Office for Nuclear Regulation
An agency of HSE

Licensing Nuclear Installations

This guide provides an overview of the nuclear regulatory regime and the processes for licensing and delicensing nuclear sites. It replaces the HSE publication *The licensing of nuclear installations* issued in March 2007. This replacement document is published on the Office for Nuclear Regulation's website only at www.hse.gov.uk/nuclear.

Contents

List of abbreviations

ALARP	As low as reasonably practicable
AWE	Atomic Weapons Establishment
CDG 2009	The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (as amended)
CNS	Civil Nuclear Security
COMAH	Control of Major Accident Hazards Regulations1999
DECC	Department for Energy and Climate Change
DSEAR	Dangerous Substances and Explosive Atmospheres Regulations 2002
EA	The Environment Agency for England and Wales
EU	European Union
Euratom	The European Atomic Energy Community
GDA	Generic Design Assessment
GDF	Geological Disposal Facility
HSE	Health and Safety Executive
HSW Act	Health and Safety at Work etc Act 1974
IAEA	United Nations' International Atomic Energy Agency
LC	Licence Condition
MoD	Ministry of Defence
NDA	Nuclear Decommissioning Authority
NEPLG	Nuclear Emergency Planning Liaison Group
NIA65	The Nuclear Installations Act 1965
NISR	Nuclear Industries Security Regulations 2003
OECD	Organisation for Economic Co-operation and Development
ONR	Office for Nuclear Regulation
PBO	Parent body organisation
PCmSR	Pre-commissioning safety report
PCSR	Pre-construction safety report
POSR	Pre-operational safety report
R2P2	Reducing risks, protecting people
REPPIR	Radiation (Emergency Preparedness and Public Information) Regulations 2001
RMT	Radioactive Materials Transport Team
SAPs	Safety Assessment Principles for Nuclear Facilities
SEPA	The Scottish Environment Protection Agency
SLC	Site licence company
SMP	Safety management prospectus
TAGs	Technical Assessment Guides
WENRA	Western European Nuclear Regulators' Association

Foreword

The Office for Nuclear Regulation (ONR) is Britain's independent regulator for safety and security at nuclear facilities and for the transport of nuclear materials. Our mission is to secure the protection of people and society from the hazards of the nuclear industry. We are committed to ensuring that the nuclear industry controls its hazards effectively and has a culture of continual improvement and sustained excellence. We discharge our regulatory functions through applying a rigorous "permissioning regime" which requires organisations wishing to carry out prescribed nuclear activities to apply for, and be granted, a nuclear site licence before they start construction of nuclear safety-related plant. The licence holder must then comply with conditions that are attached to the licence, and their compliance is enforced by ONR.

This document provides guidance on the licensing process and the factors that ONR may take into account when reviewing a licence application. A prospective licensee should be aware that the granting of a nuclear site licence is a significant step but is not itself permission to start nuclear-related construction. That requires a regulatory permission under a licence condition, which is based on a substantial pre-construction safety case. But before a licence is granted, ONR needs to be satisfied that the applicant's choice of site is suitable, that it understands the hazards and risks of the activities that it proposes to carry out, and that it has a sufficient outline site safety case to manage these risks and protect people and society. We also emphasise the need to gain confidence that the applicant has the organisational capability to lead and manage for safety effectively. This means that we must be satisfied with the applicant's governance arrangements, resources, competencies and management processes before we will consider granting a licence.

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

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Preface

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

This publication refers to the Health and Safety Executive and some of its branches which are responsible for the development and implementation of the regulatory regime, as follows:

The Health and Safety Executive (the **Executive** or **HSE**) was established by the Health and Safety at Work etc Act 1974 (HSW Act). HSE's primary function is to make arrangements to secure the health, safety and welfare of persons at work, and the public, in the way that undertakings are conducted. This includes developing health and safety policy, proposing new law and standards, conducting research, inspecting the premises of dutyholders, enforcing health and safety legislation, investigating work-related accidents and complaints, and providing information, guidance and advice on health and safety matters. HSE reports to the Secretary of State for Work and Pensions, though it may report on specific matters to other Secretaries of State as appropriate. HSE is the licensing authority for nuclear installations and advises the Secretary of State for Energy and Climate Change on nuclear matters.

The Office for Nuclear Regulation (**ONR**) is an agency of HSE. Its mission is: "securing the protection of people and society from the hazards of the nuclear industry". ONR brings together the regulatory functions for safety, security, safeguards, radioactive materials transport and conventional health and safety at nuclear sites.

Legal position 2012

Powers to license and regulate nuclear licensed sites rest with HSE by virtue of NIA65. Licensing and regulatory functions are administered on HSE's behalf by ONR. When ONR is established as a statutory corporation, licensing and regulatory powers will be transferred. Throughout this publication ONR is used for the sake of simplicity but readers should be aware that this may be used in places as shorthand for HSE / ONR.

Section 1: The law and the regulatory regime

The Health and Safety at Work etc Act

1 The operators of nuclear facilities in Great Britain,* like their counterparts in other industries and places of work in general, are required to comply with the Health and Safety at Work etc Act 1974 (HSW Act) and its relevant statutory provisions. The HSW Act places a fundamental duty on employers to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all their employees. It also imposes a duty on employers to ensure, so far as is reasonably practicable, that persons not in their employment are not exposed to risks to their health or safety as a result of the activities undertaken.

2 HSE's approach to enforcement of the HSW Act's requirements is governed by the principles of **proportionality** in applying the law and securing compliance; **consistency** of approach; **targeting** of enforcement action; **transparency** about how the enforcing authorities operate and what those regulated may expect; and **accountability** for its actions. These principles apply both to enforcement in particular cases and to the management of enforcement activities as a whole: further details of HSE's policy are provided in HSE's *Enforcement Policy Statement*.[1] In addition, HSE must also have regard for the provisions of the *Regulators' Compliance Code*.[2] The code applies when regulators determine their general policies or principles about how they exercise their regulatory functions and when they set standards or give general guidance. It does not apply to individual enforcement decisions.

3 HSE has a range of tools at its disposal to help secure compliance with health and safety law, enabling it to take a proportionate approach in each case. Inspections and investigations are undertaken to gather information, and inspectors may offer dutyholders guidance and advice, both face-to-face and in writing. This could include warning a dutyholder that, in the opinion of the HSE inspector, it is failing to comply with the law. Where appropriate, inspectors may serve Improvement and Prohibition Notices, withdraw approvals, take action under the conditions attached to certain types of licences, or prosecute.

