materials (plutonium, uranium and thorium) for nuclear explosives purposes. Global recognition of the need for such verification is reflected in the requirements of the Treaty on the Non-Proliferation of Nuclear Weapons, which relates to the application of safeguards by the International Atomic Energy Agency (IAEA). The treaty establishing Euratom (the Euratom Treaty) also includes requirements for the application of safeguards by the European Commission.

Nuclear Safety Directive

- 55 As a member state of the European Union the UK is bound by legislation set down under the Euratom Treaty relating to radioactive substances. Council Directive 2009/71/Euratom established a Community Framework for the Nuclear Safety of Nuclear Installations. Since the Directive reflected the philosophy underpinning the regulatory framework in Great Britain most of the provisions were considered to be already transposed and only minor changes were needed to two licence conditions. Similarly, ONR considers that the current regulatory regime also fulfils obligations placed on member states under Directive 2001/70/Euratom which establishes a Community framework for the Safe Management of Spent Fuel and Radioactive Waste.

Other International obligations

- 56 The UK is also a member state of a number of international organisations with an interest in radioactive substances. These include the Organisation for Economic Co-operation and Development (OECD)

Nuclear Energy Agency, which contributes to the development of nuclear energy as a safe, environmentally acceptable energy source, and the IAEA, which promotes the safe use of radioactive substances through a series of “safety standard” documents setting down best practice in the fields of nuclear energy production, radioactive waste management, radioactive materials transport safety and radiation protection. The development of the UK regulatory regime is influenced by the work of the IAEA and the standards it promulgates.

- 57 Additionally, the UK is a contracting party to two important international conventions:

The 1994 Convention on Nuclear Safety aims to legally commit participating states operating land-based nuclear power plants to maintain a high level of safety by setting international benchmarks (Articles) to which member states subscribe. These are based, to a large extent, on the principles contained in the IAEA safety fundamentals document *The safety of nuclear installations*. The Articles cover, for instance, siting, design, construction, operation, the availability of adequate financial and human resources, the assessment and verification of safety, quality assurance and emergency preparedness.

The Convention obliges contracting parties to submit reports on the implementation of their obligations for “peer review”, both by written questioning and answering and to attend periodic review meetings of the parties. At present, these occur every three years. ONR leads, on behalf of DECC, for the UK at these meetings.

The 2001 Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (the Joint Convention)²⁴ applies to spent fuel and radioactive waste resulting from civil nuclear reactors and other applications, and to spent fuel and radioactive waste from military or defence programmes if and when such materials are transferred permanently to and managed within exclusively civilian programmes, or when declared as spent fuel or radioactive waste for the purpose of the Convention by the Contracting Party. The Contracting Party can also report on its reprocessing activity if it wishes to do so. The Convention also applies to planned and controlled releases into the environment of liquid or gaseous radioactive materials from regulated nuclear facilities.

The obligations of the contracting parties include establishing and maintaining a suitable legislative and regulatory framework and ensuring that individuals, society and the environment are adequately protected against radiological and other hazards, inter alia, by appropriate siting, design and construction of facilities and by making provisions for ensuring the safety of facilities both during their operation and after their closure. Like the Convention on Nuclear

Safety, the Joint Convention obliges Contracting Parties to submit reports by correspondence on the implementation of their obligations for “peer review” at meetings of the parties to be held every three years. Again, ONR leads for the UK at these meetings.

- 58 As a member state of the IAEA, the UK has been fully involved in its Integrated Regulatory Review Service (IRRS) programme. This is a peer review service conducted by a team of international experts with experience directly relevant to the areas of evaluation. The team concentrates on key areas of regulatory activity identified within IAEA safety standards to assess the effectiveness of the regulatory body. The review (or mission) enables an objective comparison of national nuclear regulation with international guidelines. A three part IRRS mission to the UK was conducted in 2006, 2009 and 2013.

Western European Nuclear Regulators’ Association

- 59 ONR is a member of the Western European Nuclear Regulators’ Association (WENRA). This is a network of chief regulators of all EU countries and Switzerland (i.e. those reactors which are or were generating electricity). Other interested European countries have observer status. The main objectives of WENRA are to develop a common approach to nuclear safety, to provide an independent capability to examine nuclear safety in new entrant countries and to be a network of chief nuclear safety regulators in Europe exchanging experience and discussing significant safety issues. Publications from WENRA, including those relating to its work on harmonisation of approaches to the regulation of safety, are available on the association’s website www.wenra.org.

Section 2: The licensing process – New nuclear sites

The site licence is not the only legal permit or authorisation required to construct and operate a nuclear facility in Great Britain. Additional authorisations are required from ONR and other regulators, notably the planning authorities and the environment agencies, to allow the construction and operation of most nuclear facilities. Prospective operators of new sites will therefore need to seek advice from other regulators and government departments, in particular DECC and the MOD if appropriate, and all other relevant regulatory bodies, at the earliest possible stage.

Background

- 60 ONR's processes for considering applications for licences for new nuclear sites are informed by the desire to:
- build upon the proven UK nuclear regulatory process, to protect people and society from the hazards of the nuclear industry;
 - ensure a rigorous, robust and transparent examination of the safety case and the safety management arrangements for new nuclear facilities;
 - minimise uncertainties and ensure our process is clear and transparent to the public and the industry;
 - draw on advice from overseas regulators, where appropriate.
- 61 At this point it may be useful, to avoid any misconceptions about ONR's role, to highlight several of the key enablers for new nuclear development for which ONR is not the competent authority. ONR is not responsible for:

- the ‘in-principle’ determination of whether the detriment associated with undertaking a particular class of nuclear activity is justified by the resulting benefits from its use. Such decisions are made by the appropriate Government ministers, normally the Secretary of State for Energy and Climate Change or the Secretary of State for Defence, under the Justification of Practices Involving Ionising Radiation Regulations 2004 (SI 2004/1769);²⁵ see paragraphs 128 and 129 below for further information;
- planning decisions, authorising the construction of a nuclear facility in a particular location, which fall to the relevant national and local planning authorities;
- assessing the adequacy of the operator’s nuclear liability insurance, the potential licensees’ financial standing or the approval of a prospective licensee’s funded decommissioning programme. These matters are the province of DECC.

Pre-application advice

- 62 So far as its resources allow, ONR will engage in dialogue with a prospective licence applicant and provide advice on the licensing process and the expectations placed on a licensee. ONR will expect to recover its costs for such advice from the prospective applicant.

Site selection

- 63 Since the start of the UK’s nuclear power programme in the 1950s, successive Governments have developed policies on the siting of nuclear power stations which relate to population density in the vicinity of proposed sites. The intent of these policies is to limit the number of people that might be affected in the unlikely event of a major radiation release. UK Government responsibility for siting policy is held by DECC, but ONR acts on behalf of the UK Government to administer those policies and is required to take them into account when deciding whether to grant a nuclear site licence. Prospective applicants will therefore need to satisfy themselves that the proposed location would satisfy the Government siting policy for that type of installation.
- 64 The UK Government’s general position on siting policy is set out in the fifth national report to the Convention on Nuclear Safety.²⁴ As part of the planning process under the Planning Act 2008 for nationally significant infrastructure, the Government has produced a National Policy Statement for Nuclear Power Generation. The statement lists locations in England and Wales that it has determined are strategically suitable for new nuclear power stations²⁶ and will apply when decisions are made on applications for development consent.

Site suitability

65 Nuclear site licences are, by definition, site specific and so the prospective operator of a new facility will need to identify the site on which it proposes to build a nuclear power station or other installation. There are three main aspects on which it must be able to satisfy ONR. These are:

- the design safety case must show that the nuclear facility would have robust defences against a range of local external hazards, including seismic disturbances and extreme weather events such as flooding;
- the location must be suitable for the establishment of an adequate emergency plan in accordance with the licence conditions and REPPiR. The proximity of schools, hospitals and other institutions will feature in considering the feasibility of implementing emergency countermeasures (including possible evacuation of areas around the site);
- the proposal must conform with Government siting policy, as described above.

66 ONR's Safety assessment principles for nuclear facilities (2006 edition, Revision 1)¹⁰ provides the overarching approach to the regulatory assessment of site suitability. It includes three main aspects to be considered in assessing sites:

- the location and characteristics of the population around the site, and the physical factors affecting the dispersion of released radioactivity that might have implications for the radiological risk to people;
- external hazards that might preclude the use of the site for its intended purpose;
- the suitability of the site for the engineering and infrastructure requirements of the facility.

More detail is provided in the siting SAPs and their supporting text.

New nuclear power stations and generic design assessment

67 ONR and the EA have developed a process of generic design assessment (GDA)²⁷ for new reactor designs. Under the GDA process ONR assesses the safety case for the generic design of a specific type and make of reactor. The GDA process may be applied where ONR is asked to assess a new reactor's safety case in advance of an application for a nuclear site licence being made. GDA is non site-specific but can give a prospective new build operator a clear indication of whether the design would in principle meet regulatory

requirements in the event that a licence application was made for the installation of a nuclear power station based on that design.

- 68 If ONR is content with the safety case and security aspects of the generic design, then it will provide the requesting party with a design acceptance confirmation (DAC). The provision by ONR of a DAC for a design will mean it is confident that, based on the submitted information on safety and security, the generic design is capable of being built and operated in the UK, on a site bounded by the generic site envelope in a way that is safe and secure. ONR would take the DAC into consideration in assessing the adequacy of any future licensee's case for requesting a Consent under Licence Condition (LC)19^c(4) for nuclear safety related work to commence on the nuclear island for that type of reactor design at a specific site in Great Britain licensed for that purpose. GDA does not replace the licensing process but will make a significant contribution to ONR's assessment of the licence applicant's safety case. As the latter involves consideration of wider issues, a DAC does not guarantee that a site licence will subsequently be granted. If a GDA has been completed, ONR will also consider:
- site-specific aspects not covered by GDA;
 - other changes to the design or safety documentation since GDA.

Design acceptance period of validity

- 69 Any DAC issued would be valid for the assessed generic design for a period of ten years, subject to no significant new information arising during this period to undermine ONR's confidence in the safety and security of the design. Any proposed changes to the design would need reassessment on a case-by-case basis. This period of validity is consistent with the requirement for licensees to conduct periodic safety reviews of their existing nuclear facilities every ten years and report them to ONR.

