



Office for
Nuclear Regulation

Licensing nuclear installations



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Licensing nuclear installations

Contents

Chief Executive and Chief Nuclear Inspector’s Foreword.....	1
Map of regulated sites/facilities.....	2
Introduction.....	3
Section 1: Nuclear site licensing and the law.....	4
The Nuclear Installations Act 1965.....	4
The Health and Safety at Work etc. Act 1974 (HSWA)	5
Reducing risk and the ALARP principle.....	5
The Energy Act 2013 (TEA 13)	5
The Nuclear Industries Security Regulations 2003 (NISR 2003).....	6
Nuclear Safeguards (EU Exit) Regulations 2019 (NSR19).....	6
Other legislation relevant to safety on licensed nuclear sites	6
Fire Safety	8
Prescribed or licensable installations	8
The nuclear site licence.....	9
Licence conditions (LCs)	10
Regulatory controls through the site licence and LCs	11
Assessment.....	11
Powers conferred on ONR by the licence	12
Section 2: The licensing process – new nuclear sites	12
Background	12
Pre-application advice	13
Site selection	13
Site suitability	14
New nuclear power stations and generic design assessment	15
GDA output period of validity	16
The point of licensing.....	16
Early licensing	16
Latest point of licensing	17
The licensing process.....	17
Step 1 - Preparing to be a licensable organisation	24

Applicant organisation status.....	24
Dual and joint licensing	24
Leadership: duties of directors	25
Relationship between a parent company and a licensed subsidiary	26
Organisational capability	27
Core safety capability	28
Developing licence condition compliance arrangements	29
Step 2 - Collation of licence application dossier	30
Step 3 - Licence application.....	31
Step 4A - Assessment of the application	32
Assessment of the safety case submissions	32
Assessment of the licence applicant's organisational capability	32
Assessment of the site	33
Defining the site boundary.....	33
Security of tenure	33
Assessment of licence condition compliance arrangements	33
Decommissioning plans and programmes.....	34
Radioactive waste management and disposal	34
Assessment of emergency preparedness and response.....	35
Assessment of security requirements.....	35
Safeguards.....	36
Step 4B - Consultation.....	36
Mandatory consultation with the environment agencies	36
Public body notification.....	36
Approved funded decommissioning programme	37
Nuclear liability insurance.....	38
Justification.....	38
Financial standing	38
Step 5 - Granting the licence	38
Step 6A - Regulation under the licence – construction / installation	39
Step 6B - Regulation under the licence - commissioning.....	41
Step 6C - Regulation under the licence - operation	42

Section 3: Relicensing	42
Need for relicensing	42
Proportionality	42
Relicensing for a change of operator.....	43
Relicensing for new activities	44
Relicensing to bring additional land within the licensed site boundary	45
Section 4: Delicensing	45
Delicensing and ending the licensee's period of responsibility	45
The legal basis for ending the licensee's period of responsibility	47
Overview	47
Delicensing the whole site	47
Partial delicensing by varying the site licence	47
Interpretation of 'no danger'	48
Delicensing the whole site - methodology of inspection and assessment	48
Consultation	49
Partial delicensing	49
Retention of records	50
Annex 1: Regulatory powers available to ONR.....	51
Primary powers	52
Derived 'powers'	53
Flexible permissioning	54
Annex 2: The role and duties of the Nuclear Decommissioning Authority	55
Annex 3: The site boundary and map	57
Delicensed areas.....	57
Annex 4: Licensing and regulating a future geological disposal facility	58
Site selection	58
Facility design.....	58
Latest point of licensing	58
Licensing process.....	59
Defining the site boundary.....	59
Regulation under the licence	60
Delicensing.....	60

Retention of records	60
Justification of practices involving ionising radiation.....	60
Annex 5: Advanced nuclear innovation (small modular reactors and nuclear fusion)	61
Small modular reactors (SMRs)	61
Nuclear fusion	61
References	62
Glossary	65
ONR copyright: Licensing nuclear installations.....	67

Chief Executive and Chief Nuclear Inspector's Foreword

We are Great Britain's principal statutory independent regulator for nuclear safety and security. Taking cognisance of the UK Regulators' Code we are committed to being transparent in what we do and in providing information, advice and guidance to stakeholders that we make publicly available. *Licensing nuclear installations* is one such source of guidance aimed at those organisations that are considering applying for a nuclear site licence and others that may have an interest in our work.

The safety of nuclear installations in Great Britain 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 guide provides comprehensive information on the licensing process and the factors that we may take into account when reviewing a licence application. It covers the entire life cycle, from the licensing of new sites through the relicensing of existing sites to the final de-licensing of sites where facilities have been decommissioned and sites cleaned-up. It also mentions the role of the generic design assessment in considering whether new reactor designs may be licensed in the UK.

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 fundamental 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 that nuclear facilities can be operated safely and securely.

This, our sixth revision to this document, does not represent any significant changes to the licensing process but more reflects some legal changes and includes reference to updated processes and procedures and to other documents where more information is available on our regulatory activities.

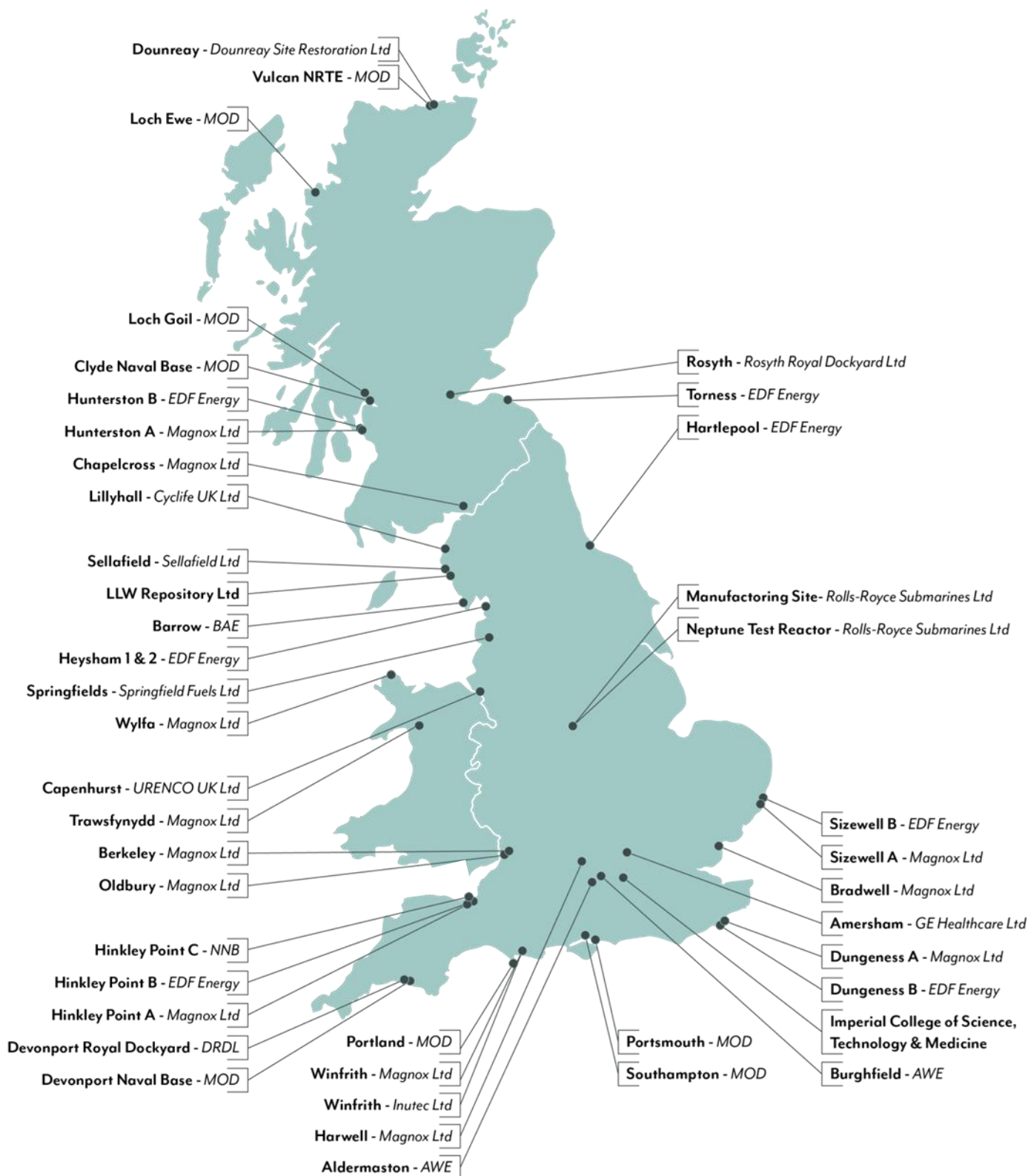
I trust that this guidance will be of interest and value to organisations considering applying for a nuclear site licence as well as the public and other stakeholders who will be able to read about the licensing process which we conduct as a key element of delivering our mission.

Mark Foy
Chief Executive and Chief Nuclear Inspector



Mark Foy, Chief Executive and Chief Nuclear Inspector

Map of regulated sites/facilities



MOD - Ministry of Defence	EDF Energy - EDF Energy Nuclear Generation Ltd	BAE - BAE SYSTEMS Marine Ltd
DRDL - Devonport Royal Dockyard Ltd	AWE - Atomic Weapons Establishment Plc	NNB - NNB GenCo HPC Ltd

Introduction

The safety and security of nuclear installations in Great Britain (GB) is assured by a system of regulatory control based on a corporate body being granted a licence to use a defined site for specified nuclear activities. This document describes, how we administer the process to enable nuclear installations in GB to gain a nuclear site licence as required by the Nuclear Installations Act 1965 (NIA 1965). 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. Currently there are 36 licensed nuclear sites in the UK.

The principal piece of legislation for the regulation of nuclear safety in the UK is the Nuclear Installations Act 1965 (NIA 1965). This incorporates many provisions of the Nuclear Installations Licensing and Insurance Act 1959, which it replaced. NIA 1965 requires certain installations to have a nuclear site licence and in 1971 regulations were enacted describing in more detail which nuclear installations require a site licence. Britain has been operating a licensing regime for more than 60 years. We were established by The Energy Act 2013 (TEA 13), and our predecessor organisations have undertaken the role of the licensing authority since 1960. In the 1990s, several defence and other sites were brought into the licensing scope, with some specific exemptions and exclusions in place. Those sites excluded remain subject to the requirements of relevant general health and safety statutes. However, they are exempt from licensing as the Ministry of Defence (MoD) is in day-to-day control of operations, and as a crown body, is not subject to the requirements of the NIA 1965.

The Health and Safety at Work Act (HSWA) came into force in 1974 and applied general duties on employers to reduce risks in all workplaces, including nuclear installations. This umbrella legislation has under it several secondary regulations which apply equally on licensed nuclear sites. In this document references to "nuclear installations" relate to those installations for which a licence is required under NIA 1965 to install or operate them.

Section 1: Nuclear site licensing and the law

The Nuclear Installations Act 1965

- 1 Relevant parts of the nuclear industry must comply with NIA 1965 which has three key purposes:
 - a) 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 (Statutory Instrument 1971/381).
 - b) 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.
 - c) It provides a special legal regime to govern the liability of nuclear site licensees and owners towards third parties for certain kinds of damage caused by nuclear matter on, or coming from, their sites.
- 2 The licensing function is administered in Great Britain by us and in Northern Ireland by the Secretary of State (SoS). The other two functions are the responsibility of the SoS for Business, Energy and Industrial Strategy (BEIS) for sites in England and Wales, and Scottish Ministers for Scotland.
- 3 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 us and is in force. The sections of NIA 1965 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 Energy Act 2013 (TEA13). Thus, these sections are subject to the TEA 13 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 NIA 1965. The use of any licensed site for such activities requires a permit granted by the SoS for BEIS, or Scottish Ministers for sites in Scotland.

Third party liability: NIA 1965 places an absolute liability on 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 NIA 1965 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 Health and Safety at Work etc. Act 1974 (HSWA)

- 4 Operators of nuclear installations in Britain, are also required to comply with the Health and Safety at Work Act (HSWA) and its relevant statutory provisions ('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 HSWA places a 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

- 5 The requirement for risks to be reduced so far as is reasonably practicable or as low as reasonably practicable (ALARP)^{ref 1} is fundamental and applies to all activities within the scope of the HSWA and NIA 1965. Put simply, 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). Fundamental to demonstrating that nuclear safety risks are ALARP for a nuclear installation, is the requirement to produce a 'safety case', which demonstrates that nuclear related facilities and activities can be operated within safe limits and conditions.