* **Separate, but similar, legislation applies in Northern Ireland and is enforced by Northern Ireland authorities.**

Reducing risk and the ALARP principle

4 In determining whether any measures are necessary to reduce risk and achieve compliance with the HSW Act, employers should compare the sacrifice involved, whether in money, time or trouble, and the risk which would be averted by their implementation. Such measures should be implemented unless the sacrifice is grossly disproportionate to the risk which would be averted. In short, risks must be reduced so far as is reasonably practicable, which is generally termed "as low as reasonably practicable" – the ALARP principle. This concept and the general approach to the regulation of safety risks in the UK is explained in HSE's publication *Reducing risks, protecting people*,[3] also known as R2P2, which is based on the earlier HSE publication *The tolerability of risks from nuclear power stations*.[4] It is further developed in HSE's ALARP suite of guidance[5] and supplemented by ONR's guidance to its inspectors.[6]

The Nuclear Installations Act 1965

5 Relevant parts of the nuclear industry must also comply with the Nuclear Installations Act 1965 (NIA65) 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 may be prescribed. Currently the latter are prescribed via the Nuclear Installations Regulations 1971 (SI 1971/381). In this guide references to "nuclear installations" relate to those installations for which a licence is required under NIA65 to install or operate them.

(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 towards third parties for certain kinds of damage caused by nuclear matter on, or coming from, their sites.

6 The licensing function is administered on HSE's behalf by the Office for Nuclear Regulation (ONR). The other two are the responsibility of the Secretary of State for Energy and Climate Change for sites in England and Wales, and Scottish Ministers for Scotland. Taking each function in turn:

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

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

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

The nuclear site licence

7 The safety of nuclear installations in Great Britain is secured primarily through the nuclear site licence and the conditions attached to it (see below). Any organisation wanting to install or operate a prescribed nuclear installation will need a nuclear site licence. A nuclear site licence is granted for an indefinite period and, providing there are no material changes to the basis on which the licence was granted, it can cover the entire lifecycle of a site from installation and commissioning through operation and decommissioning to site clearance and remediation.

8 NIA65 provides for a nuclear site licence to be granted to a named corporate body to install or operate specified nuclear installations in a defined location. Therefore, the three key themes ONR addresses in assessing a licence application are:

- the capability, organisation and resources of the applicant corporate body;
- the nature of the prescribed activities and the relevant safety case;
- the nature and location of the site.

A register of extant nuclear site licences is available on the ONR website.[7]

9 A licence is not transferable, but a replacement licence may be granted to another corporate body if that body demonstrates it is fit to hold a licence. Other circumstances which may lead to the need to relicense a site include changes to the site boundary and changes to the types of prescribed activity for which the site is licensed. In considering an application for a replacement licence ONR would take a proportionate approach and focus particularly on those aspects of the licensing basis which are the subject of the change.

10 Each nuclear site licence is unique to its site. It may be varied by ONR to exclude any part of the site which the licensee no longer needs for licensable activities. Before granting such a Variation, ONR is required by NIA65, section 3(6), 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).

11 A licence may be revoked by ONR or surrendered by the licensee. However, depending upon the circumstances, the licensee may be required to retain certain responsibilities for the site. This "period of responsibility" is ended only when a new licence has been granted for the site or ONR has given written notice that in its opinion there has ceased to be any danger from ionising radiations from anything on the site. Before such a notice is issued ONR needs to be satisfied that the site has been decommissioned and adequately decontaminated (see Section 4 of this guide).

Licensable activities (prescribed activities)

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

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

Consequently, the licensing regime encompasses research reactors, fuel manufacturing and isotope production facilities, fuel reprocessing and the bulk storage of certain types of radioactive materials as well as nuclear power stations.

13 Other types of installation may be prescribed from time to time. For example, the Government has declared an expectation that any future geological disposal facility would be licensed. Prospective nuclear operators should familiarise themselves with the provisions of the Nuclear Installations Act 1965 and the associated Nuclear Installations Regulations but enquiries regarding the prescribed status of a proposed installation or activity can be made to HM Chief Inspector of Nuclear Installations at Redgrave Court, Merton Road, Bootle, Merseyside L20 7HS.

Licence conditions

14 NIA65 requires ONR to attach to each nuclear site licence such conditions as it considers necessary or desirable in the interests of safety or with respect to the handling, treatment and disposal of nuclear matter. The licence and licence conditions apply at all times throughout the life of a licensed nuclear site and therefore cover design, construction, commissioning, operation, maintenance, modifications, decommissioning etc. NIA65 empowers ONR to add, vary or revoke conditions at any time allowing ONR the flexibility, if it considers it necessary, to tailor the requirements placed on the licensee to specific circumstances and the phase of the installation's life.

15 In the main, the licence conditions require the licensee to make and implement adequate arrangements to address the matters identified. Each licensee can develop licence condition compliance arrangements which best suit its business whilst demonstrating that safety is being managed properly. Similarly, the arrangements made to comply with them may change as the plant progresses through its life from initial design to final decommissioning.

16 The licence conditions provide the basis for regulation by ONR. They do not relieve the licensee of the responsibility for safety. They are generally non-prescriptive and set goals which the licensee is responsible for meeting, amongst other things by applying detailed safety standards and safe procedures. The arrangements which a licensee develops to meet the requirements of the licence conditions constitute elements of a safety management system. ONR reviews the licensee's licence condition compliance arrangements to ensure they are clear and unambiguous and address the main safety issues adequately. Procedures which comply with nuclear site licence conditions are likely to satisfy the requirements of other health and safety legislation under the HSW Act which relate to nuclear hazards, for example the Management of Heath and Safety at Work Regulations 1999. However, compliance with these other requirements must still be demonstrated.

Operational methods

17 The nuclear licensing function is delegated by HSE to ONR which therefore is responsible for granting licences and attaching appropriate conditions. ONR

also makes judgements on the acceptability of licensees' responses to the requirements of those conditions.