The point of licensing

Early licensing

- 70 ONR considers that there are advantages in granting a nuclear site licence as early as possible, as this enables regulatory control and influence to be brought to bear under the licence conditions. A licence may be granted when ONR is satisfied that the licence applicant's safety documentation provides assurance that the site will be suitable for the proposed activities if the plant is adequately designed, constructed and operated. A full pre-construction safety case report

c LC19: "Construction or installation of new plant"

(PCSR) is not necessary at this stage. The licence applicant must be able to show that it has an adequate organisational capability and arrangements in place to manage nuclear safety and comply with the nuclear site licence conditions when the licence is granted. It also needs to demonstrate how security of tenure will be achieved on the site. Additional benefits of licensing early in the development of a new site include:

- formal implementation of a licensee's due processes including, for example, the establishment of the licensee's nuclear safety committee, and time for these to bed in;
- formalising licensee responsibilities for development of the design and procurement of long lead items;
- reassurance to stakeholders that appropriate regulatory controls are in place;
- alignment of security and licensing requirements;
- clarifying the relationship between the licensee and its Architect Engineer/Responsible Designer

- 71 Early licensing enables ONR to ensure that the prospective licensee demonstrates a clear understanding of, and commitment to, developing a suitable organisational capability through both the safety management prospectus and underpinning documents, and through its plans for developing the organisation through the build programme. It should be noted that granting a licence will not itself permit the licensee to commence nuclear safety-related construction on the site; further permissions from ONR, as specified, will be required before construction commences. If the development does not proceed for any reason after a site licence has been granted (for example, planning consent is refused or the project is abandoned), the licensee would have to demonstrate to ONR's satisfaction that the site is safe to be delicensed or the site would have to be licensed to another licensee.

Latest point of licensing

- 72 Section 1(1) of NIA65 prohibits any person from using a site to install or operate a nuclear reactor, or other prescribed nuclear installation, unless a licence to do so has been granted for the site in question by ONR. A nuclear site licence should be granted to a developer before they may undertake construction work that could, if inadequately conceived or executed, affect nuclear safety when the plant is operational. Based on this, the latest point at which a licence is required is commencement of construction which ONR defines as the placement of the first structural concrete for buildings with nuclear safety significance. This means that some preparatory groundworks etc may take place prior to the granting of the licence. However,

it is anticipated that the applicant will engage with ONR prior to excavation and the placing of the concrete blinding layer in order to reduce the risk of subsequent re-engineering being required.

The licensing process

73 For convenience, the licensing process has been divided into the steps shown in Table 1, below, with key activities identified with respect to an application for a new nuclear power plant. These steps are expanded upon in the following pages. Although the activities are set out in sequence, in practice there will often be overlap between certain steps; for example preparation of the licence application dossier will usually commence before Step 1 is completed. The stages of construction and commissioning that ONR decides to permission will depend upon the nature of the installation and Table 1 should be regarded as illustrative.

Table 1 Regulation of new nuclear sites – Step-by-step licensing & permissioning process

Step	Responsibility	
	Licensee/Applicant	ONR
1. Preparing to be a licensable organisation	Establish corporate body Develop organisational capability Develop management arrangements	Advise applicant
2. Creation and collation of licence application dossier	Identify activities to be licensed Address the following: <ul style="list-style-type: none"> ● site safety documentation and proposal to deliver a schedule of safety submissions leading to pre-construction safety report (PCSR) ● develop organisational capability, company structures, governance and procedures, including: <ul style="list-style-type: none"> ● safety management prospectus ● company manual ● core capability ● employment model ● nuclear baseline ● intelligent customer ● design authority ● internal challenge ● procurement ● licence condition compliance arrangements ● emergency arrangements ● nuclear safety committee terms of reference ● definition of site and arrangements to demonstrate security of tenure ● A map of the proposed site and details of local demographics 	Advise applicant

Step	Responsibility	
	Licensee/Applicant	ONR
3. Licence application	<p>Submit written application to Chief Nuclear Inspector, ONR</p> <p>Include activities to be licensed and application dossier</p> <p>Notify DECC Secretary of State</p>	<p>Acknowledge receipt</p> <p>Establish project governance and project management arrangements</p>
4A. Nuclear site licence assessment	<p>Continue to develop organisational capability, arrangements and safety case submissions</p> <p>Agree position on nuclear liability insurance with DECC</p> <p>Start to prepare funded decommissioning plan</p>	<p>Assess site, organisation, facility safety case submissions; adequacy of licence condition compliance arrangements and implementation where appropriate; security of tenure and security arrangements</p> <p>Prepare assessment reports</p> <p>Decide whether public body notification is required prior to grant of licence (NB not required for new power station sites prior to licensing). If yes, issue NIA65 section 3(4) direction to licence applicant</p>
4B. Consultation	<p>Respond to ONR direction under NIA65 section 3(4) to notify public bodies having duties in relation to the site (not applicable to civil power reactors)</p>	<p>Consider responses from public bodies</p> <p>Formally consult relevant environment agency as required by NIA65 section 3(13)</p> <p>Consult DECC on applicant's financial standing and nuclear liability insurance arrangements</p> <p>Prepare licence and consult Treasury Solicitors Department; factual check by licensee</p>
5. Granting of licence	<p>Formally confirm readiness to receive licence</p>	<p>Produce licensing report and peer review</p> <p>Chief Nuclear Inspector's review of the licensing report recommendations and matters arising</p> <p>Grant nuclear site licence</p>

Step	Responsibility	
	Licensee/Applicant	ONR
6A. Regulation under the licence ● Construction	Continue developing PCSR to support stages of construction Maintain control and oversight of all safety significant matters Sustain adequate organisational capability to manage for safety Implement arrangements for licence condition compliance and ensure continued adequacy Manage construction activities and modifications to design and organisation Prepare pre-commissioning safety submissions (PCmSR) to support inactive and active commissioning	Following grant of NSL and the commencement of construction ONR will carry out interventions to gain confidence in the licensees' arrangements for design/ procurement; organisational development and safety case submissions. Licence instruments issued to permission commencement of or thereafter progress from one stage of construction to the next using primary powers or derived powers under licensee arrangements as necessary Confirm Funded Decommissioning Programme (FDP) is in place before permission to commence nuclear safety-related construction Continued inspection and regulatory oversight of the plant, the licensee organisation, the development and implementation of the safety case and compliance with the conditions attached to the nuclear site licence

Step	Responsibility	
	Licensee/Applicant	ONR
6B. Regulation under the licence ● Commissioning	Maintain control and oversight of all safety significant matters Sustain adequate organisational capability to manage for safety Implement licence condition compliance arrangements and ensure continued adequacy Manage commissioning activities Prepare pre-operational safety report (POSR)	Licence instruments to permission commencement of or thereafter progress from one stage of commissioning to the next using primary powers or derived powers under licensee arrangements as necessary Continued inspection and regulatory oversight of the plant, the licensee organisation, the development and implementation of the safety case and compliance with the conditions attached to the nuclear site licence
6C. Regulation under the licence ● Operation	Safe operation and maintenance of the plant Maintain control and oversight of all safety significant matters Sustain adequate organisational capability to manage for safety Implement licence condition compliance arrangements and ensure continued relevance	Licence instruments to permission start of operations using primary powers or derived powers under licensee arrangements as necessary Continued inspection and regulatory oversight of the plant, the licensee organisation, the implementation of the safety case and compliance with the conditions attached to the nuclear site licence

Step 1 - Preparing to be a licensable organisation

74 During this preparatory step the prospective applicant should make and implement plans to become an organisation which is licensable under NIA65. This means that, among other things, it has to:

- establish itself as a corporate body;
- set up suitable organisational structures, resources and competencies;
- develop appropriate management arrangements.

These themes are expanded upon in the following paragraphs.

Applicant organisation status

- 75 NIA65 specifies that no person shall use any site for a prescribed activity unless a nuclear site licence is in force for that site. NIA65 also provides that a licence can be granted only to a corporate body and is not transferable. It follows that the licence applicant must be a corporate body and a user of the site. Persons who could hold a site licence include companies formed and registered under the Companies Act 2006, statutory corporations and bodies incorporated by Royal Charter.
- 76 The applicant organisation does not have to be incorporated in the UK but ONR would normally expect applicants based in the European Union to have been incorporated in an EU member state. The company should maintain that incorporation in accordance with the laws in force in that state. For applicants incorporated in a state outside the EU, ONR would seek advice from DECC as to whether this would be acceptable under the terms of relevant UK legislation.
- 77 Notwithstanding the above, as frequent interaction between the licence applicant and ONR and other regulators will be necessary throughout the licence application process, it is in the interests of all parties if the applicant establishes a UK-based corporate entity that would act as the focus for regulatory interactions.
- 78 ONR's working assumption is that the organisation applying for the site licence will be the corporate body that will operate the installation. If this is not the intention, the potential applicant will need to discuss this with ONR early in the licensing process.

Dual and joint licensing

- 79 Section 4(10) of NIA65 places an absolute responsibility upon the holder of the nuclear site licence as regards compliance with the conditions attached to that licence. It provides that in the event of a breach of a licence condition both *“the licensee, and any person having duties upon the site in question who committed the contravention”* is guilty of an offence. The licensee should be in a position to exercise effective day-to-day control over all activities on the site, whether undertaken by its own people, by contractors or by tenants. The holder of the nuclear site licence also has an absolute no-fault financial liability under the insurance provisions of NIA65 for injury to persons or damage to property.
- 80 It is, therefore, essential that there is clarity regarding which body has legal responsibility for the safe operation of a licensed site and the attendant criminal and financial liabilities. Consequently, ONR will seek to avoid granting two or more licences for the same site (dual licensing) or granting a single licence jointly to two or more corporate bodies (joint licensing).

Leadership: Duties of directors

- 81 ONR will expect the applicant’s Board to:
- set the direction for effective health and safety management;
 - establish a health and safety policy that is an integral part of the organisation’s culture, values and performance standards;
 - take the lead in communicating health and safety duties and benefits;
 - adequately resource health and safety arrangements;
 - ensure that it has access to competent health and safety advice;
 - maintain oversight of, and challenge, the organisation’s health and safety performance;
 - include appropriate consideration of health and safety in all its decision making.