The Energy Act 2013 (TEA 13)

- 6 Part 3 of The Energy Act 2013 established ONR as a statutory corporation. This makes us 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 NIA 1965 as well as the Nuclear Industries Security Regulations 2003 (NISR), the Nuclear Safeguards Regulations 2019 and the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (CDG 2009) as they apply to the carriage of radioactive material for civil purposes. It refers to the 'appropriate national authority', which in England, Wales and Scotland is ONR. In relation to Northern Ireland, it is the SoS.

The Nuclear Industries Security Regulations 2003 (NISR 2003)

- 7 NISR 2003 provides for the regulation of the civil nuclear industry for security purposes and provides definitions of nuclear material (NM), other radioactive material (ORM) and sensitive nuclear information (SNI) for security purposes. It contains provisions for the security of nuclear premises, the transport of nuclear material and the security of SNI. NISR 2003 is enforced by ONR's Civil Nuclear Security and Safeguards (CNSS) Division, which has produced Security Assessment Principles (SyAPs) and guidance to assist inspectors make consistent regulatory judgements.
- 8 For licensing, the applicant must produce a security plan that meets specified outcomes. We will expect the security plan to be developed as security risks change during construction and operation. Security assessments will draw from the SyAPs and guidance to meet regulatory expectations. Further information about our CNSS division is available on our website^{ref.2}

Nuclear Safeguards (EU Exit) Regulations 2019 (NSR19)

- 9 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 Agency (IAA). Our Safeguards Sub-Division is responsible for regulating safeguards domestically and enforcing the provisions of NSR19^{ref.3}. These regulations require operators of qualifying civil nuclear facilities to maintain standards and arrangements for nuclear material accountancy in accordance with an accountancy and control plan (ACP). NSR19 is a relevant statutory provision of TEA 13. The Safeguards Sub-Division has issued guidance on expectations for nuclear material accountancy, control and safeguards (ONMACS)^{ref.4} and guidance to assist inspectors in making consistent regulatory judgements. Further information about ONR Safeguards is available on our website^{ref.5}

Other legislation relevant to safety on licensed nuclear sites

- 10 In addition to the acts mentioned above, we have functions under and enforce other legislation which is particularly relevant to the safety of nuclear installations in Britain including:

The Ionising Radiations Regulations 2017 (IRR17): These regulations and their associated approved code of practice^{ref.6} cover the protection of workers and the public from work 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.

The Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999 (EIADR): Under EIADR the dismantling or decommissioning of nuclear power stations and most nuclear reactors is subject to environmental impact assessment and various procedural requirements^{ref.7}. In carrying out the environmental impact assessment, the licensee must submit an environmental statement to us, seeking consent for the work to start. We consult on the environmental statement with expert bodies (for example, the environment agencies, nature conservation bodies, local authorities, and other relevant organisations) and consider submissions from members of the public and other stakeholders. We 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 we grant consent.

The Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR19): REPPIR19^{ref.8} provides a framework for the protection of the public and workers from and in the event of radiation emergencies that originate from sites.

REPPIR19 requires the licensee to undertake a hazard evaluation and consequence assessment and present the conclusions in a consequences report that is used to inform off-site emergency planning. The licensee must also produce an operator's on-site emergency plan where the hazard evaluation shows a radiation emergency may arise.

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 the local authority. 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.

The Construction (Design and Management) Regulations 2015 (CDM 2015)^{ref.9} These regulations apply to all construction projects from concept to completion. The regulations identify key collaborative roles, detailing the responsibilities of each dutyholder to ensure health and safety. The role of the client is central, as the client directly influences how a project is managed. The regulations require the client to make arrangements for managing a project, to allocate sufficient resources and provide pre-construction information.

A new role of principal designer has been created to co-ordinate the work of the project team to ensure risks are managed. All parties with roles under the regulations must have the skills, knowledge and experience to fulfil their designated duties.

The Management of Health and Safety at Work Regulations 1999 (MHSW): Require a suitable and sufficient risk assessment and effective arrangements for planning, organising, controlling, monitoring and review of preventive and protective measures.

Control of Major Accident Hazards Regulations 2015 (COMAH): COMAH applies mainly to the chemical industry. However, some nuclear sites are also COMAH sites

since threshold quantities of dangerous substances identified in the regulations are kept or used.

Other relevant health and safety legislation includes:

- The Pressure Systems Safety Regulations 2000:
- 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: and
- The Lifting Operations and Lifting Equipment Regulations 1998.

Approved codes of practice (ACoP) associated with these regulations contain relevant advice on methods that may be adopted to comply with the regulations and can be used in safety cases when demonstrating what is reasonably practicable.

Fire Safety

- 11 We also enforce fire safety legislation on licensed nuclear sites via the Regulatory Reform (Fire Safety) Order 2005 and the Fire (Scotland) Act 2005.

Prescribed or licensable installations

- 12 NIA 1965 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. Such installations are prescribed by the Nuclear Installations Regulations 1971 (NIR 1971) (SI 1971/381) and, are those designed or adapted for (in summary):

- 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; and
 - irradiated nuclear fuel

- bulk quantities¹ of radioactive matter 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: and
- the production from nuclear matter of isotopes for industrial, chemical, agricultural, medical or scientific purposes.

13 Other types of installation may be prescribed from time to time. For example, the Government policy for a future Geological Disposal Facility (GDF) will require it to be licensed by ONR (see [Annex 4](#)). Prospective nuclear operators should familiarise themselves with the provisions of the NIA 1965 and the NIR 1971. However, enquiries regarding the prescribed status of a proposed installation or activity can be made to ONR's Chief Nuclear Inspector at Redgrave Court, Merton Road, Bootle, Merseyside L20 7HS.

The nuclear site licence

- 14 Once granted a nuclear site licence is in force for an indefinite period. This is providing there are no material changes to the basis on which the licence was granted. It can remain valid for the entire lifecycle of a site from construction and commissioning through to operation, then decommissioning and finally site clearance.
- 15 NIA 1965 provides for a nuclear site licence to be granted to a named corporate body to install or operate specified prescribed nuclear installations in a defined location. So, the three key themes we address in assessing a licence application are:
- the capability, organisation and resources of the applicant corporate body;
 - the nature of the prescribed installations and the associated safety case; and
 - the location and nature of the site.

A register of extant nuclear site licences is available at www.onr.gov.uk^{ref.10}

- 16 A site 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 installation for which the site is licensed. In considering an application for a replacement licence we would take a proportionate approach and particularly focus on those aspects of the licensing basis which are changing.
- 17 Each nuclear site licence is unique to its site. It may be varied by us to exclude any part of the site which the licensee no longer needs. Before granting such a variation, we are required by NIA 1965, 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).

¹ ONR intends to publish a revised statement on the interpretation of 'bulk quantities' in relation to the storage and disposal of radioactive matter in due course.

- 18 A licence may be revoked by us or surrendered by the licensee. However, depending on 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 we have given written notice that in our opinion there isn't any danger from ionising radiations from anything on the site. Before such a notice is issued, we need to be satisfied that the site has been decommissioned and has been decontaminated to meet the required standard (see Section 4 of this guide).

Licence conditions (LCs)

- 19 NIA 1965 requires us to attach conditions^{ref.11} to each nuclear site licence which it considers necessary or desirable in the interests of safety. We may attach conditions with respect to the handling, treatment and disposal of nuclear matter. The LCs apply throughout the lifecycle of a licensed nuclear site and are applicable to design, procurement, construction, commissioning, operation, maintenance, modifications, decommissioning etc. NIA 1965 gives us the power to add, vary or revoke conditions at any time allowing the flexibility, to tailor the requirements placed on the licensee to specific circumstances and the lifecycle phase of an installation.
- 20 In general, LCs require the licensee to make and implement adequate arrangements to address the matters identified in each condition. Each licensee can develop its own LC compliance arrangements suitable for its facilities and activities to demonstrate that safety is being adequately managed. For approximately 30 years we have adopted a suite of standard LCs which are almost identical for each licensed site. Some LCs have been varied from time-to-time, usually in response to other changes, to incorporate new requirements. The benefit of this approach has been a lower administrative burden for both licensees and us. Although sites may have very different nuclear facilities and activities in practice standard LCs have become accepted, and where an LC does not affect a particular site the licensee states this to be the case. Similarly, the arrangements made to comply with LCs may change as the plant progresses through its lifecycle.
- 21 LCs provide the principal basis for regulation of nuclear safety by us. They are generally non-prescriptive and set goals which the licensee is responsible for meeting, amongst other things by applying relevant safety standards and safety procedures. The licensee's management system will incorporate the arrangements it has developed to meet the requirements of the LCs. We review the licensee's LC compliance arrangements to ensure they are clear and unambiguous and address safety adequately i.e. it meets the required standard. Procedures which comply with nuclear site LCs are likely to satisfy the requirements of other health and safety legislation under the HSWA which relate to nuclear hazards. For example, the Management of Health and Safety at Work Regulations (MHSW). However, compliance with these other requirements must still be demonstrated.

Regulatory controls through the site licence and LCs

- 22 As the licensing and enforcing authority we have a range of powers available as a means of exerting control over significant nuclear safety related facilities and activities. We use a number of controls derived from NIA 1965 and powers conferred through the LCs. These enable us 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 further ONR approval:
 - 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 specific operations; and
 - revoke a nuclear site licence.
- 23 The first three and the last two of these are not common occurrences. Most of the others 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 by, a licensee (or prospective licensee).

Assessment

- 24 Under the licence conditions, arrangements and actions by the licensee having significance for nuclear safety are subject to technical expert assessment by us. This may require prior regulatory permission before work starts or significant changes are implemented. The nuclear regulatory regime is therefore described as a permissioning regime. Our approach to permissioning regimes is described in our guidance document *The Purpose and Use of Permissioning* (NS-PER-GD-001)^{ref.12} To give effect to such permissions we assess the licensees' safety justifications. This is the process by which our assessors, who are inspectors with technical expertise 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. To assist inspectors in making judgements on the adequacy of a safety case we have developed our Safety Assessment Principles (SAPs) for Nuclear Facilities. In addition to the SAPs are a suite of technical assessment guides (TAGs). The TAGs provide more detailed guidance on the application of the SAPs. The SAPs and TAGs are available on our website ^{refs.13,14}

- 25 Further information on how ONR discharges its role as an independent nuclear safety and security regulator can be found in its publication *A Guide to Nuclear Regulation in the UK*, which is available on the website^{ref.15}

Powers conferred on ONR by the licence

- 26 Once the nuclear site licence has been granted, the licensee must comply with the relevant provisions of NIA 1965 including the conditions that we have attached to the licence and other relevant statutory provisions. We have a range of powers available to us both under the licence and other statutes to secure compliance with legal requirements, or to introduce regulatory hold-points in the interests of safety beyond which the licensee cannot proceed; these powers are described in [Annex 1](#).

Section 2: The licensing process – new nuclear sites

- 27 The site licence is not the only legal permit or authorisation required to construct and operate a nuclear facility in Britain. Additional authorisations are required from ourselves and other regulators - notably the planning authorities and the environment agencies to allow the construction and operation of most nuclear facilities. So, prospective operators of new sites will need to seek advice from other regulators and government departments, BEIS in particular, at the earliest opportunity.

Background

- 28 ONR's processes for considering applications for licences for new nuclear sites are informed by the desire to:
- build on 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 industry;
 - ensure that dutyholders have security arrangements to protect the public from the risks arising from the theft or sabotage of nuclear or radioactive material and supporting systems or through the compromise of sensitive nuclear information; and
 - where appropriate draw on advice from overseas regulators.
- 29 There are several key enablers for new nuclear development for which we are **not** the competent authority. We are 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 government ministers, normally the SoS for BEIS or the SoS for Defence, under the Justification of Practices Involving Ionising Radiation Regulations 2004 (SI 2004/1769)^{ref.16} (see paragraphs 113 and 114 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; and
- assessing the adequacy of the operator's nuclear liability insurance, the potential licensees' financial standing or the approval of a prospective licensees' funded decommissioning programme. These are matters for BEIS.

Pre-application advice

- 30 As far as resources allow, we will engage with a prospective licence applicant and provide advice on the licensing process and the expectations placed on a licensee. Early engagement is beneficial to both parties and helps to ensure a ‘right first time’ licence application. We will recover our costs for such advice from the prospective applicant.

Site selection

- 31 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, relating 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 BEIS. However, we act on behalf of the UK Government to administer those policies and are required to take them into account when deciding whether to grant a nuclear site licence. Prospective applicants should satisfy themselves that the proposed location would satisfy government siting policy for that type of installation.
- 32 The UK government’s general position on siting policy is set out in the seventh national report to the Convention on Nuclear Safety^{ref.17} As part of the planning process under the Planning Act 2008 for nationally significant infrastructure projects, 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 stations and will apply when decisions are made on applications for development consent. Section 15 of the Planning Act 2008 mean that the construction or extension of a nuclear generating station with a capacity of more than 50 megawatts in England, or of a capacity more than 350 megawatts in Wales, is a nationally significant infrastructure project. Local planning authorities would deal with planning applications for nuclear generating stations not meeting the criteria for a nationally significant infrastructure project.