18 Nuclear safety inspectors are appointed under the HSW Act. They enforce the relevant requirements of NIA65 (including the licence conditions) and other health and safety legislation relevant to nuclear and radiological safety issues at licensed nuclear sites. Non-nuclear health and safety aspects are also monitored and regulated either by inspectors from ONR or by inspectors drawn from other parts of HSE. Inspectors' activities include prior assessment of the safety of proposed nuclear facility designs and operational regimes; assessment of the competence and capability of the licensee's organisation; inspection of the implementation of the licensee's licence condition compliance arrangements; and investigation of incidents and complaints.

Assessment

19 Under the licence conditions, arrangements and actions by the licensee having significance for nuclear safety are subject to expert assessment by ONR and may require prior regulatory permission before work commences or changes are implemented. The nuclear regulatory regime is therefore described as a permissioning regime. HSE's policy statement *Our approach to permissioning regimes*, which is available on HSE's website[9] explains the regulatory philosophy within which the nuclear licensing regime is operated.

20 Assessment is the process by which ONR's assessors, who are inspectors and technical experts in specific fields, establish whether a licensee has demonstrated that it understands the hazards associated with its activities and how to control them adequately. This is based, amongst other things, on the licensee's safety case. The technical principles which ONR uses to judge a licensee's safety case are expressed in ONR's Safety Assessment Principles for Nuclear Facilities (SAPs). They are developed further in a series of internal guides to inspectors – Technical Assessment Guides (TAGs). The SAPs and TAGs are available on the ONR website.[10,11]

The safety case

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

demonstrations of safety provided. Accordingly, the requirements to produce and maintain safety cases are embodied in the conditions attached to all nuclear site licences. Guidance on ONR's expectations of the scope and content of safety cases is available on the ONR website.[12]

22 Each licensee is required, by Licence Condition 15, to make and implement adequate arrangements for the periodic and systematic review of safety cases. ONR assesses the major periodic safety reviews and, in order to permit continued operation, needs to be satisfied that the facility continues to meet its original design standards; that the licensee has implemented all reasonably practicable modifications to close any gaps between those standards and modern standards; and that there are robust measures in place to manage any safety-related ageing mechanisms in order to permit continued operation. If satisfied on all these aspects, ONR consents to continued operation of the facility subject to continuing monitoring and inspections not revealing any new information that undermines the safety case.

Inspection

23 Nuclear licensed sites are subject to a high level of inspection with one or more site inspectors being allocated to major sites. A site inspector typically spends around 30% of his or her available time at site, the balance of time being committed to reviewing the licensee's justifications of safety with other site inspectors and with technical assessors, and administering the nuclear site licence for the site. inspectors also seek to advise and encourage licensees to enhance nuclear safety where this is consistent with the ALARP principle.

24 The scope of inspections at site and at the licensee's corporate headquarters and elsewhere includes:

- reviewing implementation of the licensee's arrangements for managing nuclear safety, covering:
  - corporate governance and organisational structures;
  - the maintenance of a capable organisation with suitable staffing resources and competences to deliver nuclear safety;
  - in-house nuclear safety assurance, including access to expert advice, internal inspection and a "challenge" culture;
  - evidence of learning from events and experience, both from within and outside the organisation;
  - effective implementation of appropriate change management arrangements;
- monitoring compliance with the conditions attached to the nuclear site licence;
- observing the condition of the plant and verifying that it is being operated within the limits set by the safety case.

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

25 Additionally, ONR undertakes team inspections on particular topics. These may be regular events, such as witnessing the annual demonstration emergency exercise for a site, or special inspections on a selected aspect of safety. Team inspections typically involve a mixture of site inspectors and technical assessors.

26 All inspection and assessment is done on a sampling basis. The size and scope of the sample is determined by factors such as the potential hazard of the activity, the findings from initial examinations, the novelty and complexity of proposed changes, the maturity of the organisation and ONR's knowledge of the licensee's safety performance history. This reflects the normal regulatory practice of targeting and proportionality, whilst retaining the basic principle that safety is the responsibility of the licensee. It depends for its success on an independent, suitably qualified and experienced inspectorate; on the quality of information supplied by the licensee; and on the readiness of the licensee to report to ONR matters which have safety significance.

Regulatory controls

27 ONR's regulatory powers are employed in accordance with HSE's *Enforcement policy statement*.[1] In exercising its licensing function ONR makes use of a number of controls derived from NIA65 and the licence conditions. These enable ONR to:

- grant a licence to an applicant;
- attach conditions to the licence, and to vary or revoke those conditions;
- vary a licence, to reduce the area of the licensed site;
- consent to particular actions, usually to the commencement of a given activity;
- approve particular arrangements or documents, generally to "freeze" them so they cannot be changed without ONR agreement;
- notify the licensee that it requires certain information to be submitted, for example a safety case;
- issue specifications to require the submission of particular documents for examination, or specify that something must be done in a particular way, for example a form of waste material;
- issue agreements to permission variations to certain of the licensee's procedures;
- direct the licensee to shut down particular operations;
- revoke a nuclear site licence.

28 The first three of these are comparatively infrequent events, as are the last two. Most of the remainder are likely to be much more frequent, and generally reflect the rate of change on the site. They result from requests from, or applications made by, a licensee (or prospective licensee). In general they will have been signalled to ONR in advance of the formal request, and will often be the subject of considerable discussion, during which the views of each side will be well aired, before ONR exercises its powers.

29 In addition, a licensee's licence condition compliance arrangements may provide mechanisms for ONR to permission activities via licence instruments issued under powers derived from the arrangements themselves. Since licensees' arrangements can differ these "derived powers" may vary from licensee to licensee. Licence instruments issued under derived powers consist of agreements, acknowledgements and specifications.

30 ONR may from time to time reject or refuse a licensee's formal application or submission. On occasion ONR may deem it necessary to call on its power to issue a Direction to shut down particular operations for safety reasons. ONR inspectors may also use their enforcement powers under the HSW Act to issue Prohibition and Improvement Notices and to prosecute for breaches of that Act or the relevant statutory provisions (including the relevant statutory provisions of NIA65). Breaches of the licence conditions are offences for which the licensee, and any other person having duties upon the site by whom the breach was committed, may be prosecuted. ONR's enforcement powers are summarised in Annex 1.