It should be noted that licence conditions such as LC12^d and LC36^e have application throughout a licensee’s organisation, up to and including the executive team and Board.

- 82 When Board members do not lead effectively on the management of health and safety the consequences can be severe, for the individual as well as the organisation. If a health and safety offence is committed with the consent or connivance of, or is attributable to neglect on the part of a director, manager or similar role holder then that person can be prosecuted under section 37 of the HSW Act. Equivalent provision is made in EA13 for offences under that Act. Those found guilty are liable for fines and, in some cases, imprisonment. In addition, the Company Directors Disqualification Act 1986 empowers the court to disqualify an individual convicted of an offence in connection with the management of a company, and this includes health and safety offences. This power is exercised at the discretion of the court; it requires no additional investigation or evidence.

- 83 Under the Corporate Manslaughter and Corporate Homicide Act 2007 an organisation may commit an offence if its activities are managed or organised in a way which causes a person’s death and that amounts to a gross breach of a relevant duty of care owed by the organisation to the deceased. An offence will only have been committed, however, if the way in which its activities are managed or organised by its senior management is a substantial element in that breach. The 2007 Act defines a “gross” breach of duty for these purposes, as well as defining “senior management”. Guidance on the agenda for effective health and safety leadership, produced jointly by HSE and the Institute of Directors, is available on the HSE website.²⁸

d LC12: “Duly authorised and other suitably qualified and experienced persons”
 e LC36: “Organisational capability”

Relationship between a parent company and a licensed subsidiary

- 84 Where another corporate body owns the licence applicant, whether as a subsidiary of a group parent or a joint venture company, the parent company can be expected to adopt a strategic role including, for example, oversight of business planning and monitoring the performance of its subsidiary. However, the licence applicant will need to demonstrate that this relationship will neither be detrimental to safety nor impinge on the licensee's legal responsibilities. For example:
- the parent company should not usurp the licensee's authority over the day-to-day operation of the prescribed installations;
 - the licensee must have authority to operate in a manner that maintains safety; for example, it must have the autonomy to shut down, stop operations or take any other actions necessary to ensure safety without recourse to the parent company;
 - the strategic control of funding and other resources exercised by a parent company should not impede a licensee's access to adequate resources to meet its safety obligations, including decommissioning;
 - the parent company should not be able to divert or dilute the technical skills and experience available to, and needed by, the licensee to maintain safety without agreed alternatives being put in place.

Post-licensing, ONR will expect the parent company to continue to recognise and support the case made to ONR by its subsidiary for the purpose of acquiring the site licence. If any significant changes affecting this case are subsequently proposed by either the parent company or the licensee they will need to be developed in accordance with the licensee's due processes including, where appropriate, submission to ONR for consideration prior to implementation.

Organisational capability

- 85 The primary responsibility for the safety of a nuclear installation is placed on the licensee by NIA65. Before granting a licence, ONR must be satisfied that the applicant is a corporate body which will use the site for licensable activities and has adequate management structures, capability and resources to discharge the obligations associated with holding a nuclear site licence. The type of organisation and level of resources that will need to be in place when prescribed operations begin must be commensurate with the risk posed by the operations across the site.
- 86 ONR requires that the licensee is fully in control of activities on its site; can demonstrate sufficient knowledge of the plant design and safety case for all plant and operations on the licensed site; and has sufficient competent resource within the licensee organisation to be an 'intelligent customer' for any work it commissions externally. ONR will expect

the licence applicant to have robust arrangements for procurement of goods and services which could affect safety so as to ensure that it specifies and secures quality products which are right first time. The licence conditions require suitably qualified and experienced staff to undertake all activities that could affect safety on the site, and it is the licensee's responsibility to ensure that this requirement is fulfilled both throughout its own organisation and its supply chain.

- 87 ONR expects an applicant to develop a safety management prospectus (SMP), which documents and demonstrates the adequacy of its arrangements for managing nuclear safety. The SMP should provide a clear description of the company and its structure and how it is intended to operate. The SMP should include a description of the governance of the organisation, and its management system and staffing arrangements, and show how these will ensure safety in the context of its activities and the nuclear hazards to which they give rise. Further guidance is available in a technical assessment guide for inspectors: *Function and content of a safety management prospectus*.²⁹ The applicant may wish to develop a combined safety, security and environment management prospectus, and this is encouraged by both ONR and the appropriate Environment Agency.
- 88 The SMP should be complemented by an adequate and up-to-date organisational nuclear baseline. The principal purpose of the nuclear baseline is to provide a demonstration that the licensee has suitable and sufficient organisational structures, staffing and competences in place to effectively and reliably carry out those activities which could impact on nuclear safety. Further guidance is available in a technical assessment guide for inspectors: *Function and content of the nuclear baseline*.³⁰
- 89 The organisation and management structure set out in the nuclear baseline is not expected to be static; it should evolve as the licensee's organisation develops; for example, for a new nuclear power station the organisational structure and resources will continue to develop through the phases of construction, commissioning and generation. ONR therefore expects the original SMP to be accompanied by plans detailing how the organisation will evolve, including arrangements for review and revision of the areas addressed by the prospectus. The licensee must continue to maintain the licensing requirements throughout the duration of the licence and should be able to demonstrate how it will maintain the necessary organisational capability.

Core capability

- 90 The licence applicant should be able to demonstrate that it has the core capability needed to understand its safety case, manage activities on the nuclear licensed site and deliver nuclear safety. It should be able to demonstrate its approach to the identification of its 'intelligent customer' capability within the core capability to

understand, specify, oversee and accept nuclear safety related work undertaken on its behalf by contractors. Further guidance is available in an ONR technical assessment guide for inspectors: *Licensee Core and Intelligent customer Capabilities*.³¹

- 91 The licence conditions require the licensee to have suitably qualified and experienced staff undertaking all activities that could affect safety on the site.³² For many plant designs the expert knowledge will initially rest with the vendor and, consequently, ONR expects to see appropriate strategies to transfer this knowledge and information to the prospective site licensee. The transfer of knowledge must be sufficient for the prospective licensee to demonstrate to ONR's satisfaction that it is ready to take control of all activities on the site before the licence is granted and that it has plans in place to develop its organisational capability as work progresses.
- 92 To ensure ongoing control of the design of the plant there needs to be a Design Authority function as defined in INSAG-19 *Maintaining the design integrity of nuclear installations throughout their operating life*.³³ Initially, the detailed design capability will reside within the vendor's organisation but the Design Authority is a function which must reside within the licensee. Consequently, there needs to be a process for the transfer of knowledge from the designer to the licence applicant to ensure it will have adequate Design Authority capability by the time of licensing. The applicant should make and implement arrangements for knowledge transfer and technical support from the reactor vendor and discuss these arrangements with ONR. ONR expects these arrangements to be based on the vendor maintaining a strong UK presence. For further guidance see INSAG-19 and the technical assessment guide for inspectors: *Licensee Design Authority capability*.³⁴

Developing licence condition compliance arrangements

- 93 ONR will agree with the prospective applicant a programme for developing adequate licence condition compliance arrangements.³⁵ Arrangements are needed for all of the licence conditions, but these are expected to be proportionate and appropriate to the activities that are being performed. They will be expected to evolve as plant construction and commissioning proceeds. Initially, ONR expects the applicant to focus on putting in place fully developed arrangements covering activities scheduled to commence as soon as the nuclear site licence comes into force. The agreed programme will need to satisfy ONR that more developed arrangements for the balance of the licence conditions will be put in place in a timely manner.
- 94 ONR will expect the licensee to demonstrate how licence condition compliance is assured through the management system. However, ONR does not expect that compliance arrangements should drive the

design of the management system. Indeed, inasmuch as licensees are encouraged to put in place an integrated management system, it may be appropriate to demonstrate, via a “route map” through the management system, how compliance with the licence conditions is delivered and assured.

Step 2 - Collation of licence application dossier

- 95 The documents must be in English. The applicant should discuss with ONR its expectations for the content and style of the safety submissions. The supporting evidence required within the licence application dossier will include:
- a description of the installation and activities to be licensed;
 - a demonstration of conformity with relevant UK Government siting policies;
 - a map of the site and its location, with details of the local demographics;
 - details of the ownership of the site, or arrangements for its leasing, by which the applicant will achieve security of tenure and rights of access to the site commensurate with its obligations under NIA65 and the site licence conditions;
 - details of inter-site safety and security agreements - where there is an adjacent nuclear site,
 - a safety management prospectus including the nuclear baseline;
 - licence condition compliance arrangements;
 - adequate safety submissions complemented by a programme setting out their continued development where necessary (see paragraphs 102-104 below). If the proposed installation is a power station whose design is subject to a GDA, these submissions should show that the characteristics of the proposed licensed site are bounded by the site envelope specified in the safety case for which ONR has issued, or will issue, a DAC prior to the consent to start nuclear safety related construction. Alternatively, submissions showing how additional site-specific aspects are addressed will be necessary;
 - details of appropriate emergency arrangements and a suitable emergency plan (this may be limited in extent for the period before nuclear fuel is brought onto the site);
 - terms of reference for the proposed licensee’s nuclear safety committee;³⁸
 - a statement setting out a strategy for decommissioning the proposed installation;

- a statement regarding the status of the “justification” of the proposed operational activities as required by the Justification of Practices Involving Ionising Radiation Regulations 2004.
- 96 Detailed requirements for the above are given in documents published by ONR and are mostly available on ONR’s website. However, specific questions and requests for further information may be addressed, initially, to the Chief Nuclear Inspector, Building 4 Redgrave Court, Bootle, L20 7HS, ONRenquiries@onr.org.uk.
- 97 A potential applicant should seek the advice of ONR on the adequacy of the application dossier before it is submitted.

Step 3 - Licence application

- 98 An application for a nuclear site licence must be made in writing to the Chief Nuclear Inspector at ONR’s Redgrave Court offices. ONR will advise the applicant on the required format of the submission (for example, number of copies, use of electronic media etc).
- 99 Although prospective nuclear power station operators may prefer the design to have completed the GDA process before submitting a site licence application it is also possible to apply directly for, and be granted, a site licence without the design having gone through a GDA, or the GDA process having been completed.
- 100 Following an initial review of the licence application, ONR will provide an estimate of the timescale required to complete the licensing assessment. However, the exact timescale will be influenced by a number of factors, including:
- the adequacy of the licence application dossier;
 - the quality of the licence applicant’s safety submissions and how successfully it provides assurance that the site will be suitable for the proposed activities if the plant is adequately designed, constructed and operated;
 - the development of the licence applicant’s organisational structure and capability;
 - the development of the licence applicant’s licence compliance arrangements;
 - the establishment of arrangements to achieve security of tenure; and,
 - the applicant’s indicative timescale for concluding its own review of its readiness to be granted the licence.