- 33 The National Policy Statement for Nuclear Power Generation (NPSNPG)^{ref.18} lists sites determined by the UK Government to be potentially suitable for the siting of new nuclear power stations in England and Wales before the end of 2025. The UK Government is currently working on a new NPSNPG to apply to sites with at least one nuclear reactor, with each reactor having an electricity generating capacity of above 1 gigawatt and being deployable before the end of 2035.
- 34 The Nuclear Sector Deal (NSD) notes that the government is also actively considering the question of siting for small modular reactors (SMRs) which will fall outside the scope of this new National Policy Statement. Once the UK Government's policy on the siting of SMRs is established this document will be updated.

Site suitability

- 35 The sites listed in the NPSNPG were assessed at a strategic level via a strategic siting assessment (SSA). The conclusion of the SSA is that a site is potentially suitable for deployment of new nuclear power stations in England and Wales before the end of 2025. The listing of a site as potentially suitable does not guarantee that applications to the Planning Inspectorate for development consent on that site will be granted or that we will consider the site to be suitable. Before a licence is granted, a licence applicant must demonstrate to our satisfaction that the site is suitable to support safe nuclear operations. To allow adequate time for our assessment, a licence applicant is expected to submit a site justification report (SJR) with its licence application. The SJR should be produced in line with the applicant's proposed LC 14² arrangements.
- 36 The SJR should be based on suitable and sufficient characterisation of the site. If an application for development consent is being assessed at the same time as our assessment of a nuclear site licence application, the licence applicant should ensure that the information in the SJR is consistent with the information in the development consent application.
- 37 To facilitate parallel processing of a development consent application and a nuclear site licence application, the SJR should cover matters on which the Planning Inspectorate will liaise closely with us or rely on our processes. These matters are described by relevant nuclear impacts and flags for local consideration in the NPSNPG.
- 38 Nuclear site licences are, by definition, site specific and so the prospective operator of a new facility must identify the site it proposes to build a nuclear installation on. Our SAPs for nuclear facilities [2014 edition, Revision 1] provide the overarching approach to the regulatory assessment of site suitability. The main aspects for assessing site suitability include:
- the safety case must show that the design of a nuclear facility would have sufficient defences against a range of local external hazards, including seismic disturbances and extreme weather events such as flooding;

² LC14 Safety Documentation

- the location must be suitable for the production of an adequate emergency plan in accordance with the licence conditions and REPP19. The proximity of schools, hospitals and other institutions will be considered in the assessment of the feasibility of implementing emergency countermeasures (including possible evacuation of areas around the site);
- the suitability of the site for the engineering and infrastructure requirements of the facility; and
- the proposal must conform with government siting policy (as described above).

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

- 39 NIA 1965 provides for a nuclear site licence to be granted to a named corporate body to install or operate prescribed nuclear installations in a defined location. The SJR is the licence applicant's means to satisfy us, prior to a licence being granted, that its proposed site, as defined on its site boundary and map (see [Annex 3](#)) would be suitable for the nuclear installations it wants to install or operate. The SJR must cover the matters in Paragraphs 67 and 68. A full site-specific pre-construction safety case report (PCSR) would also be required to support the start of construction or installation after a nuclear site licence is granted. The SJR is more limited in scope than the PCSR - its purpose is to ensure that site specific geological conditions, the proposed size of the site, local external hazards, and the proximity to local populations etc. are compatible with subsequent construction or installation. The SJR removes the risk of discovering that the site is not suitable after a licence has been granted.

New nuclear power stations and generic design assessment

- 40 ONR and the Environment Agency have a process of generic design assessment (GDA)^{ref.19} that can be applied to new reactor designs. GDA is not a mandatory process but, because of its benefits, it's expected that it will usually be requested for new Nuclear Power Plants. Under the GDA process, we assess the safety and security cases for the generic design of a proposed reactor. The GDA process may be applied where we are asked to assess a new reactor's safety case prior to an application for a nuclear site licence being made. GDA, as its title suggests, is not site-specific, so does not consider matters relating to proposed deployment at a specific site or the actual operating organisation. However, GDA is aimed at providing confidence that the proposed design is capable of being constructed, operated and decommissioned in accordance with the standards of safety, security and environmental protection required in GB. For the organisation(s) requesting the GDA, this offers a reduction in uncertainty and project risk to be an enabler to future licensing, permitting, construction and regulatory activities.
- 41 The GDA process was originally developed in response to the government's 2006 Energy Review and has continued to evolve since then. The current revision incorporates the lessons learned and reflects changes in the nuclear industry since GDA was devised. This includes the potential for more mature advanced nuclear technologies (ANTs) to enter GDA in the near term.

- 42 There are a number of potential outputs that can be provided on completing a GDA, depending on the scope agreed, including GDA statements or a design acceptance confirmation (DAC). Further details are provided in the Guidance to requesting parties^{ref.20}. The GDA outputs all give an indication of confidence, based on the assessments conducted, of our judgement of whether the design is capable of being built and operated on a site bounded by the generic site envelope, in a way that is acceptably safe and secure.
- 43 GDA is not a substitute for the licensing process but it will make a significant contribution to our assessment of the future site-specific safety case. During the licensing process and subsequently, we will consider wider issues not covered in the GDA. This includes site-specific aspects and changes to the design or the safety and security documentation since the GDA concluded. However, our granting a DAC or issuing GDA statements does not guarantee that we will subsequently grant a NSL or consent to the start of nuclear safety related construction. However, we will take into account GDA outputs to avoid unnecessary reassessment of safety and security matters already considered and judged to be adequate.

GDA output period of validity

- 44 Any GDA output issued would be valid for the assessed generic design for a period of ten years from the date of issue. This is subject to no significant new information arising during this period to undermine our confidence in the safety and security of the design. If significant new information emerges (for example, due to changes to the proposed design, or relevant codes and standards) these 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 us.

The point of licensing

Early licensing

- 45 A licence may be granted when ONR is satisfied that the licence applicant's safety and security documentation provides assurance that the site will be suitable for the proposed activities if the plant is adequately designed, constructed and operated. A pre-construction safety report (PCSR) is not necessary at this stage, only an SJR. The licence applicant must also be able to show that it has adequate organisational capability and arrangements in place to manage nuclear safety and security and comply with the nuclear site LCs when the licence is granted. It also needs to demonstrate how security of tenure will be achieved on the site. In most cases, a new build project will require a Development Consent Order (DCO), issued by the Planning Inspectorate. Where this is not the case, local planning authorities will deal with planning permission under the Town and Country Planning Act 1990. It may be desirable to align when the licence is granted with the issue of the relevant planning permission.

- 46 Granting a licence will not in itself normally permit the licensee to start nuclear safety-related construction on the site; further permissions from us, as specified, will be required before construction begins. 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 our satisfaction that the site is safe to be delicensed or the site would have to be licensed to another suitable organisation.

Latest point of licensing

- 47 Section 1(1) of NIA 1965 prohibits any person from using a site to install or operate a nuclear reactor, or other prescribed nuclear installation, unless a licence has been granted for the site in question by us. A nuclear site licence must be granted to a developer before they start construction work that could, if inadequately conceived or executed, affect nuclear safety when the plant is operational. So, the latest point at which a licence is required is the start of construction. We define this 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 expected that the applicant will engage with us prior to excavation and the placing of the concrete blinding layer to reduce the risk of subsequent reengineering being required.

The licensing process

- 48 The licensing process is divided into the steps shown in Table 1, below, with key activities for a new nuclear power plant identified. These steps are expanded on 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 begin before Step 1 is completed. The stages of construction and commissioning that we decide to permission will depend on the nature of the installation and Table 1 should be regarded as illustrative.

Table One: Regulation of new nuclear sites - step-by-step licensing and permissioning process

Step	Responsibility	
	Licensee / Applicant	ONR
1. Preparing to be a licensable organisation	<ul style="list-style-type: none"> • Establish corporate body • Develop organisational capability • Develop management arrangements 	Advise applicant
2. Creation and collation of licence application dossier	<ul style="list-style-type: none"> • Identify prescribed installations to be licensed • Address the following: <ul style="list-style-type: none"> • A SJR produced in line with the licence applicant's Licence Condition (LC) 14 arrangements. This should be based on suitable and sufficient characterisation of the site; use information consistent with the licence applicant's development consent/planning application; and, for a development consent application, cover matters for which the Planning Inspectorate may liaise with, or rely on us. • A proposal to deliver a schedule of safety submissions leading to a site-specific preconstruction safety report (PCSR). • Develop organisational capability, company structures, governance and procedures, and document them in: 	Advise applicant

Step	Responsibility	
	Licensee / Applicant	ONR
	<ul style="list-style-type: none"> • Safety Management Prospectus (including security elements drawn from SyAPs strategic enablers and selected other principles) which describes: <ul style="list-style-type: none"> • organisation structure • core capability • employment model • intelligent customer • design authority • internal challenge • nuclear safety and security governance • supply chain strategy • company manual which describes corporate governance arrangements • nuclear baseline which defines nuclear safety and security related roles and posts • LC compliance arrangements • emergency arrangements • nuclear safety committee terms of reference • definition of site and arrangements to demonstrate security of tenure 	

Step	Responsibility	
	Licensee / Applicant	ONR
	<ul style="list-style-type: none"> map of the proposed site and details of local demographics 	
3. Licence application	<ul style="list-style-type: none"> Submit written application to ONR's Chief Nuclear Inspector. Include prescribed installations to be licensed and application dossier. Notify SoS for BEIS. 	<ul style="list-style-type: none"> Acknowledge receipt. Establish project governance and project management arrangements.
4A. Nuclear site licence assessment	<ul style="list-style-type: none"> Continue to develop organisational capability, arrangements, safety case and other (security) submissions. Agree position on nuclear liability insurance with BEIS. Prepare funded decommissioning programme and submit it to the SoS for BEIS. 	<ul style="list-style-type: none"> Assess site, organisation, facility safety case submissions; adequacy of licence condition compliance arrangements and implementation where appropriate; security of tenure and security arrangements Prepare assessment reports. Decide whether it is a public body. Notification is required prior to grant of licence. If yes, issue NIA 1965 section 3(4) direction to licence applicant.
4B. Consultation	<ul style="list-style-type: none"> Respond to our direction under NIA 1965 section 3(4) to notify public bodies having duties in relation to the site (may not apply to civil power reactors). 	<ul style="list-style-type: none"> Consider responses from public bodies Formally consult relevant environment agency as required by NIA 1965 section 3(13).

Step	Responsibility	
	Licensee / Applicant	ONR
		<ul style="list-style-type: none"> • Consult BEIS on applicant's financial standing and nuclear liability insurance arrangements. • Prepare licence and consult Government Legal Department; factual check by licensee.
5. Granting a site licence	<ul style="list-style-type: none"> • Formally confirm readiness to receive licence. 	<ul style="list-style-type: none"> • Produce licensing report and peer review. • Chief Nuclear Inspector's review of the licensing report recommendations and matters arising to grant nuclear site licence.
6A. Regulation under the licence – construction	<ul style="list-style-type: none"> • Continue developing PCSR to support stages of construction. • Maintain control and oversight of the supply chain used to manufacture nuclear safety related items or provide nuclear safety related services (the security implications are also relevant). • Develop adequate organisational capability to manage for safety and security • Implement arrangements for licence condition compliance and ensure continued adequacy. • Maintain control, oversight and assurance of engineering, procurement and construction 	<ul style="list-style-type: none"> • Following the granting of NSL and the start of construction we will carry out inspections to gain confidence in the licensees' arrangements for plant and equipment design, supply chain management, construction management, organisational development and safety case submissions • Licence instruments issued to permission the start of or for the progress from one stage of construction to the next using primary powers or derived powers under licensee arrangements as necessary

Step	Responsibility	
	Licensee / Applicant	ONR
	<p>activities. This includes activities which may be undertaken by the supply chain on behalf of the licensee.</p> <ul style="list-style-type: none"> • Maintain control, oversight and assurance of modifications to plant and equipment design including where those activities may be undertaken by the supply chain on behalf of the licensee, and organisation capability. • Prepare pre-commissioning safety report. • pre-commissioning safety report for submission to us to support inactive and active commissioning. • Develop the security plan to reflect the management of risks as they appear during construction with a forward plan that includes the security 'end state' and route to it. Maintain effective supply chain oversight for security-related products or services. 	<ul style="list-style-type: none"> • Confirm FDP is in place before permission to start 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 and security arrangements.
6B. Regulation under the licence – commissioning	<ul style="list-style-type: none"> • Maintain control and oversight of all safety significant matters. • Sustain adequate organisational capability to manage for safety and security. 	<ul style="list-style-type: none"> • Issue licence instruments to permission the start of or thereafter progress from one stage of commissioning to the next using primary powers or derived powers under licensee arrangements as necessary. For example, permissions may include bringing

Step	Responsibility	
	Licensee / Applicant	ONR
	<ul style="list-style-type: none"> • Implement licence condition compliance and security arrangements and ensure continued adequacy. • Maintain control and oversight of commissioning activities including where some of those activities may be undertaken by a Tier 1 contractor on behalf of the licensee. • Prepare pre-operational safety report (POSR). • Maintain oversight of significant security matters before bringing into operation or returning to service any facility, system or process that may affect security which should be subject to testing and a security plan. 	<p>new fuel to site, initial fuel load and approving the emergency plan.</p> <ul style="list-style-type: none"> • 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 and security arrangements. Assess an emergency demonstration exercise.
6C. Regulation under the licence – operation	<ul style="list-style-type: none"> • Safe operation and maintenance of the plant. • Maintain control and oversight of all safety significant matters. • Sustain adequate organisational capability to manage safety at the site. • Implement licence condition compliance arrangements and ensure continued relevance. • Compliance against the approved security plan and NISR 2003. 	<ul style="list-style-type: none"> • 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

49 During this preparatory step the prospective applicant should make and implement plans to become an organisation which is licensable under NIA 1965. This means that it must do the following:

- establish itself as a corporate body;
- set up a suitable leadership team and governance arrangements, and develop its organisational capability through acquiring the necessary financial and human resources; and
- develop suitable management arrangements.