Appeals

31 Nuclear site licensees, like all dutyholders under the HSW Act, have the right of appeal to an employment tribunal in respect of Improvement and Prohibition Notices issued to them. However, the appeals process in section 44 of the HSW Act does not apply in relation to licensing decisions made by ONR under NIA65. This reflects the nature of the hazard being regulated and the particularly complex technical arguments that underpin most key licensing decisions. A licensee who is dissatisfied with a particular licensing decision may still raise concerns with the site inspector and the relevant management in ONR. Although HM Chief Inspector of Nuclear Installations is the final arbiter of licensing decisions, a licensee may seek a review by HSE of the process by which a licensing decision was reached.

Regulatory costs

32 Section 24A of NIA65 enables ONR to recover costs from licensees and licence applicants for expenses associated with its nuclear site licensing and inspection work. The total costs are distributed between licensees and licence applicants

in proportion to the amount of staff time applied to their sites or applications. Charges may also cover the costs of research and of nuclear safety studies commissioned to assist ONR and ensure that it has access to independent technical advice and information. Such costs are allocated to licensees according to the nature of the work done under each contract.

33 ONR uses The Health and Safety (Fees) Regulations 2010[13] made under the HSW Act to recover the costs of pre-licensing assessments, including Generic Design Assessment of new reactor designs, and the cost of advising prospective licence applicants during the pre-application phase.

Other legislation relevant to the safety of nuclear sites

34 In addition to the HSW Act and NIA65 ONR enforces other legislation which is particularly relevant to the safety of nuclear installations in Great Britain, including:

Ionising Radiations Regulations 1999 (IRR99): These Regulations and their associated Approved Code of Practice[14] cover the protection of workers and the public from work activities involving ionising radiations. They include a general duty to keep exposures ALARP and, among other requirements, set limits on such exposure. They implement, in part, the latest revision of the European Atomic Energy Community's (Euratom) Basic Safety Standards Directive.

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

Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR): REPPIR[16] establishes a framework of emergency preparedness measures to ensure that the population local to a licensed nuclear site is:

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

REPPIR places obligations on the licensee to produce an on-site emergency plan for

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

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

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

Security

37 ONR has responsibility for Civil Nuclear Security (CNS), regulating security for the civil nuclear industry and enforcing the Nuclear Industries Security Regulations (NISR) 2003. It approves and inspects licensees' security arrangements. Civil nuclear operators must have site security plans in place to protect nuclear sites and nuclear and other radioactive material. These arrangements cover, for example, physical protection features such as fencing, CCTV and turnstile access, the roles of security guards and the Civil Nuclear Constabulary, protecting proliferation-sensitive data, and the trustworthiness of the individuals with access to them. CNS inspectors vet nuclear industry personnel with access to sensitive nuclear material or information and transporters of nuclear material also have to be approved. Further information about CNS is available on the ONR website.[17]

Transport

38 ONR's Radioactive Materials Transport Team (RMT) is responsible for the enforcement of The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (as amended) (CDG 2009) concerning the transport and security of radioactive material, except for the security of material which falls within scope of the Nuclear Industries Security Regulations 2003. ONR also acts as a Competent Authority on behalf of the Department for Energy and Climate Change (DECC). The Office of Rail Regulation is also an enforcing authority of CDG 2009 insofar as regulatory provisions apply to railway infrastructure. The Maritime and Coastguard Agency and the Civil Aviation Authority are the UK competent authorities for the safe transport of radioactive material by sea and air respectively. ONR-RMT advises the Maritime and Coastguard Agency and Civil Aviation Authority on all matters relating to the safe transport of radioactive materials by sea and air.

The Department of the Environment Northern Ireland is the competent authority for the safe transport of radioactive material by road in Northern Ireland. ONR-RMT advises Department of the Environment Northern Ireland on all matters relating to the road transport of radioactive materials in Northern Ireland.

Environment

39 The Environment Agency for England and Wales (EA), and the Scottish Environment Protection Agency (SEPA) are responsible for environmental protection matters, including authorising discharges of radioactive waste from nuclear licensed sites under the Environmental Permitting (England and Wales) Regulations 2010 or the Radioactive Substances Act 1993 (Scotland).[18]

40 NIA65 places a statutory obligation on ONR to consult the appropriate environment agency before:

- granting or revoking a licence;
- varying a licence or attaching, varying or revoking a condition attached to a licence, if the variation of the licence or, as the case may be, the condition itself relates to or affects the creation, accumulation or disposal of radioactive waste within the meaning of the Environmental Permitting (England and Wales) Regulations 2010 or the Radioactive Substances Act 1993 (as appropriate).

41 In addition to these statutory requirements for consultation, ONR, EA and SEPA are committed to working together to deliver effective and efficient regulation of the nuclear industry. The working arrangements between HSE and the environment agencies have been set out in a Statement of Intent with the EA,[19] and separate Memoranda of Understanding with EA[20] and SEPA.[21] ONR and EA have introduced

supplementary arrangements to co-ordinate assessment work relating to new nuclear power station developments.

Regulation of sites operated on behalf of the Nuclear Decommissioning Authority

42 The Nuclear Decommissioning Authority (NDA) is a non-departmental public body which was set up in April 2005 under the Energy Act 2004 – see Annex 2. Its purpose is to ensure that the licensed nuclear sites designated to it by the Secretary of State are decommissioned and cleaned up safely, securely, cost effectively and in ways that protect the environment. The NDA is responsible for 19 designated civil public sector sites operated under 18 nuclear site licences – almost half of the licensed sites in the UK – including Sellafield, Dounreay, Harwell and the magnox-class power stations. Each of the 19 sites is operated by a site licence company (SLC) under contract to the NDA. The SLC is responsible for day-to-day operations and the delivery of the site programme. A parent body organisation (PBO), selected through a competitive process bringing in private sector expertise, owns the SLC for the duration of their contract with the NDA, earning fee based on performance and efficiencies gained. It is therefore important to understand the NDA's role and duties in relation to the licensed nuclear sites within its estate and an overview is provided in Annex 2 to this guide. The NDA is also responsible for planning and delivering a geological disposal facility for higher activity radioactive wastes.