Depending on the factors above, typically it might be expected to take years from site licence application to the completion of ONR’s assessment, subject to adequate and timely submissions from the

applicant. ONR recovers its costs from the applicant using the power provided by section 24A of NIA65.

Step 4A - Assessment of the application

- 101 ONR’s internal process for dealing with applications for licences for new nuclear sites is available on ONR’s website.³⁹ ONR will develop an intervention strategy which will be shared with the applicant. Its key elements are summarised below:

Assessment of the safety case submissions

- 102 A site-specific PCSR does not need to be in place when the nuclear site licence is granted. However, the applicant will be expected to have agreed with ONR a schedule of safety submissions leading up to the granting of the licence, and subsequently the safety case, to support the grant of licence instruments to permission construction to proceed from one stage to the next. ONR’s intervention strategy will set out some of the key topics to be assessed in the applicant’s safety case submissions. The safety documentation for power reactors may draw upon a generic safety case for which ONR has issued a DAC but will need to include additional information relating to site-specific aspects of the application.
- 103 ONR will expect to maintain a dialogue with the applicant throughout the development of the safety case so that submissions can be made as aspects of the design reach the point where their safety can be assessed. ONR’s assessment of these submissions may indicate where it considers that further analysis or design modifications are necessary before a licence can be granted. To help assess the applicant’s submissions ONR may seek independent data and advice from external sources.
- 104 ONR’s expectations for safety cases are set out in the safety case SAPs. ONR has also published its internal guidance on its expectations for safety cases, including for PCSR, in TAG T/AST/051, NS-TAST-GD-051.¹²

Assessment of the licence applicant’s organisational capability

- 105 ONR will seek assurance that the applicant has suitable and sufficient organisational structures, resources and competencies to lead and manage for safety effectively by applying the “Leadership and management for safety” SAPs and the suite of supporting assessment guides set out on ONR’s website. ONR will focus attention on a number of key areas including:
- Core capability including Design Authority and Intelligent Customer arrangements

- Competency and training
- Independent Challenge and Oversight arrangements
- Management of organisational change and
- Procurement arrangements

Assessment of the site

- 106 ONR will apply the siting SAPs¹⁰, which set out the key safety factors by which it judges the acceptability of any proposed site.

Defining the site boundary

- 107 It is important that the boundary of any licensed site is defined clearly. The extent of the site must encompass the licensable activities and allow a sufficient margin for the maintenance of facilities, services, plants and buildings. The boundary should, so far as is practicable:

- be obvious and permanent;
- avoid passing through a building and, in particular, avoid being three-dimensional, i.e. the boundary should be a simple vertical limit;
- encompass all underground workings.

Annex 3 to this document sets out the requirements for the site boundary plan which will be attached to the nuclear site licence.

Security of tenure

- 108 It is ONR's policy to ensure that a licensee has full rights of access to, and control of, the site so that it can satisfy the demands placed upon it by the licence and NIA65. When granting a licence ONR will require evidence of security of tenure to show that sufficient consideration has been given to such issues. Where the applicant does not own the site, evidence is normally required in the form of a lease or some other legally binding contract or documentation setting out the relationship between the prospective licensee and the owner of the site.

Assessment of Licence Condition Compliance Arrangements

- 109 The licensee will also need to demonstrate that its management system and arrangements for complying with the nuclear site licence conditions are adequate and that they are being implemented effectively before the licence is granted. ONR will assess the adequacy of the applicants proposed licence condition compliance arrangements including the prospective licensees' own assurance activities. Where necessary, ONR will undertake inspections of both headquarters and site based activities to inform its regulatory judgments.

Decommissioning strategies, plans and programmes

- 110 Facilities should be designed and operated so that they can be safely decommissioned. Consequently, before granting a licence, ONR will need to be satisfied that the licensee has developed adequate strategies, plans and programmes for the decommissioning of nuclear plant and facilities and for the treatment and disposal of radioactive wastes. Further guidance on ONR's expectations of licensees' strategies for decommissioning and radioactive waste management is in the Decommissioning SAPs on ONR's website.

Waste management and disposal

- 111 Management of radioactive waste is a function potentially spanning all the stages in the lifecycle of a facility. Consequently, minimisation and control of waste should be taken into account at all stages in the lifecycle of a facility, starting at the planning and design stage through operation, to decommissioning and site clearance. Related issues to be considered by ONR include the applicant's waste management strategy, waste characterisation, arrangements for segregation, passive safety (in relation to the form of the waste itself and its storage conditions), and the requirement for the keeping of records. Other relevant factors when considering radioactive waste management include the quantity of waste involved, the magnitude of radiological hazard, the potential for the hazard to be realised, the potential dose uptake and the cost. Further guidance can be found in the radioactive waste SAPs on ONR's website.
- 112 Some new licensing proposals, such as those for waste management facilities and waste repositories, will be affected by external constraints such as the NDA's strategic role in waste management and disposal. ONR will expect the applicant to have consulted the operators of the disposal facilities to which radioactive waste may be destined, for example, the Low Level Waste Repository (LLWR) or NDA's Radioactive Waste Management Directorate (for a future geological disposal facility).
- 113 Although geological disposal is not currently a prescribed activity under the Nuclear Installations Act 1965 (NIA65), Government have made it clear that it will require a Nuclear Site Licence and they will keep under review the legislative and regulatory provisions available to the safety regulator to ensure they are sufficient to enable ONR to undertake the necessary staged licensing of the Geological Disposal Facility development. The basic principles of licensing will apply to this as to any other licensed site, although due to the unique nature of the facility some amendments to licence conditions may be necessary⁵⁰.
- 114 Article 37 of the Euratom Treaty requires the UK to make a submission to the European Commission (EC) of an assessment of the potential

impact on other member states of planned or accidental discharges or disposals of radioactive waste from nuclear facilities. Time therefore needs to be built into the overall process for preparation and submission of data to the EC and to allow for it to give its opinion. A permit under Environmental Permitting (England and Wales) Regulations 2010, or a Radioactive Substances Act 1993 authorisation (for Scotland) for radioactive discharges and disposals, would not be issued until after a favourable opinion had been received from the EC. Although Article 37 submissions are a matter for Government, advice should be sought in the first instance from the Environment Agency, SEPA or Natural Resources Wales, as appropriate. ONR will also be able to provide a view in relation to the proposed approach to accidental releases.

Assessment of emergency preparedness and response

- 115 In addition to the relevant licence conditions, the applicant will need to satisfy the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR).¹⁶ The key licence condition is LC11^f, which requires the licensee to generate and own the on-site emergency plan,³⁶ but others such as 7, 10, and 36 also apply. It should be noted that REPPIR places specific requirements on the licensee, such as the need under regulation 6(1) (a) to provide a report identifying the hazards and evaluating the associated risk of a radiation accident to ONR, 12 months before commencement of work with ionising radiation.
- 116 The generation of the off-site plan under REPPIR is the responsibility of the local authority supported by information provided by the licensee. Therefore, allowance will need to be made in accordance with the timescales identified in REPPIR for the processes required by the Regulations to be completed. Guidance on emergency planning requirements can be found on DECC's website. Responsibilities of the UK Nuclear Emergency Planning Liaison Group (NEPLG), who produced the guidance, have been subsumed into the Nuclear Emergency Planning Delivery Committee.³⁷

Assessment of Security requirements

- 117 ONR regulates nuclear security requirements at civil nuclear sites and associated premises. ONR will not grant a licence until it is satisfied that appropriate measures are in place to manage all relevant aspects of security.
- 118 A licence applicant must have an approved Construction Site Security Plan in place before undertaking any preparatory construction activity on the site prior to licence grant. Once the nuclear site licence is

^f LC11: "Emergency arrangements"

granted there is a similar requirement for a Nuclear Site Security Plan and this requirement will continue through the arrival of nuclear material or other radioactive material onsite, through the operating phase, and will remain until all nuclear material and other radioactive material has been removed from the site as part of the decommissioning of the site. ONR will regulate to ensure that the licensee has an appropriate approved security plan in place and that the measures contained within the plan are effectively implemented to achieve the agreed security objectives. Further information is available on ONR's website.¹⁶

Safeguards

- 119 ONR's safeguards team works with the safeguards inspectorates of the European Commission and the IAEA to ensure that international safeguards obligations for the UK are complied with. Good procedures for nuclear materials accountancy are crucial to ensuring effective and proportionate implementation of such safeguards measures. Early engagement with ONR and thus the international inspectorates, who are the primary safeguards "regulators", is both a requirement (for example, preliminary information on new facilities must be provided to the inspectorates before construction starts) and also key to defining effective and efficient arrangements for the inspectorates' safeguards verification and inspection activities that are suitably aligned with other domestic regulatory requirements. More detailed information is available on ONR's website.²³

Step 4B - Consultation

Mandatory consultation with the environment agencies

- 120 NIA65 places a requirement on ONR to consult the appropriate environment regulator (Environment Agency in England, Natural Resources Wales and SEPA in Scotland) before granting a new nuclear site licence. This is to ensure that granting a new licence will not conflict with the relevant environment regulator's environmental protection responsibilities, or prejudice any legal process under the Environmental Permitting (England and Wales) Regulations 2010, or for Scotland, the Radioactive Substances Act 1993, or other environmental legislation. The arrangements for this consultation are set out in Memoranda of Understanding between ONR and each agency.^{20, 21} ONR will not normally grant a licence unless it has been assured by EA or SEPA that they expect to be able to grant a permit under the Environmental Permitting (England and Wales) Regulations 2010 or a Radioactive Substances Act 1993 authorisation. The process for applications for new authorisations is given in EA's *The regulation of radioactive substances activities on nuclear licensed sites*.⁴⁰

Public body notification

- 121 ONR has a discretionary power under section 3(4) of NIA65 to direct a licence applicant to serve notice on the public bodies the ONR specifies. These bodies will normally be local to the site in question and may include, for example, local authorities, emergency services, river authorities, fisheries committees, statutory water undertakings and national parks authorities. The intention of public body notification⁴¹ is to ensure that relevant public bodies who have statutory duties in relation to the site to have an opportunity to be informed of the licence application and to advise ONR whether their duties may be affected by the licensable activities. This enables ONR to consider whether there is a need to amend any of the licence conditions that are normally attached to the nuclear site licence.
- 122 In deciding whether to direct an applicant to undertake public body notification, the key factors considered by ONR are the significance of the development associated with the application, the related impact on public bodies' duties and activities associated with a site, and consistency with previous use of ONR's discretionary powers.
- 123 When this power is invoked, ONR will require the applicant to provide specified bodies with details of the proposed development and must allow the consultees up to three months to submit their comments to ONR. ONR will also consider and evaluate any comments submitted by other stakeholders.
- 124 ONR's discretionary power to direct a licence applicant to undertake public body notification does not apply in relation to licence applications for proposed nuclear power stations. This is because a Public Inquiry was anticipated to be held for all such applications. Under the Planning Act 2008, nuclear power stations are 'nationally significant infrastructure projects' and prospective developers are now required to consult widely before applying to the Planning Inspectorate for a Development Consent Order. This wide consultation process will encompass all relevant public bodies and should ensure that they are adequately informed of the development and its consequences for their areas of responsibility.