50 These themes are expanded on in the following paragraphs.

Applicant organisation status

51 NIA 1965 specifies that no person may use a site for the purpose of installing or operating a prescribed installation unless a nuclear site licence is in force. NIA 1965 also ensures that a licence can only be granted to a corporate body and is not transferable. So, 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.

52 The applicant organisation does not have to be incorporated in the UK. For applicants from outside the UK, we would seek advice from BEIS as to whether this would be acceptable under the terms of relevant UK legislation.

53 As frequent interaction will be required between the licence applicant, ourselves and other regulators throughout the licence application process, it is in the interests of all parties if the applicant establishes a UK-based corporate entity to act as the focus for regulatory interactions.

54 Our 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 early in the licensing process with us.

Dual and joint licensing

55 Section 4(10) of NIA 1965 places an absolute responsibility on the holder of the nuclear site licence regarding compliance with the conditions attached to that licence. 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 able to exercise effective day-to-day

control over all activities on the site, whether undertaken by its own people, contractors or tenants. The holder of the nuclear site licence also has an absolute no-fault financial liability under the insurance provisions of NIA 1965 for injury to persons or damage to property. So, it is essential that there is clarity regarding which body has legal responsibility for the safe operation of a licensed site and the potential criminal and financial liabilities.

Leadership: duties of directors

56 We expect the applicant's Board to do the following:

- set the direction for effective health, safety and security management;
- establish a health, safety and security policy that is an integral part of the organisation's culture, values and performance standards;
- take the lead in communicating health, safety and security duties and benefits and establishing an effective health, safety and security culture;
- introduce management systems and practices that ensure risks are dealt with sensibly, responsibly and proportionately;
- adequately resource health, safety and security arrangements;
- ensure that it has access to competent health, safety and security advice;
- maintain oversight of, and challenge, the organisation's health, safety and security performance; and
- include appropriate consideration of health, safety and security in all its decision making.

Licence conditions such as LC12³ and LC36⁴ apply throughout a licensee's organisation, up to and including the executive team and Board.

57 When Board members do not lead effectively on the management of health and safety the consequences can be severe, for individuals and the organisation. If a health and safety offence is committed with the consent or support 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 HSWA. Equivalent provision is made in TEA 2013 for offences under that Act. Those found guilty are liable for fines and, in some cases, imprisonment. Additionally, 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. This includes health and safety offences. This power is exercised at the discretion of the court and requires no additional investigation or evidence.

58 Under the Corporate Manslaughter and Corporate Homicide Act 2007 an organisation may commit an offence if its activities are managed or organised in a

³LC12: "Duly authorised and other suitably qualified and experienced persons"

⁴LC36: "Organisational capability"

way which causes a person's death. This amounts to a gross breach of a relevant duty of care owed by the organisation to the deceased. However, an offence will only have been committed, 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^{ref.21}

Relationship between a parent company and a licensed subsidiary

59 Where another corporate body owns the licence applicant - whether as a subsidiary of a group parent or as a shareholder in a joint venture company - the parent company can be expected to adopt a strategic role. 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 not be detrimental to safety or affect 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 way 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 controlled by a parent company should not impede a licensee's access to adequate resources to meet its safety obligations, including decommissioning;
- the board of the licensee company should comprise an appropriate mix of suitably qualified and experienced executive and non-executive directors who will act in the interests of the licensee company. It should not be dominated by representatives of the parent company or joint venture shareholders; and
- 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.

60 In October 2017 BEIS issued a direction requiring nuclear site licence holders, tenants on nuclear sites, nuclear site developers, GDA requesters and NISR 2003 approved carriers to supply information to us relating to ownership changes. This applies to any transfer or creation of 5% or more of shares in the company concerned^{ref.22}.

61 Post-licensing, we will expect the parent company to continue to recognise and support the case made to it 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 processes for managing organisational change. This includes, where appropriate, submission to us for consideration prior to implementation.

Organisational capability

- 62 NIA 1965 places the primary responsibility for the safety of a nuclear installation on the licensee. Before we grant a licence, we must be satisfied that the licence applicant is a corporate body which will use the site to install or operate the prescribed installations and has adequate management structures, associated with holding a nuclear site licence. The type of organisation and level of resources that will need to be in place when operations begin must be appropriate to the risk posed by the operations across the site. There is also an expectation in NISR 2003 and SyAPs that security is enabled within a dutyholders' organisation. Directors, managers and leaders at all levels should focus on achieving and maintaining high standards of security. They must encourage and embed an organisational culture that recognises and promotes the importance of security.
- 63 We require that a licensee retains overall responsibility for control and oversight of, the nuclear and radiological safety and security of all its business. This includes work carried out on its behalf by its supply chain. The licensee must be able to demonstrate that it will; retain adequate and enduring control of the nuclear safety risks, understand the hazards associated with its activities and how to control them, and have sufficient competent resource within the licensee organisation to be an 'intelligent customer' for any work it commissions externally.
- 64 This is important where the licensee's supply chain strategy envisages contractors doing engineering, procurement and construction activities or other key safety or security activities on its behalf. We will expect the licence applicant to have sufficient 'intelligent customer' capability to specify, oversee and accept the products or services covered by such an arrangement regardless of the supply chain tier.
- 65 The licensee is expected to establish robust supply chain management arrangements. This includes carrying out effective oversight, assurance and acceptance of items or services being supplied or done on its behalf where their sub-standard delivery has the potential to impact on nuclear safety or security. The LCs require suitably qualified and experienced staff for all activities that could affect safety on the site. It is also the licensee's responsibility to ensure that this requirement is fulfilled both within its own organisation and its supply chain. Further guidance is provided in the TAG: *Supply Chain Management arrangements for the Procurement of Nuclear Safety Related Items of Services*^{ref.23}.
- 66 We expect a licence applicant to demonstrate the adequacy of its arrangements for managing nuclear safety. This may be achieved by producing a safety management prospectus (SMP). The SMP should provide a clear description of the company and its structure and how it is intended to operate. It should include a description of the

governance of the organisation, and its management system and staffing arrangements. It should also show how these will ensure safety in the context of its activities and the associated nuclear hazards. It should be accompanied by plans detailing how the organisation will evolve. This includes arrangements for review and revision of the areas addressed by the prospectus. Further guidance is available in the TAG: *Function and content of a safety management prospectus* ^{ref.24} The relevant environmental agencies and ourselves encourage applicants to develop a combined safety, security and environment management prospectus.

- 67 All licensees should be able to demonstrate that they are meeting the requirements of the site licence throughout the lifecycle of the site. The licensee should have an adequate and up-to-date organisational nuclear baseline at the point of licensing. This should be kept current as the licensee's organisation evolves. For example, for a new nuclear power station the organisational structure and resources will continue to develop through the phases of construction, commissioning and operation. The principal purpose of a nuclear baseline is to provide a demonstration that a 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 the TAG: *Function and content of the nuclear baseline* ^{ref.25}
- 68 In addition to having an appropriate organisational structure and governance arrangements, the licensee should foster a strong safety culture through appropriate safety leadership, organisational learning and decision-making processes. These should take account of the conflict between safety, security and business goals. As the organisation prepares for licensing it is expected to demonstrate these attributes and have the capability for self-assessment and internal challenge. There is further guidance available in challenge culture, independent challenge capability and the provision of nuclear safety advice.
- 69 We expect a licence applicant to undertake a period of 'shadow working' during the nuclear site licence assessment period. Shadow working is an opportunity for the licence applicant to test the adequacy and robustness of its management arrangements as if it were operating under the constraints of a nuclear site licence, allowing it time to refine its arrangements based on learning from experience. This period should ideally be six to nine months prior to us completing our assessment phase ahead of potential nuclear site licence grant, enabling us to sample the implemented arrangements and gain confidence in their overall adequacy.

Core safety capability

- 70 The licence applicant should be able to demonstrate that it has the knowledge, functional specialisms and resources in its own organisation to maintain control and oversight of safety on the licensed nuclear site at all times. This core safety capability will include technical, operational and managerial elements. It should be able to demonstrate its approach to the identification of its 'intelligent customer' capability, within the core safety capability, to understand, specify, oversee and accept nuclear safety related work done on its behalf by contractors. Further

guidance is available in the TAG: *Licensee Core Safety and Intelligent Customer Capabilities*^{ref.26}

- 71 The LCs require the licensee to have suitably qualified and experienced staff for all activities that could affect safety on the site^{ref.27} For many plant designs the expert knowledge will initially be with the vendor. However, we expect to see that the licence applicant has appropriate strategies to transfer this knowledge and information to its organisation.
- 72 The transfer of knowledge must be sufficient for the licence applicant to demonstrate to our satisfaction that it is ready to take control of all activities on the site before the licence is granted. This includes control of the design, the safety case and safety-related procurement and that it has plans in place to develop its organisational capability as work progresses.
- 73 To ensure ongoing control of the design of the plant there needs to be a design authority capability as defined in INSAG-19 maintaining the design integrity of nuclear installations throughout their operating life^{ref.28} Initially, the detailed design capability will reside within the vendor's organisation. However, 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 when the licence is granted. The licence applicant should make and implement arrangements for development of its design authority capability including knowledge transfer and technical support from the reactor vendor. These arrangements should be discussed with us. We expect these arrangements to be based on the vendor maintaining a strong UK presence. For further information see INSAG-19 and the TAG: *Licensee Design Authority capability*^{ref.29}
- 74 The licence applicant will also need to demonstrate a similar capability for the security function guided by SyAPs and relevant good practice (RGP). Security expertise should be represented within the licence applicant's organisation to develop the output from GDA to the site, through construction to operating, as security-based risks evolve. The expectation is that the licensee has the capacity to develop a security plan.

Developing licence condition compliance arrangements

- 75 We will agree a programme for developing adequate licence condition compliance arrangements^{ref.30} Where the licence condition requires compliance arrangements, they are expected to be proportionate and suitable for the activities being undertaken. They are expected to evolve as plant construction and commissioning progresses. Initially, we expect the applicant to focus on putting in place fully developed arrangements covering those activities underway at the point of licensing (this includes the development of the design and safety case) or scheduled to start soon after the nuclear site licence comes into force. The agreed programme will need to satisfy us that more developed arrangements for the balance of the LCs will be put in place in a timely manner.

- 76 ONR will expect the licence applicant to demonstrate how LC compliance is assured through the management system. However, we do not expect that compliance arrangements should drive the design of the management system. It may be appropriate to demonstrate this via a 'route map' through the management system, to show how compliance with the LC is delivered and assured.

Step 2 - Collation of licence application dossier

- 77 The documents must be in English. The licence applicant should discuss with us our expectations for the content and style of the licence application dossier. The supporting evidence required within the dossier includes:
- a description of the installation 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, which the applicant will achieve security of tenure and rights of access to the site to meet its obligations under NIA 1965 and the site LCs,
 - details of inter-site safety and security agreements - where there is an adjacent nuclear site;
 - a site justification report;
 - a safety management prospectus (including security aspects), company manual and nuclear baseline;
 - LC and NISR compliance arrangements;
 - adequate safety submissions complemented by a programme setting out their continued development where necessary (see paragraphs 85-88 below). If the proposed installation is a design which 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 that GDA. Alternatively, submissions showing how additional site-specific aspects are addressed will be necessary;
 - Details of how they will develop the security plan for the current site. This includes a forward-looking schedule outlining the changes in security risk over time, together with a concept for their security regime at all phases up to operations;
 - details of appropriate emergency arrangements and a suitable emergency plan (this may be limited for the period before nuclear fuel is brought onto the site);
 - terms of reference for the proposed licensee's nuclear safety committee^{ref.31}
 - a statement setting out a strategy for decommissioning the proposed installation; and

- 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.