Regulation of defence-related nuclear sites

43 Some defence-related licensed nuclear sites are operated for the Ministry of Defence (MoD) by contractors and it is the contracting companies that hold nuclear site licences granted by ONR. These include the privately-owned and operated Devonport and Rosyth dockyards. The Atomic Weapons Establishment (AWE plc) sites at Aldermaston and Burghfield remain in MoD ownership, but are occupied and operated by a contractor, AWE plc, which holds the nuclear site licences. MoD ministers account to Parliament on nuclear safety matters for these sites. It should be noted that MoD sites that are not licensed – such as the Clyde naval base and Vulcan – are still subject to the provisions of the HSW Act.

44 NIA65 applies only to a limited extent to the Crown: MoD sites are not covered by the NIA65 licensing requirements, and in any case NIA65 excludes any nuclear reactor comprised in a means of transport such as a submarine. MoD is not, however, exempt from the HSW Act, IRR99 or REPPIR, and ONR regulates MoD nuclear sites under these regulations and other legislation.[22] As a Crown body the MoD cannot be prosecuted; however, there are administrative arrangements in place whereby Crown bodies may be censured in respect of offences which would have led to prosecution.

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

International obligations

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

47 As a member state of the European Union the UK is bound by legislation set down under the Euratom Treaty relating to radioactive substances.

48 The UK is also a member state of a number of international organisations with an interest in radioactive substances. Currently these include the OECD Nuclear Energy Agency, which contributes to the development of nuclear energy as a safe, environmentally acceptable energy source, and the IAEA, which promotes the safe use of radioactive substances through a series of "safety standard" documents setting down best practice in the fields of nuclear energy production, radioactive waste management, radioactive materials transport safety and radiation protection. As a member state, the development of the UK regulatory regime is influenced by the work of the IAEA and the standards it promulgates.

49 Additionally, the UK is a signatory to two important international conventions:

The Convention on Nuclear Safety: The Convention on Nuclear Safety[24] was drawn up during a series of expert level meetings from 1992 to 1994 and was adopted in Vienna in June 1994. Its aim is to legally commit participating states operating land-based nuclear power plants to maintain a high level of safety by setting international benchmarks to which member states subscribe. The

obligations of the parties are based to a large extent on the principles contained in the IAEA safety fundamentals document *The safety of nuclear installations*. These obligations cover, for instance, siting, design, construction, operation, the availability of adequate financial and human resources, the assessment and verification of safety, quality assurance and emergency preparedness.

The Convention is an incentive instrument. It is not designed to ensure fulfilment of obligations by parties through control and sanction, but is based on their common interest to achieve higher levels of safety which will be developed and promoted through regular meetings of the parties. The Convention obliges parties to submit reports on the implementation of their obligations for "peer review", both by written questioning and answering and at periodic review meetings of the parties. At present, these occur every three years. ONR leads for the UK at these meetings.

The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management: The Joint Convention[24] applies to spent fuel and radioactive waste resulting from civil nuclear reactors and other applications, and to spent fuel and radioactive waste from military or defence programmes if and when such materials are transferred permanently to and managed within exclusively civilian programmes, or when declared as spent fuel or radioactive waste for the purpose of the Convention by the contracting party. The Convention also applies to planned and controlled releases into the environment of liquid or gaseous radioactive materials from regulated nuclear facilities. The Convention entered into force on 18 June 2001.

The obligations of the contracting parties with respect to the safety of spent fuel and radioactive waste management are based largely on the principles contained in the IAEA safety fundamentals document *The principles of radioactive waste management*, published in 1995. They include, in particular, the obligation to establish and maintain a legislative and regulatory framework to govern the safety of spent fuel and radioactive waste management and the obligation to ensure that individuals, society and the environment are adequately protected against radiological and other hazards, inter alia, by appropriate siting, design and construction of facilities and by making provisions for ensuring the safety of facilities both during their operation and after their closure. Like the Convention on Nuclear Safety, the Joint Convention requires parties to submit reports by correspondence on the implementation of their obligations for "peer review" at meetings of the parties to be held every three years. Again, ONR leads for the UK at these meetings.

Western European Nuclear Regulators' Association

50 The Western European Nuclear Regulators' Association (WENRA) is a network of chief regulators of EU countries with nuclear power plants and Switzerland, as well as of other interested European countries which have been granted observer

status. The main objectives of WENRA are to develop a common approach to nuclear safety, to provide an independent capability to examine nuclear safety in applicant countries and to be a network of chief nuclear safety regulators in Europe exchanging experience and discussing significant safety issues. Publications from WENRA, including those relating to its work on harmonisation of approaches to the regulation of safety, are available on the association's website www.wenra.org.

Section 2: The licensing process – New nuclear sites

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

Background

51 ONR's processes for considering applications for licences for new nuclear sites are informed by the desire to:

- build upon the proven UK nuclear regulatory process, to protect people and society from the hazards of the nuclear industry;
- ensure a rigorous, robust and transparent examination of the safety case and the safety management arrangements for new nuclear facilities;
- minimise uncertainties and ensure our process is clear and transparent to the public and the industry;
- draw on advice from overseas regulators, where appropriate.

52 At this point it may be useful, to avoid any misconceptions about ONR's role, to highlight several of the key enablers for new nuclear development for which ONR is not the competent authority. ONR is not responsible for:

- the in-principle determination of whether the detriment associated with undertaking a particular class of nuclear activity is justified by the resulting benefits. Such decisions are made by the appropriate government ministers, normally the Secretary of State for Energy and Climate Change, under the Justification of Practices Involving Ionising Radiation Regulations 2004 (SI 2004/1769);[25] see paragraphs 116 and 117 below for further information;

- planning decisions, authorising the construction of a nuclear facility in a particular location, which fall to the relevant national and local planning authorities;
- assessing the adequacy of the operator's nuclear liability insurance, the potential licensees' financial standing or the approval of a prospective licensee's funded decommissioning programme. These matters are the province of DECC.

Pre-application advice

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

Site selection

54 Since the start of the UK's nuclear power programme in the 1950s, successive governments have developed policies on the siting of nuclear power stations which relate to population density in the vicinity of proposed sites. The intent of these policies is to limit the number of people that might be affected in the unlikely event of a major radiation release. UK Government responsibility for siting policy is held by DECC, but ONR acts on behalf of the UK Government to administer those policies and is required to take them into account when deciding whether to grant a nuclear site licence. Prospective applicants will therefore need to satisfy themselves that the proposed location would satisfy the Government siting policy for that type of installation.