Approved funded decommissioning programme

- 125 For new nuclear power stations, the Energy Act 2008 introduced a statutory requirement on nuclear site licence applicants, requiring them to have in place an approved funded decommissioning programme (FDP). The FDP will require operators to make adequate arrangements for covering the cost of decommissioning the site and managing any operational or decommissioning wastes and must be approved by the DECC SoS before using the site for activities that need to be licensed. DECC guidance interprets this point as the placement of first structural concrete for buildings which have nuclear

safety significance. The FDP does not therefore need to be approved at the point of licensing. However, once the Nuclear Site Licence (NSL) has been granted and before permissioning the commencement of nuclear safety-related construction, ONR will seek confirmation from DECC or the MoD that the licensee can meet the requirements of the Energy Act 2008.

Nuclear liability insurance

- 126 Under NIA65 section 19(1) the licensee is required to provide cover for third-party claims within the limits prescribed by the Act and for the arrangements to be approved by the Minister. DECC, MoD or the Scottish Government for sites in Scotland, will review the adequacy of the licensee's section 19 cover, which may be provided by insurance, indemnity or other approved means. Prospective licensees can apply to the DECC SoS, the MoD SoS or the Scottish Government for deferral of Nuclear Liability Insurance and, if they consent, a nuclear site licence may include provision with respect to the time from which section 19(1) is to apply (section 3(11) of NIA65). For example, this may be linked to the point at which nuclear fuel is to be brought onto the site for the first time.
- 127 A licensee will commit a criminal offence if suitable third-party cover is not in place at any time when section 19(1) of NIA65 applies in relation to the relevant licensed site. Unless provision has been made for a deferral of cover as described above, cover must usually be in place when the new nuclear site licence comes into force. To avoid the risk of the licensee not having the legally necessary cover in place, ONR will seek confirmation that a licence applicant has made appropriate arrangements for insurance cover by liaising with DECC or the Scottish Government before granting the licence. However, it is not ONR's responsibility to audit or validate the licence applicant's arrangements for liability cover.

Justification

- 128 Justification is a principle of radiation protection embodied in successive European Basic Safety Standards Directives. It requires member states to ensure that the benefits of using ionising radiations in a particular situation outweigh the detriment to health that may be caused. Government policy is that Justification is a matter determined by Ministers. The requirements for Justification have been translated into UK law by the Justification of Practices Involving Ionising Radiation Regulations 2004 (SI 2004/1769).
- 129 ONR will require the licence applicant to indicate whether any proposed activities involving radiation are already justified or if they are in the process of being so. Licence applicants should check whether there is an existing UK Government decision on the

Justification of the types of activity which are to be undertaken at the site.²⁵ For nuclear power stations, and most prescribed civil nuclear activities, the Secretary of State for Energy and Climate Change is the justifying authority.

Financial standing

- 130 ONR may invite interested Government departments and agencies to draw to its attention anything relating to the licence applicant's financial standing which they consider ONR should take into consideration before granting a licence.

Step 5 - Granting the licence

- 131 At the conclusion of its assessment of the licence application, and if relevant consultations have been completed, ONR will draft a report which sets out the findings of its assessment and makes a recommendation to the Chief Nuclear Inspector as to whether a nuclear site licence should be granted. ONR will also draft the nuclear site licence (if appropriate) which will be checked for accuracy with the Treasury Solicitors' Department and the applicant before it is granted.
- 132 The prospective licensee should formally inform ONR that it is ready to receive a licence and that it has satisfied itself that it will be compliant with all licence conditions when the licence is granted. A date at which the licence comes into force will be agreed.
- 133 The Chief Nuclear Inspector will review ONR's assessment together with any matters arising and convene a scrutiny panel to review and challenge any aspect of the assessment conducted. Subject to the Chief Nuclear Inspector being content to grant the licence, a paper copy of the licence, signed by the Chief Nuclear Inspector or a nominated Deputy Chief Nuclear Inspector, will be despatched to the applicant.

Step 6A - Regulation under the licence - Construction/ Installation

- 134 Once the nuclear site licence has been granted, the licensee must comply with the relevant provisions of NIA65 and all the conditions that ONR has attached to the licence. During this period ONR's regulatory activities will focus on equipment procurement, construction, design modification and pre-commissioning issues and the development of the licensee's organisation. ONR expects the licensee to provide a PCSR to support the start of nuclear safety related construction.
- 135 Granting the licence does not, in itself, give the licensee permission to begin nuclear safety-related construction on the site, as ONR will

ordinarily use the primary power provided by LC19^g (4) to specify that the licensee should not commence nuclear safety-related construction without a regulatory Consent. Throughout construction and installation, ONR may employ LC19 (4) to identify further “hold points” where ONR Consent is required before the licensee may proceed from one stage to the next. However, ONR expects the licensee to manage the construction and installation process under its own arrangements and, in practice, the LC19(4) power is used sparingly. In addition, ONR expects that the licensee’s arrangements, made under LC19(1), should include provision for ONR to specify that progress from one stage to the next shall not proceed without ONR’s agreement.

- 136 ONR expects the licensee to consider the adequacy of its organisational capability when making a case for moving through the different stages of construction and installation, whether the stage transition entails seeking a formal Consent or Agreement from ONR or involves only internal due process. The licence application will have included programmes for development of its organisational capability, and ONR will expect to see evidence that these are being implemented, monitored and managed accordingly. The licensee needs to build up the number of trained staff progressively through installation and commissioning in order to be ready for full operation.
- 137 At all times, the licensee must ensure that it has sufficient in-house expertise (core capability) to manage and make informed decisions on issues affecting nuclear safety, and be able to demonstrate that it is an intelligent customer for any bought-in items or services as well as being in control of contractors working on the site.
- 138 The licensee needs to demonstrate how it will manage construction to ensure that nuclear safety related matters, as well as conventional safety are adequately addressed. In particular the licensee will need to demonstrate how it satisfies itself that the construction and any work that is subcontracted will meet the design intent and will be conducted safely.
- 139 ONR and the licensee will agree a schedule for the submission of safety documentation throughout the period of installation and on-site testing. In particular:
- the Pre-Commissioning Safety Report (PCmSR) must be acceptable to ONR before active commissioning starts;
 - technical specifications, or operating rules deriving from the safety case, should be submitted to ONR during construction and before commissioning. ONR may choose to approve the operating rules;
 - the maintenance schedule must also be submitted and agreed by this stage.

g LC19: “Construction or installation of new plant”

- 140 ONR is responsible for inspections and regulatory oversight of the plant. It will usually appoint a site inspector, and a programme of regulatory inspections will be introduced. Its expectations for licence condition compliance will be on a proportionate basis. Particular attention will be paid to LC20 on “modification to design of plant under construction”.
- 141 The inspections will need to satisfy ONR that all the issues arising from the assessment of the PCmSR, the technical specifications and the maintenance schedule are resolved satisfactorily before proceeding to active commissioning or operation.

Step 6B - Regulation under the licence - Commissioning

- 142 Before active commissioning may begin, ONR will need to issue the appropriate licence instrument. For a nuclear power station the licensee will usually need to seek ONR consent to bring nuclear fuel on site and a further consent linked to first criticality. During commissioning the licensee must comply with all licence conditions including, specifically, LC21 on “Commissioning”. Well in advance, the licensee should agree with ONR a schedule for the submission of further safety documentation for the period of commissioning and on-site testing, leading to a Pre-Operational Safety Report (POSR). Guidance on ONR’s expectations for safety cases including the commissioning and pre-operational stages is given in NS-TAST-GD-051.¹² The safety case for these later stages should evolve from the Pre-Construction Safety Report (PCSR).
- 143 ONR can use powers provided by LC21(4) to Specify that ONR’s Consent is required to commence and thereafter progress from one commissioning stage to the next. As noted above, in practice these powers are used sparingly, and ONR expects the licensee to manage the commissioning process under its own arrangements. ONR will expect the licensee’s arrangements, made under LC21(1), to include provision for ONR to specify that progress from one stage to the next should not proceed without its agreement.
- 144 Before the start of active commissioning, adequate emergency arrangements should be in place and exercised as appropriate
- 145 The POSR should include the commissioning results and report on any anomalies. Through its inspection and assessment processes ONR will need to be assured that all the issues arising from its assessment of the POSR and from commissioning are resolved satisfactorily before proceeding to operation.
- 146 ONR expects the licensee to continue to develop its organisational capability throughout the project, ensuring that it has sufficient staff with the right skills for the particular project phase. It is also important

that it is able to demonstrate that it has a 'core capability' of staff to manage its activities as a nuclear site licensee and to ensure nuclear safety. Within this core capability it must also maintain its Nuclear Baseline to ensure that key nuclear safety roles are fulfilled. Where the licensee identifies changes that it wishes to make to its organisational structure it is important that the implications of such changes are assessed using robust management of change (MOC) arrangements.