78 Detailed requirements for the above are given in documents published on our 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, contact@onr.gov.uk

79 A licence applicant should seek our advice to check the adequacy of the application dossier before it is submitted.

Step 3 - Licence application

80 An application for a nuclear site licence must be made in writing to the Chief Nuclear Inspector at our Redgrave Court offices. We will advise the applicant on the required format of the submission (for example, number of copies, use of electronic media etc.)

81 Prospective nuclear power station operators may prefer the design to have completed the GDA process before submitting a site licence application. However, it is 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.

82 Following an initial review of the licence application, we will provide an estimate of the timescale required to complete the licensing assessment. However, the exact timescale will be influenced by the following factors:

- the adequacy of the licence application dossier
- the quality of the licence applicant's safety and security submissions. Also, how successfully the site justification report 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 licence applicant's indicative timescale for concluding its own review of its readiness to be granted the licence; and
- The licence applicant's security capability to deliver a security plan and meet the expectations in the SyAPs.

83 Depending on the factors above, it might take several years from site licence application to the completion of our assessment. This is subject to adequate and timely submissions from the applicant and the level of maturity of implementation of the applicant's arrangements. We will recover our costs from the applicant using the power provided by section 24A of NIA 1965.

Step 4A - Assessment of the application

- 84 Our internal process for dealing with applications for licences for new nuclear sites is available on our website^{ref.32} We will develop an intervention strategy which will be shared with the applicant. Its key elements are summarised below:

Assessment of the safety case submissions

- 85 A site-specific PCSR does not need to be in place when the nuclear site licence is granted. However, the licence applicant will be expected to have agreed with us 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. Our intervention strategy will set out some of the key topics to be assessed in the applicant's safety case submissions, including assessment of the site justification report. The safety documentation for power reactors may draw on a generic safety case for which we issued a DAC. This will need to include additional information relating to site-specific aspects of the proposed installation.
- 86 We will expect to maintain a dialogue with the licence 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. Our assessment of these submissions may indicate where we consider further analysis or design modifications are necessary before a licence can be granted. To help assess the applicant's submissions we may seek independent data and advice from external sources.
- 87 Our expectations for safety cases are set out in the SAPs. We have also published internal guidance on our expectations for safety cases, including for PCSR, in the TAG: *Guidance on the Purpose, Scope and Content of Nuclear Safety Cases*^{ref.33}
- 88 In addition to safety case submissions, ONR will expect a similar approach to security. Drawing on the output of GDA, the applicant should describe how security risks over time will be addressed, with a clear understanding of the security 'end-state'. These expectations are outlined in SyAPs and related assessment guides.

Assessment of the licence applicant's organisational capability

- 89 We will seek assurance that the licence applicant has suitable and sufficient organisational structures, resources and competencies to lead and manage safety effectively by applying the 'Leadership and management for safety' SAPs, plus the supporting assessment guides on our website. There is an expectation in SyAPs that the applicant's case describes how security is captured in the 'strategic enablers' that are inclusive to the points below. We will focus on the following key areas:
- Corporate governance arrangements;
 - Core capability including design authority and 'intelligent customer' capabilities;

- Competency and training;
- Independent Challenge and Oversight arrangements;
- Management of organisational change;
- Supply chain strategy; and
- Safety and security culture.

Assessment of the site

90 We will apply the siting SAPs, [Ref 13](#) which set out the key safety factors involved in judging the acceptability of any proposed site.

Defining the site boundary

91 It is important that the boundary of any licensed site is clearly defined. It is essential that the extent of the site is adequate to encompass the prescribed installations. It also needs to allow sufficient margin for the maintenance of facilities, services, plants and buildings, before any nuclear safety related construction starts. The boundary should, so far as is practicable:

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

92 [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

93 Our policy is to ensure that a licensee has full rights of access to, and control of the site, so that it can satisfy the demands placed on it by the licence and NIA 1965. When granting a licence, we will require evidence of security of tenure to show that sufficient consideration has been given to such issues. Where the licence applicant does not own the site, evidence is normally required in the form of a lease or some other legally binding contract or documentation which sets out the relationship between the applicant and the owner or lessee of the site.

Assessment of licence condition compliance arrangements

94 The licence applicant must also demonstrate that its management system and arrangements for complying with the nuclear site LCs are adequate and they are being implemented effectively before the licence is granted. We will assess the adequacy of the applicant's proposed licence condition compliance arrangements including the prospective licensee's own assurance activities. Where necessary, we will carry out inspections of both headquarters and site-based activities to inform our regulatory judgments.

Decommissioning plans and programmes

- 95 Facilities should be designed and operated so that they can be safely decommissioned. So, before granting a licence, we must be satisfied that the licence applicant has developed adequate strategies, plans and programmes for the decommissioning of a nuclear plant and facilities and for the treatment and disposal of radioactive wastes. New nuclear power stations must have a Funded Decommissioning Programme approved by BEIS. Further guidance on our expectations of licensees' strategies for decommissioning and radioactive waste management is in the Decommissioning SAPs on our website.

Radioactive waste management and disposal

- 96 Safe and secure management of radioactive waste is an activity that usually spans all the stages in the lifecycle of a facility. The UK waste hierarchy should be considered at all stages in the lifecycle of a facility. This should start at the planning and design stage through operation, to decommissioning and final site clearance. Related issues to be considered by us include the licence 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 include the likely quantity of waste that may be generated, 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 and TAGs on our website.
- 97 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. We will expect the licence applicant to have consulted the operators of the disposal facilities to which radioactive waste may be consigned. For example, the Low-Level Waste Repository (LLWR) and/or NDA's Radioactive Waste Management Limited (for emplacement in a future GDF).
- 98 Geological disposal is not currently a prescribed activity under NIA 1965. However, government policy is that a GDF will require a Nuclear Site Licence and it intends to make the necessary legislative and regulatory provisions to facilitate licensing. 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 necessary. [Annex 4](#) sets out our expectations for licensing and regulating a future GDF.
- 99 Article 37 of the Euratom Treaty required the UK to make a submission to the European Commission (EC) with an assessment of the potential impact on other member states of planned or accidental discharges or disposals of radioactive waste from nuclear facilities. The UK's obligation under article 37 ceased on 1 January 2021. The Transboundary Radioactive Contamination (England) Direction 2020 requires the Environment Agency to consider, as part of its assessment of an

application for an environmental permit, whether the planned disposal of radioactive waste is liable to result in significant contamination in EU member states and Norway. Advice should be sought in the first instance from the Environment Agency, the Scottish Environment Protection Agency and Natural Resources Wales, as appropriate.

Assessment of emergency preparedness and response

- 100 In addition to the relevant licence conditions, the licence applicant will need to satisfy the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPP19)^{ref.8} The key licence condition is 11⁵ – this requires the licensee to generate and own the onsite emergency plan^{ref.34} but others such as 7, 10, and 36 also apply. REPP19 places specific requirements on the licensee. This includes the need to conduct a hazard evaluation and consequence assessment (regulations 4 and 5 respectively). The licensee also has to submit a consequences report to the local authority (regulation 7) in addition to the production of the operator's emergency plan (regulation 10 and schedules 6 and 7). REPP19 specifies the information that the operator's emergency plan must contain. This includes mitigation and response actions, requirements for communications, training, testing, equipment and radiation protection measures, and which organisations should be consulted on the content. REPP19 also places duties on the licensee to co-operate with the local authority responsible for producing the off-site emergency plan. This is to ensure they co-ordinate arrangements for notifications and communications during an emergency. It also places duties on employers (tenants, contractors) who might be affected by a radiation emergency to co-operate with the operator in emergency planning and testing.
- 101 The generation of the off-site emergency plan under REPP19 is the responsibility of the local authority, supported by information provided by the licensee. REPP19 requires both the operator's plan and the local authority's off-site plan to be in place for the operator to carry out work with ionising radiation. So, allowance will need to be made in accordance with the timescales identified in REPP19 for the processes required by the regulations to be completed. Guidance on emergency planning requirements can be found on BEIS's website (insert link). The responsibilities of the UK Nuclear Emergency Planning Liaison Group (NEPLG), who produced the guidance, have been taken over by the Nuclear Emergency Planning Delivery Committee^{ref.35}

Assessment of security requirements

- 102 Security expectations, consistent with SyAPs, are included elsewhere in this document. The requirement is that we will not grant a licence until security arrangements and plans are in place which meet the expectations in SyAPs and that they will develop over the lifetime of the site. At licence grant the arrangements and

⁵ LC11 Emergency Arrangements

plan should be included in a SyAPs aligned security plan. We must approve the security plan as a pre-requisite for the granting of a site licence.

- 103 We regulate nuclear security requirements at civil nuclear sites and associated premises. We will not grant a licence until we are satisfied that appropriate measures are in place to manage all relevant aspects of security. Further information is available on our website^{ref.2}

Safeguards

- 104 Following the UK's exit from the European Union and European Atomic Energy Community (Euratom), we are now responsible for the new domestic safeguard's regime. This includes delivering a UK State System of Accountancy for and Control of Nuclear Material (UK SSAC). ONR's Safeguards Sub-Division works with the safeguards inspectorate of the IAEA to ensure UK compliance with international safeguards obligations. Good procedures for nuclear materials accountancy are crucial to ensuring effective and proportionate implementation of safeguards measures. Early engagement with us is both a requirement under NSR19 (for example, preliminary information on new facilities must be provided to ONR before construction starts) and key to defining effective and efficient arrangements for safeguards verification and inspection activities. More detailed information is available on our website^{ref.5}

Step 4B - Consultation

Mandatory consultation with the environment agencies

- 105 NIA 1965 places a requirement on us to consult the appropriate environment authority (the Environment Agency in England, Natural Resources Wales and Scottish Environmental Protection Agency) 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. It is also to ensure that it will not prejudice any legal process under the Environmental Permitting (England and Wales) Regulations 2016 for sites in England and Wales, or for Scotland, the Environmental Authorisations (Scotland) Regulations 2018, or other environmental legislation. The arrangements for this consultation are set out in memoranda of understanding (MoU) between us and each agency^{refs.36,37,38} We will not normally grant a licence unless it has been assured by the appropriate environment authority that it expects to be able to grant a permit under the relevant environmental regulations. The process for applications for new authorisations is shown in the Environment Agency's *The regulation of radioactive substances activities on licensed nuclear sites*^{ref.39}

Public body notification

- 106 We have a discretionary power under section 3(4) of NIA 1965 to direct a licence applicant to serve notice on the public bodies we specify. These bodies will normally

be local to the site in question. For example, they may include local authorities, emergency services, river authorities, fisheries committees, statutory water undertakings and national parks authorities. The intention of public body notification^{ref.40} is to ensure that relevant public bodies who have statutory duties in relation to the site have an opportunity to be informed of the licence application and to advise us if their duties may be affected by the licensable activities. This enables us to consider if there is a need to amend any of the licence conditions that are normally attached to the nuclear site licence.

- 107 When deciding whether to direct a licence applicant to undertake public body notification, certain key factors will be considered by ONR. These include 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 our discretionary powers.
- 108 When this power is invoked, we will require the licence applicant to provide specified bodies with details of the proposed development and they must allow the consultees up to three months to submit their comments to us. We will also consider and evaluate any comments submitted by other stakeholders.
- 109 Our 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 is expected for all such applications. Under the Planning Act 2008, nuclear power stations over a capacity defined in the act are 'nationally significant infrastructure projects'. Prospective developers are now required to consult widely before applying to the Planning Inspectorate for a DCO. This consultation process will include 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

- 110 For new nuclear power stations, section 45 of the Energy Act 2008 introduced a statutory requirement on licence applicants, beginning as soon as the licence application is made, requiring them to have an approved funded decommissioning programme (FDP). The FDP will require operators to make adequate arrangements for covering the cost of decommissioning the site. They will also be required to manage any operational or decommissioning waste, and this must be approved by the SoS for BEIS before using the site for activities that need to be licensed. BEIS guidance interprets this point as the placement of first structural concrete for buildings which have nuclear safety significance. So, the FDP does not need to be approved at the point of licensing. However, once the nuclear site licence has been granted, and before permissioning the start of nuclear safety-related construction, we will seek confirmation from BEIS or the MoD that the licensee can meet the requirements of the Energy Act 2008.