55 The UK Government's general position on siting policy is set out in the fifth national report on compliance with the convention on nuclear safety obligations.[24] As part of the new planning process under the Planning Act 2008 for nationally significant infrastructure, the Government has produced a National Policy Statement for Nuclear Power Generation. The statement lists locations in England and Wales that it has determined are strategically suitable for new nuclear power stations[26] and will apply when decisions are made on applications for development consent.

Site suitability

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

- the design safety case must show that the nuclear facility would have robust defences against a range of local external hazards, including seismic disturbances and extreme weather events such as flooding;

- the location must be suitable for the establishment of an adequate emergency plan in accordance with the licence conditions and REPPIR. The proximity of schools, hospitals and other institutions will feature in considering the feasibility of implementing emergency countermeasures (including possible evacuation of areas around the site);
- the proposal must conform with government siting policy, as described above.

57 Paragraph 103 of ONR's *Safety assessment principles for nuclear facilities* (2006 edition, Revision 1)[10] provides the overarching approach to the regulatory assessment of site suitability. It says:

103. Siting characteristics are relevant to various circumstances – new facilities or sites or modifications to them. The factors that should be considered in assessing sites cover three main aspects:

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

More detail is provided in the SAPs ST.1 to ST.7 and their supporting text.

New nuclear power stations and generic design assessment

58 ONR and the Environment Agency have developed a process of generic design assessment (GDA)[27] for new reactor designs. Under the GDA process ONR assesses the safety case for the generic design of a specific type and make of reactor. The GDA process may be applied where ONR is asked to assess a new reactor's safety case in advance of an application for a nuclear site licence being made. GDA is non site-specific but can give a prospective new build operator a clear indication of whether the design would in principle meet regulatory requirements in the event that a licence application was made for the installation of a nuclear power station based on that design.

59 If ONR is content with safety and security aspects of the safety case for the generic design, then it will provide the requesting party with a design acceptance confirmation (DAC). The provision by ONR of a DAC for a design will mean it is confident that, based on the submitted generic safety case, the design is capable of being built and operated in the UK, on a site bounded by the generic site envelope in a way that is safe and secure. ONR would take the DAC into consideration in assessing the adequacy of any future licensee's case for requesting a Consent under

Licence Condition (LC)19[†](4) for nuclear safety work to commence on the nuclear island for that type of reactor design at a specific site in the UK licensed for that purpose. GDA does not replace the licensing process but will make a significant contribution to ONR's assessment of the applicant's safety case. As the latter involves consideration of wider issues, DAC does not guarantee that a site licence will subsequently be granted. If a GDA has been completed, ONR will also consider:

- site-specific aspects not covered by GDA;
- other changes to the design or safety documentation since GDA.

Design acceptance period of validity

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

The point of licensing

Early licensing

61 ONR considers that there are advantages in granting a nuclear site licence as soon as possible, as this enables regulatory control and influence to be brought to bear under the licence conditions. A licence may be granted when ONR is satisfied that the licence applicant's safety documentation provides assurance that the site will be suitable for the proposed activities if the plant is adequately designed, constructed and operated. A full pre-construction safety case report (PCSR) is not necessary at this stage. The licence applicant must be able to show that it has an adequate organisational capability and arrangements in place to manage nuclear safety and comply with the nuclear site licence conditions when the licence is granted. It also needs to have security of tenure on the site. Additional benefits of licensing early in the development of a new site include:

- formal implementation of a licensee's due processes including, for example, the establishment of the licensee's nuclear safety committee, and time for these to bed in;
- formalising licensee responsibilities for the procurement of long lead items;
- reassurance to stakeholders that appropriate regulatory controls are in place;
- alignment of security and licensing requirements.

[†] **LC19: "Construction or installation of new plant".**

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

Latest point of licensing

63 Section 1(1) of NIA65 prohibits any person from using a site to install or operate a nuclear reactor, or other prescribed nuclear installation, unless a licence to do so has been granted for the site in question by ONR. A nuclear site licence must be granted to a developer before they may undertake construction work which could, if inadequately conceived or executed, affect nuclear safety when the plant is operational. Based on this, ONR defines the latest point at which a licence is required as the placement of the first structural concrete for buildings with nuclear safety significance. This means that some preparatory groundworks etc may take place prior to the granting of the licence. However, it is anticipated that the applicant will engage with ONR prior to excavation and the placing of the concrete blinding layer in order to reduce the risk of subsequent re-engineering being required.

The licensing process

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

Table 1 Licensing new nuclear sites – Step-by-step licensing process

Step	Responsibility	
	Licensee/Applicant	**ONR**
1. Preparing to be a licensable organisation	Establish corporate body Develop organisational capability Develop management arrangements	Advise applicant
2. Creation and collation of licence application dossier	Identify activities to be licensed Address the following: > site safety documentation and proposal to deliver a schedule of safety submissions leading to pre-construction safety report (PCSR) > develop organisational capability, company structures, governance and procedures, including: – safety management prospectus – company manual – nuclear baseline – intelligent customer – design authority – internal challenge – procurement – licence condition compliance arrangements – emergency arrangements – nuclear safety committee terms of reference – definition of site and arrangements to demonstrate security of tenure	Advise applicant
3. Licence application	Submit application to ONR Notify DECC Secretary of State	Acknowledge receipt
4A. Nuclear site licence assessment	Continue to develop organisational capability, arrangements and safety case Agree position on nuclear liability insurance with DECC Prepare funded decommissioning plan	Assess site, organisation, facility safety case and adequacy of licence condition compliance arrangements Decide whether public body notification is required prior to grant of licence (NB not required for new power station sites). If yes, issue NIA65 section 3(3) direction to licence applicant