- 147 ONR will also seek continued assurance that the licensee has made adequate provision for the transfer of knowledge from the Responsible Designer principally to the licensee's Design Authority.
- 148 The licensee will need to be able to demonstrate that its staff are competent for the roles they are expected to fulfil and should have a training strategy in place to support this demonstration. In addition, the licensee needs to establish a positive safety culture within its own organisation, tenant organisations and within contractors on the construction site.

Step 6C - Regulation under the licence - Operation

- 149 The licensee remains responsible for safe operation and maintenance of the plant, and for meeting all licence conditions, throughout the life of the site, including the decommissioning phase. ONR will maintain appropriate regulatory oversight throughout the life of the licensed site.

Section 3: Relicensing

Need for relicensing

- 150 A nuclear site licence is granted for an indefinite period and, in principle, one licence could cover the entire lifecycle of the site from installation and commissioning, through operation and decommissioning to site clearance and remediation. In practice, for many sites a replacement licence will be required from time to time.
- 151 As a site licence is granted to a particular corporate body to undertake specified prescribed activities in a defined location, such a replacement licence will be needed when there is to be a material change to the basis on which the existing nuclear site licence was granted, that is:
- where there is to be a change of operator, since NIA65 section 3(1)(b) precludes nuclear site licences being transferred between corporate bodies;
 - if the incumbent licensee wishes to install and operate a type of prescribed installation which is not covered by its current licence;
 - where the site boundary is to be extended.^h

ONR's guidance to inspectors on site relicensing is available on ONR's website.⁴²

Proportionality

- 152 The relicensing process requires ONR to assess the licence applicant's case for the grant of a replacement nuclear site licence. In doing so, ONR will consider all relevant aspects of the licence applicant's case and this may mean addressing most of the issues which are considered when licensing a new site for the first time. However, ONR will adopt a proportionate approach in line with its *Enforcement policy statement*.¹ This means that assessment effort will focus particularly on those areas where changes are taking place or which are judged to be potentially important for nuclear safety reasons.

^h Section 3(12) of NIA65 provides for the variation of a nuclear site licence to exclude part or parts of a site if certain criteria are satisfied but there is no parallel power to vary the licence to enlarge a licensed site.

- 153 In practice, applications for replacement nuclear site licences are often driven by a change of site operator associated with a corporate or industry restructuring, or by relatively minor changes in the site boundary. In such cases, ONR will already have access to much of the evidence needed to support the granting of the replacement licence, such as safety cases and licence condition compliance arrangements where these are being taken forward unchanged. Organisations considering applying for a replacement licence for an existing site are advised, therefore, to seek pre-application advice by contacting ONR's Licensing team via ONRenquiries@onr.gsi.gov.uk
- 154 Following an initial assessment, and taking account of the extent of the changes which need to be assessed, ONR will be able to provide an estimate of the timescale for processing the licence application.

Relicensing for a change of operator

- 155 The safety of activities at a licensed nuclear site must not be compromised by a loss of capability resulting from a change of operator. ONR anticipates that where it is proposed to transfer the operation of a licensed nuclear site from one corporate body to another, the new licensee will retain the majority of the existing personnel, at least initially, to ensure continuing access to essential expertise and corporate knowledge. Any corporate restructuring, including staff changes, can be managed by the new licensee using the change management processes developed under LC36: "Organisational capability".⁴³
- 156 It is nevertheless open to the licence applicant to seek to make substantial changes to organisation or resources as part of its basis for the licence application. However, this is likely to necessitate substantial, additional, pre-relicensing scrutiny by ONR to ensure that, when implemented, the new licensee's arrangements will maintain or improve standards of safety at the site. ONR may, in these circumstances, expect to see a period of shadow working as a precursor to the granting of the new licence.
- 157 During such a period of shadow working the incumbent licensee would adopt, and run in parallel, organisational structures and management systems proposed by the organisation applying for the new licence. This would enable ONR to assess and inspect the proposed new structures and to take a view on their efficacy and potential adverse consequences for the management of nuclear safety. ONR will not grant the new licence unless and until this demonstration has been completed to ONR's satisfaction. In case they are inadequately conceived or implemented, the arrangements adopted during shadow working must be completely reversible so that operation of the site can revert to the original, proven, working arrangements.

- 158 Whether the applicant proposes no change; proposes to defer significant change for implementation under the new licence using LC36 arrangements; or proposes to effect significant change at the point of licensing, ONR will conduct a targeted and proportionate examination of organisational capability, considering the same issues as for a new licensed site, as follows:

Table 2 Relicensing for a change of operator

<i>Topic</i>	<i>Relevant paragraphs in Section 2</i>
Applicant organisation status	75 to 78
Dual and joint licensing	79 to 80
Leadership: Duties of directors	81 to 83
Relationship with parent company	84
Organisational capability	85 to 89
Core capability	90 to 92

Relicensing for new activities

- 159 Where an existing site is to be relicensed to accommodate the introduction of an additional class of prescribed activity, ONR will scrutinise the developing design safety case to assess whether the proposed operations at the site will be adequately safe. ONR will also need assurance that the particular class of activity proposed is deemed to be justified within the meaning of the Justification Regulations 2004.²⁵
- 160 Generally the incumbent licensee will have opened and maintained a dialogue with ONR throughout the development of the safety case.¹² As aspects of the design reach the point where their safety can be assessed, safety submissions should be made to ONR. These submissions may be discussed and further analysis or design modifications may be necessary before ONR permissions the relevant activity. However, relicensing is not directly dependent upon finalisation of the safety case for the new activity as its development could progress as normal business under the new licence.
- 161 ONR will expect the licensee to have reviewed the potential impact of the proposed new activity on its organisational, resource and competence requirements. If additional needs are identified the licence applicant should submit, in support of the licence application, its programme for meeting those needs.
- 162 Similarly the licensee's suite of site licence condition compliance arrangements should be reviewed to see whether they remain adequate for managing the new activity. Where necessary, the licence

application should be supported by a programme for modifying or enhancing the licence condition compliance arrangements. These will be assessed in accordance with ONR's internal guidance to inspectors.⁴⁴

Relicensing to bring additional land within the licensed site boundaryⁱ

- 163 It is ONR's policy to ensure that a licensee has full rights of access to, and control of, the site so that it can satisfy the demands placed upon it by the licence and NIA65. In considering an application for an extension to the site boundary ONR will require evidence of security of tenure for, and full rights of access to, the area to be brought within the licensing regime. If the applicant does not own the area in question, evidence is normally required in the form of a lease or some other legally binding contract or documentation setting out the relationship between the prospective licensee and the owner of the site.
- 164 The revised boundary of the licensed site must be defined clearly. The extent of the site must encompass all licensable activities and allow a sufficient margin for the maintenance of facilities, services, plants and buildings. The boundary should, so far as is practicable:
- be obvious and permanent, for example, ideally it should not cross water;
 - avoid passing through a building and, in particular, avoid being three-dimensional, i.e. the boundary should be a simple vertical limit;
 - encompass all underground workings.

Annex 3 to this guide sets out the requirements for the site boundary plan which will be attached to the replacement nuclear site licence.

- 165 Licensees will need to assess the impact of the proposed change of boundary on their existing site and on their licence condition compliance arrangements and include details of this assessment in their application for relicensing.
- 166 The licensee will also need to review which Licence Instruments are extant and should be carried forward to the new licence.

i Section 3(12) of NIA65 provides for the variation of a nuclear site licence to exclude part or parts of a site if certain criteria are satisfied but there is no parallel power to vary the licence to enlarge a licensed site

Section 4: Delicensing

Delicensing and ending the licensee's period of responsibility

167 The ending of the licensee's period of responsibility under NIA65 is sometimes referred to as "delicensing", but strictly speaking they are not the same. Delicensing can be achieved via section 5(1) of NIA65, which gives ONR and the licensee the rights, respectively, to revoke or to surrender the licence. The licensee's right to surrender the licence is not constrained by any qualifying conditions, providing the site is no longer being used for any activity which should be licensed (using a site to install or operate a nuclear installation without a licence being in force would be an offence under section 1 of NIA65). However, in itself, the surrender or revocation of the licence does not end the licensee's period of responsibility.

168 The period of responsibility is defined in section 5(14) and 5(15) of NIA65 as follows:

5(14) In this Act the expression "period of responsibility" in relation to the licensee under a nuclear site licence means, as respects the site in question or any part of it, the period

(a) beginning with the grant of the licence, and

(b) ending with whichever of the following dates in subsection (15) is the earliest,

except that it does not include any period during which section 19(1) does not apply in relation to the site.

5(15) Those dates are -

(a) the date when the ONR gives notice in writing to the licensee that in ONR's opinion there has ceased to be any danger from ionising radiations from anything on the site or, as the case may be, on the part of it in question;

(b) the date when a new nuclear site licence in respect of a site comprising the site in question or, as the case may be, that part of it, is granted (whether to the same licensee or to some other person);

(c) the date when the following conditions have both become satisfied –

(i) the site in question or, as the case may be, that part of it is used or occupied by or on behalf of the Crown, and

(ii) a nuclear site licence has ceased to be required in respect of that site or part”

The statutory period of responsibility is significant because:

- it can survive the termination of the licence. As noted above, section 5(1) of NIA65 allows that, at any time, the site licence can be revoked by ONR or surrendered by the licensee. However, the person to whom the revoked or surrendered licence was granted has continuing obligations in relation to the site placed on them by sections 5(5) & (6) of NIA65 during their period of responsibility
- in the absence of a licence and for the duration of the period of responsibility ONR is empowered under section 5(5) to “ .. give to the licensee such directions as [it] may consider appropriate for preventing, or giving warning of, any risk of – (a) injury to any person, or, (b) damage to property by ionising radiations from anything remaining on the site”;
- it determines the period for which the licensee / ex-licensee has liability for injury or damage affecting third parties under the insurance provisions of NIA65 (see in particular sections 7 and 19 of NIA65, which are regulated by DECC and the Scottish Government).