Nuclear liability insurance

- 111 NIA 1965 requires licensees to provide cover for third-party claims within the limits prescribed by the act, and for the arrangements to be approved by the Minister. BEIS, MoD or the Scottish Government, as appropriate, will review the adequacy of the licensee's cover, which may be provided by insurance, indemnity or other approved means. A licensee will commit a criminal offence if suitable third-party cover is not in place at any time when section 19(1) of NIA 1965 applies in relation to the relevant licensed site. We will seek confirmation that a licence applicant has appropriate cover by liaising with the relevant government department. However, it is not our responsibility to audit or validate the applicant's arrangements for liability cover.
- 112 A licence applicant may apply, under section 3(9) of NIA 1965, for deferral of the requirement for section 19(1) cover. If we agree, subject to the consent of the SoS for BEIS, a nuclear site licence may include a provision with respect to the time from which section 19(1) is to apply. For example, this may be linked to the point at which nuclear fuel is to be brought onto the site for the first time.

Justification

- 113 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).
- 114 We 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^{ref.16} For nuclear power stations, and most prescribed civil nuclear activities, the SoS for BEIS is the justifying authority.

Financial standing

- 115 We may ask interested government departments and agencies to inform us of anything relating to the applicant's financial standing which they consider we should take into consideration before granting a licence.

Step 5 - Granting the licence

- 116 At the conclusion of its assessment of the licence application, and if relevant consultations have been completed, we will draft a report which sets out the findings of its assessment. This report makes a recommendation to the CNI as to whether a

nuclear site licence should be granted. We will draft the nuclear site licence, which will be checked for accuracy with the Government Legal Department and the applicant before it is granted.

- 117 The prospective licensee should formally inform us that it is ready to receive a licence and that it has satisfied itself that it will be compliant with all LCs when the licence is granted.
- 118 The CNI will review our assessment together with any matters arising and convene a scrutiny panel to review and challenge any aspect of the assessment. If the CNI is content to grant the licence, which is a legal document, an original signed copy will be sent to the applicant.

Step 6A - Regulation under the licence – construction / installation

- 119 During this period, our regulatory activities will focus on equipment procurement, construction, design modification and pre-commissioning issues and the development of the licensee's organisation. We expect the licensee to provide a PCSR to support the start of nuclear safety related construction.
- 120 The granting of a nuclear site licence does not, in itself, give the licensee permission to begin nuclear safety-related construction on the site. We will use the primary power provided by LC19(4)⁶ to specify that the licensee should not start nuclear safety related construction without our consent. Throughout construction and installation, we may employ LC19(4) to identify further 'hold points' where our consent is required before the licensee may proceed from one stage to the next. However, we expect the licensee to manage the construction and installation process under its own arrangements and, in practice, the LC19(4) power is used sparingly. We also expect that the licensee's arrangements, made under LC19(1), should include provision for us to specify that progress from one stage to the next will not proceed without our agreement.
- 121 We expect the licensee to consider the adequacy of its organisational capability when making a case for moving through the different stages of construction and installation. We expect this whether the stage transition entails seeking a formal consent or derived power agreement from us or involves only internal due process. The licence application will have included programmes for development of its organisational capability – we 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 to be ready for full operation.

⁶ LC 19 Construction or Installation of New Plant

- 122 At all times, the licensee must ensure that it has sufficient in-house expertise to manage and make informed decisions on issues affecting nuclear safety. It must also 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.
- 123 The licensee must 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.
- 124 Regulation 2A of The Health and Safety (Enforcing Authority) Regulations 1998 defines New Nuclear Build (NNB) sites, while Regulation 4(1)(b) of these regulations establishes us as the enforcing authority for premises which are or are on a NNB site. If a licence applicant wishes to define a NNB site, this should be discussed with us and an agreed position reached prior to us granting a nuclear site licence. If a NNB site is defined, the boundary may be shown on the site map.
- 125 We will agree a schedule for the submission of safety documentation throughout the period of installation and on-site testing with the licensee. In particular:
- the pre-commissioning safety report (PCmSR) must be acceptable to us before active commissioning starts;
 - technical specifications, or operating rules deriving from the safety case, should be submitted to us during construction and before commissioning. We may choose to approve the operating rules; and
 - the maintenance schedule must also be submitted and agreed by this stage.
- 126 We are responsible for inspections and regulatory oversight of the plant. We will usually appoint a site inspector, and a programme of regulatory inspections will be introduced. Our expectations for LC compliance will be on a proportionate basis. Particular attention will be paid to LC20 on 'modification to design of plant under construction'.
- 127 The inspections must satisfy us 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.
- 128 During construction, security risks on the site will change from managing a large workforce and contractors to the security implications of safety and security hold points and regulatory consent. Similarly, there is an expectation that the licensee and dutyholder will update the security plan and any forward work schedules to reflect these changes in risk. The security plan will require replacement or amendment and our approval in accordance with NISR 2003. The SyAPs aligned security plan should also include the dutyholders' organisational capability arrangements, thereby meeting one aspect of the expectations described within the 'strategic enablers' aspect of the fundamental principles. We will appoint a site security inspector (SSI), who together with other security experts, will be responsible for the inspections and regulatory oversight of the site against the security plan and NISR 2003.

Step 6B - Regulation under the licence - commissioning

- 129 Commissioning may not begin until we have issued the appropriate licence instrument. For a nuclear power station, the licensee must seek our 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 us 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 our expectations for safety cases including the commissioning and pre-operational stages is provided in the TAG: Guidance on the Purpose, Scope and Content of Nuclear Safety Cases^{ref.33}The safety case for these later stages should evolve from the pre-construction safety report (PCSR).
- 130 We can use powers provided by LC21(4) to specify that our consent is required to start and then progress from one commissioning stage to the next. However, in practice these powers are used sparingly, and we expect the licensee to manage the commissioning process under its own arrangements. We will expect the licensee's arrangements, made under LC21(1), to include provision for us to specify that progress from one stage to the next should not proceed without our agreement.
- 131 Before the start of active commissioning, adequate emergency arrangements should be in place and exercised as appropriate.
- 132 The POSR should include the commissioning results and report on any anomalies. Through its inspection and assessment processes we 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.
- 133 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.
- 134 We will 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.
- 135 During commissioning and before operation, the dutyholder is required to amend or replace the security plan for approval. That change should reflect the planned arrival of nuclear fuel and require the dutyholder to meet the requirements outlined within SyAPs.
- 136 The licensee must 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. The licensee must also establish a positive safety culture within its own organisation, tenant organisations and contractors on the construction site.

Step 6C - Regulation under the licence - operation

137 The licensee remains responsible for the safe operation and maintenance of the plant. It is also responsible for meeting all licence conditions and remaining compliant with the security plan, throughout the life of the site, including the decommissioning phase. We will maintain appropriate regulatory oversight throughout the life of the licensed site.

Section 3: Relicensing

Need for relicensing

138 A nuclear site licence is granted for an indefinite period. In principle, one licence could cover the entire lifecycle of the site from installation and commissioning, through to operation and decommissioning to site clearance and remediation. However, for many sites a replacement licence will be required from time to time.

139 As a site licence is granted to a particular corporate body to carry out specified prescribed activities in a defined location, 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. This includes:

- where there is to be a change of operator, since NIA 1965 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; and
- where the site boundary is to be extended

140 Our guidance to inspectors on site relicensing is available on our website^{ref.41}

Proportionality

141 The relicensing process requires us to assess the licence applicant's case for the granting of a replacement nuclear site licence. We will consider all relevant aspects of the licence applicant's case. This may mean addressing most of the issues which are considered when licensing a new site for the first time. However, we will adopt a proportionate approach in line with our enforcement policy statement^{ref.42} This means that the assessment will focus on those areas where changes are taking place or those which are judged to be potentially important for nuclear safety reasons.

142 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 these cases, we will already have access to much of the evidence needed to support the granting of the replacement licence. This includes 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, to seek pre-application advice by contacting ONR's Licensing team via contact@onr.gov.uk

- 143 Following an initial assessment and taking account of the extent of the changes which need to be assessed, we will be able to provide an estimate of the timescale for processing the licence application.

Relicensing for a change of operator

- 144 The safety of activities at a licensed nuclear site must not be compromised by a loss of capability resulting from a change of operator. We anticipate 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. This is 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'^{ref.43}
- 145 It is 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 require substantial and additional pre-re-licensing scrutiny by us to ensure that, when implemented, the new licensee's arrangements will maintain or improve standards of safety at the site. In these circumstances we may expect to see a period of 'shadow' working as a precursor to the granting of the new licence.
- 146 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 us 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 and security. We will not grant the new licence unless and until this demonstration has been completed to our 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.
- 147 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, we will conduct a targeted and proportionate examination of organisational capability. This will consider the same issues as for a new licensed site. These are as follows:

Table Two: Relicensing for a change of operator

Topic	Relevant paragraphs in Section 2
Applicant organisation status	51 - 54
Dual and joint licensing	55
Duties of directors	56 - 58
Relationship with parent company	59 - 61
Organisational capability	62 – 69
Core safety capability	70 - 74

Relicensing for new activities

- 148 Where an existing site is to be relicensed to accommodate the introduction of an additional class of prescribed activity, we will scrutinise the developing design safety case to assess if the proposed operations at the site will be adequately safe. We will also need assurance that the particular class of activity proposed is deemed to be justified within the meaning of the Justification Regulations 2004.
- 149 Generally, the incumbent licensee will have opened and maintained a dialogue with us throughout the development of the safety case^{ref.33} As aspects of the design reach the point where their safety can be assessed, safety submissions should be made to us. These submissions may be discussed, and further analysis or design modifications may be necessary before we permission the activity. However, relicensing is not directly dependent on finalisation of the safety case for the new activity - its development could progress as normal business under the new licence.
- 150 We 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.
- 151 The licensee's suite of site LC 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 our internal guidance for inspectors^{ref.44}

Relicensing to bring additional land within the licensed site boundary

- 152 Our policy is to ensure that a licensee has full rights of access to, and control of the site, so that it can satisfy the demands placed on it by the licence and NIA 1965. 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 another legally binding contract / documentation setting out the relationship between the prospective licensee and the owner of the site.
- 153 The revised boundary of the licensed site must be defined clearly. The extent of the site must include 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; and
 - include all underground workings.
- 154 Annex 3 sets out the requirements for the site boundary plan which will be attached to the replacement nuclear site licence.
- 155 Licensees will need to assess the impact of the proposed change of boundary on their existing site and on their licence condition compliance arrangements. They must include details of this assessment in their application for relicensing.
- 156 The licensee should also review which Licence Instruments are extant and should be carried forward to the new licence.

Section 4: Delicensing

Delicensing and ending the licensee's period of responsibility

- 157 The ending of the licensee's period of responsibility under NIA 1965 is sometimes referred to as 'delicensing', but strictly speaking they are not the same. Delicensing can be achieved via section 5(1) of NIA 1965, which gives us 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. This is 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 NIA 1965). However, the surrender or revocation of the licence does not end the licensee's period of responsibility.

158 The period of responsibility is defined in section 5(14) and 5(15) of NIA 1965 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 the following dates in subsection (15) which 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 ONR gives notice in writing to the licensee that in its opinion there has ceased to be any danger from ionising radiations from anything on the site or, 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, 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, that part of it 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 NIA 1965 allows that, at any time, the site licence can be revoked by us 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 NIA 1965 during their period of responsibility;
- in the absence of a licence and for the duration of the period of responsibility we are 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"; and
- it determines the period for which the licensee / ex-licensee has liability for injury or damage affecting third parties under the insurance provisions of NIA 1965 (see in particular sections 7 and 19 of NIA 1965, which are regulated by BEIS and the Scottish Government).

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

Overview

- 159 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) of a site may be brought to a close. 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. This also requires the simultaneous issue by us of a notice in writing, under section 5(15)(a) of NIA 1965, that the 'no danger' criterion had been satisfied in respect of the area(s) being delicensed.

Delicensing the whole site

- 160 Section 5(15) of NIA65 provides that, unless a replacement licence is being issued, the period of responsibility continues until we notify the licensee in writing that in our 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 we are able to make a declaration regarding the whole site.

Partial delicensing by varying the site licence

- 161 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:

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) *when 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 us 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 regarding that part of the site.

Interpretation of 'no danger'

- 162 For the period of responsibility to end, we must express an opinion that there has ceased to be any danger from ionising radiations from anything on the site. We have published a policy statement^{ref.45} setting out our criterion for judging when risks have been reduced sufficiently to satisfy the 'no danger' requirement of NIA 1965. Based on the existing published guidance Reducing risks, protecting people^{ref.46} we consider that an additional risk of death to an individual of one in a million per year, is 'broadly acceptable' to society.
- 163 Applying this to licensed nuclear 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'. We use this criterion to determine what is regarded as 'no danger' for the purposes of sections 3(12)(b) and 5(15)(a) of NIA 1965. Compliance with this criterion will normally mean that we can delicense the site, so removing it from regulatory control under NIA 1965.