Step	Responsibility	
	Licensee/Applicant	**ONR**
4B. Consultation	Respond to ONR direction under NIA65 section 3(3) to notify public bodies having duties in relation to the site (not applicable to civil power reactors)	Consider responses from public bodies Formally consult relevant environment agency as required by NIA65 section 3(6A) Consult DECC on applicant's financial standing and nuclear liability insurance
5. Granting of licence	Formally confirm readiness to receive licence	Produce licensing report Grant nuclear site licence
6A. Regulation under the licence – Construction	Continue developing PCSR to support stages of construction Maintain control and oversight of all safety significant matters Sustain adequate organisational capability to manage for safety Implement licence condition compliance arrangements and ensure continued adequacy Manage construction activities and modifications to design and organisation Prepare pre-commissioning safety report (PCmSR)	Licence instruments to permission progress from one stage of construction to the next using primary powers or derived powers under licensee arrangements as necessary Confirm FDP is in place before permission to commence nuclear safety-related construction Continued inspection and regulatory oversight of the plant, the licensee organisation, the development and implementation of the safety case and compliance with the conditions attached to the nuclear site licence
6B. Regulation under the licence – Commissioning	Maintain control and oversight of all safety significant matters Sustain adequate organisational capability to manage for safety Implement licence condition compliance arrangements and ensure continued adequacy Manage commissioning activities Prepare pre-operational safety report (POSR)	Licence instruments to permission progress from one stage of commissioning to the next using primary powers or derived powers under licensee arrangements as necessary Continued inspection and regulatory oversight of the plant, the licensee organisation, the development and implementation of the safety case and compliance with the conditions attached to the nuclear site licence
6C. Regulation under the licence – Operation	Safe operation and maintenance of the plant Maintain control and oversight of all safety significant matters Sustain adequate organisational capability to manage for safety Implement licence condition compliance arrangements and ensure continued relevance	Licence instruments to permission start of operations using primary powers or derived powers under licensee arrangements as necessary Continued inspection and regulatory oversight of the plant, the licensee organisation, the implementation of the safety case and compliance with the conditions attached to the nuclear site licence

Step 1 – Preparing to be a licensable organisation

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

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

These themes are expanded in the following paragraphs.

Applicant organisation status

66 NIA65 specifies that no person shall use any site for a prescribed activity unless a nuclear site licence is in force for that site. NIA65 also provides that a licence can be granted only to a corporate body and is not transferable. It follows that the licence applicant must be a corporate body which is also 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.

67 The applicant organisation does not have to be incorporated in the UK but ONR would normally expect applicants based in the European Union to have been incorporated in an EU member state. The company should maintain that incorporation in accordance with the laws in force in that state. For applicants incorporated in a state outside the EU, ONR would seek guidance from DECC as to whether this would be acceptable under the terms of relevant UK legislation. Such applicants would also need to seek the advice of other regulators on whether there are legal issues arising for non EU-based companies.

68 Notwithstanding the above, as frequent interaction between the licence applicant and ONR and other regulators will be necessary throughout the licence application process, it is in the interests of all parties if the applicant establishes a UK-based corporate entity that would act as the focus for regulatory interactions.

69 ONR's working assumption is that the site licence applicant organisation will be the corporate body which will operate the installation. If this is not the intention, the potential applicant will need to discuss this with ONR early in the licensing process.

Dual and joint licensing

70 Section 4(6) of NIA65 places an absolute responsibility upon the holder of the nuclear site licence as regards compliance with the conditions attached to that licence. It provides that in the event of a breach of a licence condition "*the licensee and any person having duties upon the site in question by whom that contravention*

was committed" is guilty of an offence. Hence, even if the breach is committed by a tenant or a contractor, the licensee is also guilty. The licensee should be in a position to exercise effective day-to-day control over all activities on the site, whether undertaken by its own people, by contractors or by tenants. The holder of the nuclear site licence also has an absolute no-fault financial liability under the insurance provisions of NIA65 for injury to persons or damage to property.

71 It is essential, therefore, that there is clarity regarding which body has legal responsibility for the safe operation of a licensed site and the attendant criminal and financial liability. Consequently, ONR will seek to avoid granting two or more licences for the same site (dual licensing) or the grant of a single licence jointly to two or more corporate bodies (joint licensing).

Leadership: Duties of directors

72 ONR will expect the applicant's Board to:

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

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

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

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‡ **LC12: "Duly authorised and other suitably qualified and experienced persons".**
§ **LC36: "Organisational capability".**

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

Relationship between a parent company and a licensed subsidiary

75 Where the licence applicant is owned by another corporate body, the parent company can be expected to adopt a strategic role including, for example, oversight of business planning and monitoring the performance of its subsidiary. However, the licence applicant will need to demonstrate that this relationship will be neither detrimental to safety nor impinge on the licensee's legal responsibilities. For example:

- the parent company should not usurp the licensee's authority over the day-to-day operation of the prescribed installations;
- the licensee must have authority to operate in a manner that maintains safety, for example, it must have the autonomy to shut down, stop operations or take any other actions necessary to ensure safety without recourse to the parent company;
- the strategic control of funding and other resources exercised by a parent company should not impede a licensee's access to adequate funds to meet its safety obligations, including decommissioning;
- the parent company must not divert or dilute the technical skills and experience available to the licensee when the licence was granted without devising agreed alternatives.

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

Organisational capability

76 The primary responsibility for the safety of a nuclear installation is placed on the licensee by NIA65, within the framework provided by HSW Act. Before granting a

licence, ONR must be satisfied that the applicant is a corporate body which will use the site for licensable activities and has adequate management structures, capability and resources to discharge the obligations associated with holding a nuclear site licence. The type of organisation and level of resources that will need to be in place when prescribed operations begin must be commensurate with the risk posed by the operations across the site.

77 ONR requires that the licensee is fully in control of activities on its site; understands the nuclear safety implications of its activities and how to control them; and is an intelligent customer for any work it commissions externally. ONR will expect the licence applicant to have robust arrangements for procurement of goods and services which could affect safety to ensure that it specifies and secures quality products which are right first time. The licence conditions require suitably qualified and experienced staff to undertake all activities that could affect safety on the site, and it is the licensee's responsibility to ensure that this requirement is implemented both throughout its own organisation and its supply chain.

78 ONR expects an applicant to develop a safety management prospectus (SMP), documenting and demonstrating the adequacy of its arrangements for managing health and safety. The SMP should provide a clear statement about the company, its structure and how it proposes to operate. It should provide a strategic, overarching description of the way in which nuclear safety is managed within the organisation and show how the management controls are appropriate and sufficient. The SMP should therefore include a description of the governance of the organisation, and its management system and staffing arrangements, and show how these will ensure safety in the context of its activities and the nuclear hazards to which they give rise. Further guidance is available in a technical assessment guide for inspectors: *Function and content of a safety management prospectus*.[29] The applicant may wish to develop a combined safety, security and environment management prospectus, and this is encouraged by both ONR and EA.