The legal basis for ending the licensee’s period of responsibility

Overview

169 Depending on the stage in the lifecycle of the site and / or the business plans of the licensee, there are three mechanisms by which a licensee’s period of responsibility for a site or part(s) thereof may be brought to a close (apart from the circumstances outlined in para 172). These are:

- for the whole site, by the issue of a notice under NIA section 5(15)(a);
- for part of the site:
 - by granting a licence variation under section 3(12) to exclude part(s) of the site, and this will incorporate a statement confirming that the licensee’s period of responsibility for the area(s) being excluded ends simultaneously; or
 - by the revocation of the existing licence and the granting of a new licence with a revised boundary configuration - to either the same licensee or a replacement licensee - and the simultaneous issue by ONR of a notice in writing, under section 5(15)(a) of NIA65, that the “no danger” criterion had been satisfied in respect of the area(s) being delicensed.

Delicensing the whole site

- 170 Section 5(15) of NIA65 provides that, unless a replacement licence is being issued, the period of responsibility continues until such time as ONR notifies the licensee in writing that in its opinion there has ceased to be any danger from ionising radiations from anything on the site or the site becomes a Crown site for which a licence is not required. Consequently, unless the whole site is relicensed or becomes a site which does not require a nuclear site licence, complete delicensing can only be achieved when ONR is able to make a declaration in respect of the whole site.

Partial delicensing by varying the site licence

- 171 A complementary power is provided by section 3(12) of NIA65 which allows the variation of an existing nuclear site licence to exclude part of the site, as follows:

The ONR may from time to time vary any nuclear site licence by excluding from it any part of the licensed site:

(a) which the licensee no longer needs for any use requiring such a licence, and

(b) with respect to which the ONR is satisfied that there is no danger from ionising radiations from anything on that part of the site.

In such cases the licence variation issued by ONR to exclude the appropriate part of the site will also invoke the power provided by NIA65 section 5(15)(a) to end the licensee's period of responsibility in respect of that part of the site.

Partial delicensing via relicensing

- 172 A site may need to be relicensed to accommodate a change to the licensing basis such as a change of the person operating the site, annexation of additional land into the site boundary, or the introduction of new types of prescribed activity. It is open to the licensee to seek simultaneously to exclude from the area to be covered by the new licence an area (or areas) included within the existing site boundary. As with the other mechanisms, the licensee would have to demonstrate "no danger" in order to secure the termination of its period of responsibility for the area(s) in question (see NIA65 section 5(15)(a)).
- 173 This exercise may also be carried out where part of a site is no longer required to be licensed and that part of the site is used or occupied by or on behalf of the Crown.

Interpretation of “no danger”

- 174 For the period of responsibility to end, ONR must express an opinion that there has ceased to be any danger from ionising radiations from anything on the site. ONR has published a policy statement⁴⁵ setting out its criterion for judging when risks have been reduced sufficiently to satisfy the “no danger” requirement of NIA65. Essentially, on the basis of existing published guidance such as *Reducing risks, protecting people*³ and *The tolerability of risks from nuclear power stations*,⁴ ONR considers that an additional risk of death to an individual of one in a million per year, is “broadly acceptable” to society.
- 175 Applying this to nuclear licensed sites, any residual radioactivity above the average natural background, which can be satisfactorily demonstrated to pose a risk of death to the most exposed individual of less than one in a million per year is “broadly acceptable”. For practical purposes, therefore, ONR uses this criterion to determine what is regarded as “no danger” for the purposes of sections 3(12) (b) and 5(15)(a) of NIA65. Compliance with this criterion will normally mean that ONR can delicense the site, thus removing it from regulatory control under NIA65.

Delicensing the whole site - Methodology of inspection and assessment

- 176 Although the period of responsibility can survive the surrender or revocation of the licence, ONR anticipates that in most cases licensees will seek to achieve a state of “no danger” as a precursor to delicensing, so that delicensing and the ending of the period of responsibility can be achieved simultaneously. Consideration of a licensee’s case for demonstrating “no danger” will follow ONR’s usual approach to making regulatory decisions involving assessment and inspection on a sample basis.
- 177 The licensee’s delicensing application should be supported by an appropriate safety case setting out the details of work undertaken by the licensee to assess levels of radioactivity within the area concerned, and the results obtained. This will include, but is not limited to:
- the history and use of the land;
 - the identification of areas where radioactivity could contribute significantly to radiation exposure, now or in the future, and a demonstration of their remediation;
 - documentation, records and results of radiological surveys and analyses of samples from the area to be delicensed for comparison with background data from the vicinity of the site;

- an assessment of dose and risk to the public following delicensing, based on conservative assumptions regarding future use of the site and exposure pathways, i.e. to demonstrate that any future use of the land represents no danger;

In assessing the safety case ONR will be guided by its published guidance on the interpretation and implementation of the “no danger” criterion.⁴⁶

Consultation

- 178 Section 5(2) of NIA65 requires that the ONR consult the appropriate environment authority before revoking a nuclear site licence. The framework for this consultation is set out in memoranda of understanding (MoU) between ONR and the environment regulators, the Environment Agency, Natural Resources Wales and SEPA,^{16, 17} ONR will write to the appropriate environment regulator at two stages seeking views on the proposed delicensing:

- immediately on receipt of the licensee’s application, so the environment regulator’s comments can be taken into account by ONR in planning its inspection and assessment programme in relation to the application;
- before implementing an in-principle decision to delicense the site, i.e. indicating that ONR is minded to proceed and giving the relevant environment regulator an opportunity to comment.

In accordance with the MoUs, ONR will take full and meaningful account of any environmental issues raised.

- 179 There is no statutory requirement on ONR to consult anyone other than the environment regulators in relation to an application for delicensing. ONR will decide the outcome of the application on the basis of its own reasoned assessment of the facts of the case. However, ONR encourages licensees to ensure that, wherever possible, the local community is kept fully informed via meetings of the local site stakeholder group, newsletters etc. Licensees are encouraged also to engage with appropriate stakeholders such as DECC, the Department for Business, Innovation and Skills, the Scottish Government, the MoD (for defence-related sites), and other public bodies having duties or interests in relation to the site.

Partial delicensing

- 180 Section 3(12) of NIA65 empowers ONR to grant a variation excluding part of the site from the licensed site, simultaneously ending the licensee’s period of responsibility for that part of the site. The following guidance relates to an application for a licence variation but can be applied also to a partial delicensing, effected in the course of a relicensing.

- 181 The licensee’s demonstration of “no danger” should follow the guidance in paragraph 161 above. In addition, the licensee’s case for delicensing should provide:
- details of the revised site boundary, and a map for attachment to the variation or new licence and identifying the area which is being delicensed as well as the new boundary of the licensed site (see Annex 3);
 - a review of other matters of regulatory concern which may be affected by the partial delicensing. These could include, for example:
 - arrangements for marking the revised site boundary, and details of any actions required to address security considerations arising from the change, for example dialogue with ONR’s security specialists;
 - consequences for working interfaces affecting activities on the licensed site, including supporting infrastructure and services, access etc;
 - the impact of the partial delicensing on the safety case for the remaining licensed area, and any plant thereon;
 - implications for the emergency arrangements for the licensed site;
 - whether the organisational changes associated with the release of part of a licensed nuclear site necessitate a submission under LC36.^j
- 182 Sections 3(13) and 3(14) of NIA65 require ONR to consult the Environment Agency, Natural Resources Wales or SEPA (as appropriate) before varying a nuclear site licence if the variation relates to or affects the creation, accumulation or disposal of radioactive waste, within the meaning of the Environmental Permitting Regulations 2010 or the Radioactive Substances Act 1993 (as the case may be). Consequently, ONR will consult the relevant agency as described in paragraph 178 above.
- 183 ONR will normally grant the variation if the “no danger” criterion is satisfied and the other issues outlined above are resolved to its satisfaction. However, ONR may want to ask the licensee to consider withdrawing, amending or deferring the proposed change if, for example:
- implementation is perceived to be potentially detrimental to the wider objectives of health, safety and waste management at the remaining operational site (for example, if it results in more complex operational interfaces and / or regulatory arrangements);

j LC36: “Organisational capability”

- the relevant environment agency raised reasonable objections to the variation as a result of consultation under section 3(13) of NIA65.
- 184 ONR will publish on its website the project assessment report which led to the recommendation to grant a licence revocation or variation on the grounds of “no danger”. Further information is provided in ONR’s guidance ‘Delicensing and ending the licensee’s period of responsibility’.⁵⁰

Retention of records

- 185 Any person who may have suffered harm as a consequence of activities on a licensed nuclear site is entitled to make a claim for compensation for up to 30 years after the date of the occurrence which gave rise to the claim (section 15 of NIA65). Consequently, upon delicensing and / or the ending of the period of responsibility for all or part of a licensed site, the licensee must make secure arrangements for relevant records to be retained for at least that period.

Annex 1:

Regulatory powers available for ONR to use

- 1 ONR's enforcement powers under the EA13 include:

Improvement Notice – EA13 provides for an inspector to serve a notice if the duty holder is contravening one or more applicable provisions, or ...has contravened one or more of those provisions in circumstances that make it likely that the contravention will continue or be repeated.

Prohibition Notice – EA13 provides for an inspector to serve a notice if ... relevant activities, as they are being carried on by or under the control of a person, involve a risk of serious personal injury, or relevant activities which are likely to be carried on by or under the control of a person will, as so carried on, involve a risk of serious personal injury.

- 2 ONR's enforcement powers under the HSW Act include:

Improvement Notice – The HSW Act provides (section 21) for an inspector, if they are of the opinion that a relevant statutory provision is being or has been contravened (and the contravention will continue or be repeated), to serve a notice requiring the person to remedy the contravention.

Prohibition Notice – The HSW Act provides (section 22) for an inspector, if they are of the opinion that activities are being, or are likely to be, carried out which risk causing serious personal injury, to serve a notice with immediate effect to prohibit the activity. An inspector can also serve deferred Prohibition Notices.

Prosecution – Contraventions of the provisions of both the EA13 and the HSW Act may lead to a criminal prosecution.

- 3 ONR also has powers under the NIA 65, sections 1, 3-6 22 and 24A These include the power to:

- Grant a licence
- Attach conditions to a licence
- Vary a licence
- Direct a licensee to take action
- Revoke or accept surrender of a licence

- 4 In addition to general HSW Act and EA13 powers, ONR has powers under the licence conditions to require action to bring improvements in safety, These regulatory actions are commonly known as ‘primary powers’.