Delicensing the whole site - methodology of inspection and assessment

- 164 Although the period of responsibility can survive the surrender or revocation of the licence, we anticipate that in most cases licensees will seek to achieve a state of 'no danger' as a precursor to delicensing. This will allow delicensing and the ending of the period of responsibility to be achieved simultaneously. Consideration of a licensee's case for demonstrating 'no danger' will follow our usual approach to making regulatory decisions involving assessment and inspection on a sample basis.
- 165 The licensee's delicensing application should be supported by an appropriate safety case setting out the details of work done 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; and
 - 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 we will be guided by our published guidance on the interpretation and implementation of the ‘no danger’ criterion^{ref.47} We will revoke the site security plan at the same time as the nuclear site licence is revoked.

Consultation

166 Section 5(2) of NIA 1965 requires that we consult the appropriate environment authority before revoking a nuclear site licence. The framework for this consultation is set out in the MoU between ourselves and the environmental regulators, the Environment Agency, Natural Resources Wales and the Scottish Environmental Protection Agency^{refs.36,37,38} We will write to the appropriate environment regulator at two stages seeking views on the proposed delicensing:

- a) immediately on receipt of the licensee's application. So the environmental regulator's comments can be taken into account by us when planning our inspection and assessment programme in relation to the application; and
- b) before implementing an in-principle decision to delicense the site, i.e. indicating that we intend to proceed and giving the relevant environment regulator an opportunity to comment.

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

167 There is no statutory requirement on us to consult anyone other than the environmental regulators in relation to an application for delicensing. We will decide the outcome of the application on the basis of our own reasoned assessment of the facts. However, we encourage 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 also encouraged to engage with appropriate stakeholders such as BEIS, the Scottish Government, the MoD (for defence-related sites), and other public bodies with duties or interests relating to the site.

Partial delicensing

168 Section 3(12) of NIA 1965 empowers us 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 also be applied to a partial delicensing, effected in the course of relicensing.

169 The licensee's demonstration of ‘no danger’ should follow the guidance in paragraph 162 above. In addition, the licensee's case for delicensing should provide the following:

- details of the revised site boundary, and a map to be attached 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 our 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 on it;
- implications for the emergency arrangements for the licensed site; and
- whether the organisational changes associated with the release of part of a licensed nuclear site require a submission under LC36⁷

170 Sections 3(13) and 3(14) of NIA 1965 require us to consult the Environment Agency, Natural Resources Wales and the Scottish Environmental Protection Agency (as appropriate) before varying a nuclear site licence. This applies if the variation relates to or affects the creation, accumulation or disposal of radioactive waste, within the meaning of the Environmental Permitting Regulations 2016 or the Environmental Authorisations (Scotland) Regulations 2018 (as the case may be). So, we will consult the relevant agency as described in paragraph 166 above.

171 We will normally grant the variation if the ‘no danger’ criterion is satisfied, and the other issues outlined above are resolved to our satisfaction. However, we may 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);
- the relevant environmental agency raised reasonable objections to the variation due to consultation under section 3(13) of NIA 1965.

172 We will publish the project assessment report on our website which led to the recommendation to grant a licence revocation or variation on the grounds of ‘no danger’. Further information is provided in our guidance ‘The Delicensing Process for Existing Licensed Nuclear Sites’^{ref.48}

Retention of records

173 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 incident which gave rise to the claim (section 15 of NIA 1965). Consequently, upon delicensing and / or the ending of the period of responsibility for all or part of a licensed site, the licensee must make arrangements for relevant records to be retained for at least that period.

⁷ LC 36 Organisational Capability

Annex 1: Regulatory powers available to ONR

1 Our enforcement powers under the TEA 2013 include:

Improvement Notice: TEA 2013 allows an inspector to serve a notice if the dutyholder 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: TEA 2013 allows 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 Our enforcement powers under HSWA include:

Improvement Notice: HSWA allows (section 21) 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: HSWA allows (section 22) 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 TEA 2013 and HSWA may lead to a criminal prosecution.

3 We also have powers under the NIA 1965, 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 Our enforcement powers under NISR 2003:

We have the powers under NISR 2003 to approve a security plan, its amendment or its revocation. We may also issue a direction to the responsible person under NISR 2003 when compliance against the security plan has failed to meet expectations. Non-compliance may lead to a prosecution. There are other powers within NISR

2003^{Ref 2} that include temporary security plans and the protection of nuclear transport and SNI.

- 5 In addition to general HSWA, TEA 2013 and NISR 2003 powers, we have powers under the licence conditions to require action from the licensee to bring improvements in safety. These regulatory actions are commonly known as 'primary powers'.

Primary powers

- 6 The licence conditions provide six primary powers comprising "Consent", "Approval", "Direction", "Notification", "Specification", and "Agreement". These 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 we may specify. For example, we normally specify 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 our consent.

Before being granted a consent, the licensee must satisfy us 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. This includes 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 we specify, the licensee is required to submit its arrangements etc. to us for approval. Once approved, the arrangements cannot be changed without our agreement, and the procedure itself must be done in accordance with the approved arrangements.

Directions: A direction is issued by us when we require the licensee to take a particular action. For example, LC31(1) gives us 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 us allows a licensee to proceed with an agreed course of action. For example, LC30⁸ enables us to agree the extension of a plant's operating period.

Notification: The standard LCs give us powers to request the submission of information by notifying the licensee of the requirement. For example, in LC21⁹(8) the licensee shall, if notified by us, submit a safety case and shall not start operation of the relevant plant or process without our consent.

⁸ LC30: "Periodic shutdown"

⁹ LC21: "Commissioning"

Specification - The standard licence gives us discretionary controls regarding a licensee's arrangements, and these are implemented through specifications. For example, in LC23¹⁰ if we specify, the licensee is required to refer operating rules to their nuclear safety committee for consideration.

Derived 'powers'

- 7 Some of the licence conditions require the licensee to "*make and implement adequate arrangements ...*" i.e. to meet the required legal standards. The arrangements are the licensee's responsibility. However, they may provide mechanisms for us to permission activities via licence instruments issued under powers 'derived' from the arrangements made by the licensee. Derived powers have no statutory basis - they are working level administrative arrangements put in place by a licensee as part of its LC compliance arrangements. Since licensee's arrangements may differ, the derived powers can be different between licensees. The most commonly used licence instruments issued under derived powers are:

Agreement: An agreement issued by us to permission a licensee, in accordance with the licensee's own arrangements, to proceed with a specified course of action. For example, LC22¹¹ 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 often state that for high category modifications which could, if inadequately conceived or executed, have serious nuclear safety implications. This class of modification can only be carried out with our agreement.

For many major activities, such as building new installations or complex modifications to existing plant, the project may be divided into stages. These stages have hold points which if required allow us to exert our regulatory control by explicitly agreeing before the next stage can start. Although there are primary powers which provide for such staged regulatory control by consent, there are situations where it is more proportionate to use the derived power of agreement.

Acknowledgement: An acknowledgement issued by us informs the licensee, in accordance with the licensee's own arrangements, that we will either take no further formal action on an issue or notify them that we intend to examine the licensee's proposals for ensuring safety. For example, under LC22 the licensee's arrangements will often require them to submit safety case documentation related to the more safety significant modifications. In these cases, we may consider the modification of such safety significance that we need to examine the proposal. If so, we will acknowledge receipt and notify the licensee of our intention to examine the safety documentation for the modification, either at this or at a later stage. However, we may consider the modification does not warrant further examination and simply acknowledge

¹⁰ LC23: "Operating rules"

¹¹ LC22: "Modification or experiment on existing plant"

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 specifying. In accordance with the licensee's own arrangements, that our 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 when we consider that enhanced regulatory monitoring and control of the proposal is required.

Flexible permissioning

- 8 Flexible permissioning^{ref.49} has been employed extensively by us to control certain activities at nuclear installations. There are two approaches:
- a) 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.
 - b) 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, we 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 licensees' activities. Nor does it affect the powers that our inspectors have under the HSWA or TEA 2013 which they may be used at any stage should it be judged necessary.

Our guidance to inspectors on flexible permissioning is available on the website^{Ref 49}

Annex 2: The role and duties of the Nuclear Decommissioning Authority

- 1 The Nuclear Decommissioning Authority (NDA) is a non-departmental public body created through the Energy Act 2004 (EA 2004). The NDA has a responsibility to safely and efficiently decommission and clean up the UK's nuclear legacy sites to get them ready for their next use. The NDA estate comprises 17 licensed nuclear sites in Great Britain, which are formally designated to it by the SoS for BEIS. So, it is important to understand the NDA's role and legal duties.
- 2 Section 3 of the EA 2004 lists the NDA's principal functions. Among these the NDA is given responsibility for securing the operation and decommissioning of designated nuclear installations and the cleaning up of these sites. Also, where the NDA is given responsibility for securing the operation of an installation or facility, a direction from the SoS for BEIS may also give them additional responsibilities in relation to the management of the site where that installation or facility is situated. Legally the NDA can hold nuclear site licences as it has responsibility for the operation and decommissioning of prescribed nuclear installations. However, under the operating model for the NDA it was agreed by government that they should not have day-to-day control of nuclear related operations on these sites. Instead, NDA meets its statutory obligations under the EA 2004 by sub-contracting the work to other organisations, collectively known as Site Licence Companies (SLCs). The SLCs are subject to the duties imposed by TEA 2013, NIA 1965, HSWA, and the relevant regulations and statutory provisions of these Acts.
- 3 The NDA generally owns sites designated to it, and the SLCs that undertake the decommissioning work on these sites. The NDA may transfer ownership of an SLC to another organisation, for a specific period of time by means of a contract termed the parent body organisation (PBO) model. The NDA does not currently employ PBOs and its SLCs are wholly owned subsidiaries.
- 4 The SLCs have a legal duty imposed on them by us, under LC36, to provide and maintain sufficient financial resources to ensure safe operations on the site. The financial resources required to ensure safe operations on these sites are almost exclusively obtained through NDA funding. So, if the SLC is unable to comply with LC36, it is highly likely that the NDA will be called on to meet any shortfall in funding that is not covered by agreed funding limits for that year.
- 5 As an employer conducting an undertaking the NDA has certain duties imposed on it by the HSWA. This applies both to its employees (s. 2 HSWA) and to persons who are not its employees but may be affected by its undertaking (s. 3 and 4 HSWA). Principally these duties are to conduct the undertaking in such a way as to ensure, so far as is reasonably practicable, that persons who may be affected are not exposed to undue risks to their health or safety.
- 6 The extent of an employer's duties under s.3 of HSWA, was explored by the House of Lords in *Regina v Associated Octel* (1996)^{ref.50} a case relevant to the NDA's relationship with its SLCs. In this case the court held that whether or not 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 employs employees or engages

independent contractors to carry out the work, or if control is exercised over the activity. So, if the work itself is part of the NDA undertaking, a duty may be owed under s. 3(1) of HSWA to ensure that it is done without undue risk – subject to reasonable practicability. What is reasonably practicable will be determined on a case-by-case basis.

- 7 Hence it is legitimate for the NDA to exercise a degree of direction and oversight over its SLCs. However, the extent of that oversight and direction is a matter for the NDA to determine. It is evident that the more involved the NDA becomes in the way a site is managed the more that will be expected of it to meet its legal duties relating to the site. It is worth noting that in the absence of a PBO, the NDA has representation on the SLC Board. The SLCs control, supervise and carry out the day-to-day nuclear related operations on the sites, and ultimate responsibility for nuclear safety, security and safeguards rests with the SLC who holds the nuclear site licence. The SLC must have the necessary skills and resources to satisfy the nuclear safety, security and environmental regulators that it is able to discharge its regulatory obligations. The SLC, and not its shareholder, and the NDA, must determine how safety, security, safeguards and environmental performance are managed.
- 8 The NDA also owns a non-licensed nuclear site adjoining Dounreay which is designated as an 'authorised' site by the MoD. This site remains subject to the requirements of the relevant statutory provisions of HSWA. However, it is exempt from licensing as the MoD is deemed to be in day-to-day control of operations, and as a crown body, is not subject to the requirements of the NIA 1965.
- 9 Activities on the NDA licensed sites result in the accumulation of radioactive wastes that have no final disposal route; these legacy and operational wastes are all owned by the NDA. As such, interim safe storage is controlled by the licensee. However, the liability to condition and package any highly active waste (HAW) for final disposal is for the NDA to fund. These liabilities, although not specifically included in the NDA contracts, have the potential to bear upon the NDA as an employer and as the fundholder for dealing with its legacies on these sites.
- 10 It is government policy (in England and Wales) to ultimately dispose of HAW and spent fuel by means of geological disposal. The NDA has chosen that its HAW packaging will follow a disposability assessment process (also known as the 'letter of compliance' (LOC) process). This process is administered by Radioactive Waste Management Ltd (RWM), a wholly owned subsidiary of the NDA. RWM is the organisation tasked with preparing for the design, construction and operation of a GDF, when a suitable site is identified. The policy also states that a future GDF will be subject to the requirements of the site licensing regime.
- 11 The NDA also has significant undertakings related to the transport of radioactive materials to and from licensed sites and abroad through its wholly owned subsidiary Nuclear Transport Solutions (NTS). This organisation also has its own legal identity and governing board although an NDA appointed director chairs the NTS board. We are the GB Competent Authority, issuing package approvals (akin to a licence) and regulate NTS in respect of safe and secure transport of radioactive materials. These are identified as Class 7 goods under the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDGR).

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; and
 - 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 events on a site. If a nuclear new build site is defined, the boundary may be shown on the site map. Applicants considering using GPS data to define the site boundary may find it helpful to refer to guidance on the ordnance survey website^{ref.51}
- 4 Copies of nuclear site licences are provided to BEIS. The maps attached to the licences may be used by BEIS to fulfil its obligation (see NIA 1965, section 6) to maintain a publicly available list of licensed nuclear sites. This includes a map(s) showing the position and limits of each site. 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 us on this point (or the MoD for defence-related sites).

Delicensed areas

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 NIA 1965, section 15). So, 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 NIA 1965 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.

Annex 4: Licensing and regulating a future geological disposal facility

- 1 A GDF is an engineered repository designed for the final disposal of higher activity radioactive waste deep underground in a stable geological environment, providing a long-term isolation of radionuclides from the biosphere. The act of disposal of radioactive waste on or from a licensed nuclear site is regulated, in England and Wales, by the environmental agencies under the Environmental Permitting Regulations 2016.
- 2 However, when considering the high hazard inventory of a GDF, international standards and relevant good practice, the government considers that regulation under the GB licensing regime is appropriate. So, the intention is to prescribe a GDF, so that it comes under the scope of NIA 1965, and the requirements of a nuclear site licence during the construction and operational phases of its lifecycle.

Site selection

- 3 A GDF and the associated deep boreholes for site characterisation have been designated a nationally significant infrastructure project¹². The developer of a future GDF will undertake a consent-based site selection process in England and Wales¹³, in accordance with government policy regarding planning for a GDF¹⁴. We have no formal role in decisions which lead to the selection of a suitable site. However, the developer for a future GDF will have to demonstrate to us that the facility will be safe and secure by providing a safety case prior to the granting of a nuclear site licence.
- 4 We consider that it would not be appropriate to apply demographic siting criteria for the assessment of a potential site for a GDF. This is due to the limited radiological accident potential presented by a GDF when compared to new nuclear power stations, to which siting criteria have been applied.

Facility design

- 5 Similar to the assessment of new reactor designs, prior to licensing and environmental permitting ourselves and the Environment Agency have established agreements with Radioactive Waste Management Ltd. (RWM), the developer of a GDF. These agreements provide pre-application advice and scrutiny on matters within their respective regulatory remits. The advice provided is aimed at ensuring that a GDF is designed to meet high standards for safety, security, environmental protection and radioactive waste transportation.

Latest point of licensing

- 6 A nuclear site licence is granted to a corporate body before it can undertake construction work that could, if inadequately conceived or executed, affect nuclear

¹² The infrastructure Planning (Radioactive Waste Geological Disposal) Order 2015

¹³ Implementing Geological Disposal – Government White Paper, 2014

¹⁴ National Policy Statement for radioactive waste Geological Disposal Facilities

safety when the plant is operational. For a GDF, we consider the latest point at which a licence must be in force is the start of underground excavations for its construction, including access tunnels and/or shafts.

- 7 Deep investigation boreholes for the purpose of characterising the site will not be subject to nuclear licensing. However, they will be subject to health and safety regulation by the relevant enforcing authority prior to a site licence coming into force.

Licensing process

- 8 The process for obtaining a nuclear site licence for a future GDF will be the same as set out in Section 2. The prospective licensee will have to demonstrate it is an organisation capable of holding a site licence and discharging the duties conferred by the licence. This includes submitting an application dossier in accordance with paragraph 77.
- 9 The licensee will be required to satisfy our expectations regarding the assessment of emergency preparedness and response, in addition to meeting the requirements, if applicable, of REPP19.
- 10 In addition to the safe handling of all waste sentenced for disposal to a GDF, the licensee will be required to manage radioactive wastes generated on the site. The licensee must also provide adequate decommissioning strategies, plans and programmes for the closure of the GDF.
- 11 Security of a GDF will be subject to regulation under the relevant statutory provisions as for any other licensed nuclear site, and the licence applicant must satisfy our expectations as set out in paragraphs 102 and 103.
- 12 The nuclear material accountancy, control and safeguards arrangements of a GDF will be subject to regulation under the relevant statutory provisions as for any other licensed nuclear site. The licence applicant must satisfy our expectations as set out in paragraph 104. We will ensure that the UK's international Safeguards obligations are met in relation to nuclear material disposed of at the GDF.

Defining the site boundary

- 13 On an existing licensed nuclear site, the boundary marked on the site map is deemed to extend vertically downwards to bring any subsurface structures or radioactive materials in the ground within the scope of the requirements of the licence. The extent of the underground excavated space within a GDF is almost certainly going to extend beyond a downward vertical projection of any area mapped out for GDF surface needs. This challenges the current interpretation of the nuclear site boundary projecting vertically downwards. So, it will be necessary for the site licence to clearly define the sub-surface extent of the GDF using 3-dimensional coordinates or mapping; so ensuring the site encompasses all licensable activities and underground workings that may affect safety.

Regulation under the licence

- 14 Once a nuclear site licence has been granted, the licensee must comply with all the relevant statutory provisions and any conditions attached to the licence. Due to the unique nature of the facility, some amendments to the standard LCs may be necessary. Paragraphs 119 to 136 give further information on our expectations for regulating nuclear facilities under the licence.

Delicensing

- 15 We consider that once a GDF has closed there will effectively cease to be an operational risk to the safety of workers or the public that requires regulation under a nuclear site licence. Although a GDF will hold a significant inventory of radioactive waste, its purpose is to safely dispose of that waste by isolation from the surface environment and the population.
- 16 Demonstration that the facility has been designed, constructed and operated to meet the requirements and standards for post-closure safety which should enable the licensee to show that there ceases to be any danger from the waste disposed of at the facility. Post-closure safety will be regulated by the relevant environment agency.

Retention of records

- 17 We expect licensees to have arrangements for the retention of appropriate operational records to ensure sufficient information is available to support the management of the facility over its lifetime. It is forecast that the period for construction, waste emplacement, and ultimate closure of a GDF will extend beyond 100 years; decades longer than any other operational facility. So, the licensee should ensure that the extended timescales for a GDF are properly considered when determining its record retention schedule and means of record retrieval.

Justification of practices involving ionising radiation

- 18 Waste management and disposal operations are an integral part of the practice that generates the waste and it is inappropriate to regard them as stand-alone practices that require their own justification¹⁵. So, a licence application for a GDF would not be required to provide justification under the Justification of Practices Involving Ionising Radiation Regulations 2004.

¹⁵ The Justification of Practices Involving Ionising Radiation Regulations 2004: Guidance on their application and administration. June 2015

Annex 5: Advanced nuclear innovation (small modular reactors and nuclear fusion)

Small modular reactors (SMRs)

- 1 SMRs are usually based on proven water-cooled reactor designs, but on a reduced scale with electrical power outputs less than 300 Mw. SMRs are called modular reactors because they can be manufactured in factories and transported to site for installation. There is currently no legal definition of an SMR and NIA 1965 does not contain any specific provisions for them. The UK regulatory approach to SMRs has not been decided at the time of writing this document. The UK Government has committed to opening the GDA process to SMR technologies in 2021. The government has also created an advanced nuclear fund, aiming to develop an SMR design by 2030.

Nuclear fusion

- 2 The UK Government has committed over £400 million to nuclear fusion programmes. The aim is to produce a commercially viable fusion power plant by 2040. Fusion reactors are not prescribed installations for the purposes of NIA 1965. However, government policy for the regulation of fusion reactors has not been determined at the time of writing this document.

References

- 1 [Technical assessment guide for inspectors ONR Guidance on the demonstration of ALARP NS-TAST-GD-005 Rev 6 September 2013](http://www.onr.org.uk/operational/tech_asst_guides/ns-tast-gd-005.pdf)
http://www.onr.org.uk/operational/tech_asst_guides/ns-tast-gd-005.pdf
- 2 CNSS and regulation of civil nuclear security <http://www.onr.org.uk/cnss/index.htm>
- 3 Nuclear safeguards (EU Exit) regulations 2019
[The Nuclear Safeguards \(EU Exit\) Regulations 2019 \(legislation.gov.uk\)](https://www.legislation.gov.uk/ukdsi/2019/1231000000000001/eng/full/text.html)
- 4 ONR Nuclear Material Accountancy, Control and Safeguards Assessment Principles
<https://www.onr.org.uk/operational/other/onr-cnss-man-001.pdf>
- 5 Nuclear safeguards <http://www.onr.org.uk/safeguards/>
- 6 Ionising Radiations Regulations 2017 (IRR17)
<http://www.hse.gov.uk/radiation/ionising/index.htm>
- 7 Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999 (EIADR 99) <http://www.onr.org.uk/eiadr.htm>
- 8 Guidance relating to the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR) <http://www.hse.gov.uk/radiation/ionising/reppir.htm>
- 9 The Construction, Design and Management Regulations 2015 (CDM 2015)
<http://www.hse.gov.uk/construction/cdm/2015/index.htm>
- 10 A register of companies holding nuclear site licences with details of their sites is available at <http://www.onr.org.uk/licensees/pubregister.pdf>
- 11 The standard nuclear site licence conditions <http://www.onr.org.uk/silicon.pdf>
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- 13 Safety assessment principles for nuclear facilities ONR 2014 (Revision 1)
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Glossary

ACoP	approved code of practice
ALARP	as low as reasonably practicable
ANTs	advanced nuclear technologies
AWE	Atomic Weapons Establishment
CDG 2009	The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (as amended)
CDM 2015	The Construction (Design and Management) Regulations 2015
CNSS	ONR Civil Nuclear Security and Safeguards Division
COMAH	Control of Major Accident Hazards Regulations 2015
DAC	design acceptance confirmation
BEIS	Department for Business, Energy and Industrial Strategy
DSEAR	Dangerous Substances and Explosive Atmospheres Regulations 2002
EC	European Commission
EIADR	The Nuclear Reactors (Environmental Impact Assessment Decommissioning) (Amendment) Regulations 2018
EU	European Union
Euratom	The European Atomic Energy Community
FDP	funded decommissioning programme
GB	Great Britain
GDA	The Generic Design Assessment process
GDF	geological disposal facility
HSE	The Health and Safety Executive
HSWA	Health and Safety at Work etc. Act 1974
IAEA	United Nations' International Atomic Energy Agency
IRR 17	The Ionising Radiations Regulations 2017
LC	licence condition
LLWR	Low Level Waste Repository
MCA	Maritime and Coastguard Agency
MHSW	management of Health and Safety at Work Regulations 1999
MoD	Ministry of Defence
NDA	Nuclear Decommissioning Authority
NIA 1965	Nuclear Installations Act 1965
NISR	Nuclear Industries Security Regulations 2003
NM	nuclear material
NEPLG	UK Nuclear Emergency Planning Liaison Group

NRW	Natural Resources Wales
NSL	nuclear site licence
NSR 19	Nuclear Safeguards (EU Exit) Regulations 2019
OECD	Organisation for Economic Co-operation and Development
ONMACS	ONR Nuclear Material Accountancy, Control and Safeguards guidance
ONR	Office for Nuclear Regulation
ORM	other radioactive material
PBO	parent body organisation
PCmSR	pre-commissioning safety report
PCSR	pre-construction safety case report
POSR	pre-operational safety report (i.e. installation safety report)
R2P2	'Reducing risks, protecting people' document
REPIR19	The Radiation (Emergency Preparedness and Public Information) Regulations 2019
RMT	Radioactive Materials Transport Team
RWM	Radioactive Waste Management Limited
SAPs	Safety Assessment Principles for Nuclear Facilities
SEPA	Scottish Environment Protection Agency
SJR	site justification report
SLC	site licence company
SMP	safety management prospectus
SMRs	small modular reactors
SNI	sensitive nuclear material
SoS	The Secretary of State for
SSA	Strategic Siting Assessment
SyAPs	Security Assessment Principles
TAGs	technical assessment guides
TEA 2013	The Energy Act 2013

ONR copyright: Licensing nuclear installations

This guide provides an overview of the nuclear regulatory regime and the processes for licensing and de-licensing nuclear sites. It is published on our website at www.onr.org.uk

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