Primary powers

- 5 The licence conditions provide six primary powers comprising “Consent”, “Approval”, “Direction”, “Notification”, “Specification”, and “Agreement”, which may be used as follows:

Consents – Consent is required before the licensee can carry out any activity which is specifically identified in the licence or for any other activities which ONR may specify. For example, ONR normally specifies that a licensee shall ensure that when a plant is shut down in accordance with the requirements of its maintenance schedule it shall not be started up again without the Consent of ONR. Before being granted a Consent the licensee must satisfy ONR that the proposed activity is supported by an adequate safety case and that adequate procedures to manage safety are in place.

Approvals – An Approval can be used to freeze a licensee’s arrangements and key elements of its safety management system, including the terms of reference of the Nuclear Safety Committee, Operating Rules, Maintenance Schedule and the “place and manner” in which radioactive waste can be stored or accumulated. If ONR so specifies, the licensee is required to submit its arrangements etc to ONR for Approval. Once approved, the arrangements cannot be changed without ONR’s agreement, and the procedure itself must be carried out in accordance with the approved arrangements.

Directions – A Direction is issued by ONR when it requires the licensee to take a particular action. For example, LC31 (1) gives ONR the power to direct a licensee to shut down any plant, operation or process. Such a Direction would relate to a matter of major or immediate safety importance.

Agreements – An Agreement issued by ONR allows a licensee to proceed with an agreed course of action. For example, LC30^k(2) enables ONR to agree the extension of a plant’s operating period.

Notification – The standard licence conditions give ONR powers to request the submission of information by notifying the licensee of the requirement. For example, in LC21^l(8) the licensee shall, if notified by ONR, submit a safety case and shall not commence operation of the relevant plant or process without the consent of ONR.

k LC30: “Periodic shutdown”

l LC21: “Commissioning

Specification – The standard licence gives ONR discretionary controls with regard to a licensee’s arrangements and these are implemented through Specifications. For example, in LC23^m(2), if ONR specifies, the licensee is required to refer operating rules to their nuclear safety committee for consideration.

Derived ‘powers’

- 6 A number of the licence conditions require the licensee to “make and implement adequate arrangements ... “.The arrangements are the licensee’s responsibility but they may provide mechanisms for ONR to permission activities via licence instruments issued under powers “derived” from the arrangements made by the licensee. Derived ‘powers’ have no statutory basis rather they are working level administrative arrangements put in place by a licensee as part of its licence condition compliance arrangements. Since licensee’s arrangements may differ, the derived powers can be different between licensees. Licence instruments issued under derived powers include:

Agreement: An Agreement issued by ONR permissions a licensee, in accordance with the licensee’s own arrangements, to proceed with a specified course of action. For example, LC22ⁿ requires a licensee to have adequate arrangements to control modifications to safety-related plant. Such arrangements will reflect the fact that some modifications have more safety significance than others. They will often state that for high category modifications which could, if inadequately conceived or executed, have serious nuclear safety implications, this class of modification cannot be carried out without the agreement of ONR.

For many major activities, such as building new installations or complex modifications to existing plant, the project may be divided into stages with hold points at which ONR wishes to exert its regulatory control by explicitly “agreeing” before the next stage may commence. Although there are primary powers which provide for such staged regulatory control by “Consent”, there are situations in which it is more proportionate to use the derived power of agreement.

Acknowledgement: An Acknowledgement issued by ONR informs the licensee, in accordance with the licensee’s own arrangements, that ONR either intends to take no further formal action on a topic, or notifies that it intends to examine the licensee’s proposals for ensuring safety. For example, under LC22 the licensee’s arrangements will often require the licensee to submit safety case documentation related to the more safety significant modifications. In such a case ONR may consider the modification of such safety significance that

m LC23: “Operating rules”

n LC22: “Modification or experiment on existing plant”

it judges it necessary to examine the proposal. In this case ONR will acknowledge receipt and notify the licensee of intention to examine the safety documentation for the modification, either at this or a later stage. ONR may however consider the modification does not warrant further examination and simply acknowledge receipt of the safety documentation. The licensee is then able to proceed with the proposed modification in accordance with its arrangements.

Specification – A further derived power is that of “specifying”, in accordance with the licensee’s own arrangements, that ONR agreement is needed to implement a modification when that would not normally be required under primary powers or within the licensee’s arrangements, i.e. we are intervening. This is typically used where we consider that enhanced regulatory monitoring and control of the proposal is warranted.

Flexible permissioning

- 7 Flexible permissioning has been employed extensively by ONR to control certain activities at nuclear installations. There are two approaches:
 - The use of powers derived from a licensee’s arrangements to permission activities on a licensed site. For example, the identification and release stages within a project to ensure regulatory acceptance of progression from one stage to the next through the issue of a derived powers licence instrument.
 - Enhanced implementation monitoring and control of a project or activity where the use of Licence Instruments is deemed disproportionate to the risk to nuclear safety. In this case, ONR may use other means to control hold-points agreed as part of the activity.

The use of flexible permissioning does not replace or limit the use of primary powers to achieve control of licensee’s activities when appropriate nor does it affect the powers that ONR inspectors have under the HSW Act or EA13 and may exercise at any stage should it be judged necessary.

Annex 2:

The role and duties of the Nuclear Decommissioning Authority

- 1 The Nuclear Decommissioning Authority (NDA) is a non-departmental public body which was set up in April 2005 under the Energy Act 2004. Its purpose is to ensure that the licensed nuclear sites designated to it by the Secretary of State are decommissioned and cleaned up safely, securely, cost effectively and in ways that protect the environment. The NDA is responsible for 18 designated civil public sector sites operated under 17 nuclear site licences - almost half of the licensed sites in Great Britain - including Sellafield, Dounreay, Harwell and the Magnox-class power stations. It is therefore important to understand the NDA's role and duties.
- 2 Legally the NDA can hold nuclear site licences. However it has opted to fulfil its Energy Act duties by contracting out the operation of the sites to site licensee companies (SLC), which hold the nuclear site licences, and appointing parent body organisations (PBO) to provide management and direction to each SLC. The SLC directors nominated by the PBO are part of the SLC corporate body and have duties to it under the Companies Act. Other PBO nominees may be seconded into "lead team" positions in the SLC. Providing the terms of the secondment are appropriate those secondees effectively have contracts of employment with the SLC and become "employees" of the SLC for the purposes of the HSW Act.⁴⁷
- 3 The NDA is an employer conducting an undertaking whose primary functions encompass the operation and decommissioning of prescribed installations on licensed nuclear sites, and the processing and management of hazardous material including nuclear wastes. It owns licensed nuclear sites and the assets and liabilities on those sites. So, in addition to its responsibilities to its own employees under HSW Act section 2 and the relevant statutory provisions, it has duties under HSW Act section 3 and section 4 to persons who are not their employees, i.e.:

HSW Act section 3(1): "It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health or safety."

HSW Act section 4(2): "It shall be the duty of each person who has, to any extent, control of premises to which this section applies or of

the means of access thereto or egress there from or of any plant or substance in such premises to take such measures as it is reasonably practicable for a person in his position to take to ensure, so far as is reasonably practicable, that the premises, all means of access thereto or egress there from available for use by persons using the premises, and any plant or substance in the premises or, as the case may be, provided for use there, is or are safe and without risks to health.”

- 4 A decided case on the extent of an employer’s duties under the HSW Act section 3, Regina v Associated Octel⁴⁸ is relevant to the NDA’s relationship with its SLCs. Following an unsuccessful appeal to the House of Lords by Associated Octel it was held that whether a work activity is part of the conduct of an employer’s undertaking is a question of fact. It does not depend on whether the employer engages employees or independent contractors - such as the SLCs in the case of the NDA - to carry out that work or whether control is exercised over the activity. If the work itself is part of the undertaking, a duty is owed under HSW Act section 3(1) to ensure that it is done without risk - subject to reasonable practicability. What is reasonably practicable will be determined on a case-by-case basis.
- 5 Hence it is legitimate for the NDA to exercise a degree of direction and oversight over its contractors, the SLCs. The extent of that oversight and direction is a matter for the NDA to determine. However, it is clear that the more involved the NDA becomes in the way a site is managed the more will be expected of it to meet its duties under the HSW Act.

Annex 3:

The site boundary and map

- 1 The boundary of the licensed site must encompass the licensable activities. It is important that no doubt exists in the definition of the licensed site. The boundary should be obvious and permanent and avoid, so far as is practicable, passing across water, through a building or being three-dimensional.
- 2 The nuclear site licence will define the licensed site boundary by reference to a map submitted by the prospective licensee. The map to be attached to the site licence must:
 - be produced on A3 paper;
 - have the scale and ordnance survey grid lines clearly marked;
 - cover the whole of the licensed site, and identify its boundary in colour (usually red);
 - carry an unambiguous licensee's drawing reference and revision number;
 - be clearly titled and dated;
 - provide an ordnance survey grid reference (in the form AB 123456) for a significant point on the site or its boundary;
 - show grid north, preferably using a rose-cross type identifier.
- 3 The aim is to define the site clearly so that there can be no doubt as to its limit. Such clarity will assist the application of the nuclear site licence conditions and in establishing the extent of a licensee's absolute liability for occurrences on a site. Applicants considering using GPS data to define the site boundary may find it helpful to refer to guidance on the ordnance survey website.⁴⁹
- 4 Copies of nuclear site licences are provided to DECC. The maps attached to the licences may be used by DECC to fulfil its obligation (see NIA65 section 6) to maintain a publicly-available list of licensed nuclear sites, including a map or maps showing the position and limits of each site. Consequently the licence applicant should consider security implications when determining the level of detail of the installations on the site to be represented on the site map. The applicant may wish to seek advice from ONR on this point (or the MoD for defence-related sites).

Delicensed areas

- 5 Any person who may have suffered harm as a consequence of activities on a licensed nuclear site is entitled to make a claim for compensation for up to 30 years after the date of the occurrence which gave rise to the claim (see NIA65 section 15). Consequently any area(s) of a licensed site which are being delicensed, or which have previously been delicensed (whether through a licence variation under section 3(12) of NIA65 or through an earlier relicensing) should remain identifiable over that period. This should be achieved by delineating the area delicensed by marking its boundary on the map in a distinctive manner. For example, if the licensed boundary is marked in red, by marking the delicensed area's boundary in green.

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