79 The SMP should be complemented by an adequate and up-to-date organisational nuclear baseline. The principal purpose of the nuclear baseline is to provide a demonstration that the licensee has suitable and sufficient organisational structures, staffing and competences in place to effectively and reliably carry out those activities which could impact on nuclear safety. Further guidance is available in a technical assessment guide for inspectors: *Function and content of the nuclear baseline*.[30]

80 The organisation and management structure set out in the nuclear baseline is not expected to be static; it should evolve as the licensee's organisation develops; for example, for a new nuclear power station the organisational structure and resources will continue to develop through the phases of construction, commissioning and generation. ONR therefore expects the original SMP to

be accompanied by plans detailing how the organisation will evolve, including arrangements for review and revision of the areas addressed by the prospectus. The licensee must continue to maintain the licensing requirements throughout the duration of the licence and the organisation set out in the safety management prospectus should remain current and adequate. The licensee will therefore need to review and revise the SMP when significant changes occur.

Intelligent customer capability

81 The licence applicant must be able to demonstrate sufficient knowledge of the plant design and safety case for all plant and operations on the licensed site to make sure that, when the licence is granted, the licensee will be in control of activities on its site, will understand the hazards associated with its activities and how to control them, and will be an "intelligent customer" for any work it commissions externally. Further guidance is available in an ONR technical assessment guide for inspectors: *Licensee use of contractors and intelligent customer capability*.[31]

82 The licence conditions require the licensee to have suitably qualified and experienced staff undertaking all activities that could affect safety on the site.[32] For many plant designs the expert knowledge will initially rest with the vendor and, consequently, ONR expects to see appropriate strategies to transfer this knowledge and information to the prospective site licensee. The transfer of knowledge must be sufficient for the prospective licensee to demonstrate to ONR's satisfaction that it is ready to take control of all activities on the site before the licence is granted and that it has plans in place to develop its organisational capability as work progresses.

83 To ensure ongoing control of the design of the plant there needs to be a Design Authority as defined in INSAG-19 *Maintaining the design integrity of nuclear installations throughout their operating life*.[33] Initially, the detailed design capability will reside within the vendor's organisation but the Design Authority is a function which must reside within the licensee. Consequently, there needs to be a process for the transfer of knowledge from the designer to the licence applicant to ensure it will have adequate Design Authority capability by the time of licensing. The applicant should make and implement arrangements for knowledge transfer and technical support from the reactor vendor and discuss these arrangements with ONR. ONR expects that these arrangements will be based on the vendor maintaining a strong UK presence. For further guidance see INSAG-19 and the technical assessment guide for inspectors: *Licensee Design Authority capability*.[34]

Developing licence condition compliance arrangements

84 ONR will agree with the prospective applicant a programme for developing adequate licence condition compliance arrangements.[35] Arrangements are needed

for all of the licence conditions, but these are expected to be proportionate and appropriate to the activities that are being performed. They will be expected to evolve as plant construction and commissioning proceeds. Initially, ONR expects the applicant to focus on putting in place effective arrangements covering activities scheduled to commence as soon as the nuclear site licence comes into force. The agreed programme will need to satisfy ONR that more developed arrangements for the balance of the licence conditions will be developed in a timely manner.

85 ONR will expect the licensee to demonstrate how licence condition compliance is assured by the management system. However, ONR does not expect that compliance arrangements should drive the design of the management system. Indeed, inasmuch as licensees are encouraged to put in place an integrated management system, it may be appropriate to demonstrate compliance through a "route map" showing how compliance is delivered and assured via the management system.

Emergency preparedness and response

86 In addition to the relevant licence conditions, the applicant will need to satisfy the Radiation Preparedness and Public Information Regulations 2001 (REPPIR).[16] The key licence condition is LC11,¶ which requires the licensee to generate and own the on-site emergency plan,[36] but others such as 7, 10, and 36 also apply. It should be noted that REPPIR places specific requirements on the licensee, such as the need under regulation 6(1)(a) to provide a report identifying the hazards and evaluating the associated risk of a radiation accident to ONR, 12 months before commencement of work with ionising radiation.

87 The generation of the off-site plan under REPPIR is the responsibility of the local authority supported by information provided by the licensee. Therefore, allowance will need to be made in accordance with the timescales identified in REPPIR for the processes required by the Regulations to be completed. The UK Nuclear Emergency Planning Liaison Group (NEPLG) has produced guidance on emergency planning requirements.[37]

Step 2 – Collation of licence application dossier

88 The documents must be in English. The applicant should discuss with ONR its expectations for the content and style of the safety submission. The supporting evidence required within the licence application dossier will include:

- a description of the installation and activities to be licensed;
- a demonstration of conformity with relevant UK government siting policies;
- a map of the site and its location, with details of the local demographics;

¶ **LC11: "Emergency arrangements".**

- details of the ownership of the site, or arrangements for its leasing, by which the applicant will achieve security of tenure and rights of access to the site commensurate with its obligations under NIA65 and the site licence conditions;
- a safety management prospectus including the nuclear baseline;
- licence condition compliance arrangements;
- adequate safety submissions complemented by a programme setting out their continued development where necessary (see paragraphs 95 and 96 below). If the proposed installation is a power station whose design has been subjected to a GDA, these submissions should show, or a plan should be provided to show, prior to consent to construct, that the characteristics of the proposed licensed site are bounded by the site envelope specified in the safety case for which ONR issued the DAC;
- details of appropriate emergency arrangements and a suitable emergency plan (this may be limited in extent for the period before nuclear fuel is brought onto the site);
- terms of reference for the licensee's nuclear safety committee;[38]
- a statement setting out a strategy for decommissioning the proposed installation;
- a statement regarding the status of the "justification" of the proposed operational activities as required by the Justification of Practices Involving Ionising Radiation Regulations 2004.

89 Detailed requirements for the above are given in documents published by ONR and are mostly available on the ONR website. However, specific questions and requests for further information may be addressed, initially, to Her Majesty's Chief Inspector of Nuclear Installations.

90 A potential applicant should seek the advice of ONR on the adequacy of the application dossier before it is submitted.

Step 3 – Licence application

91 An application for a nuclear site licence must be made to Her Majesty's Chief Inspector of Nuclear Installations at ONR's Redgrave Court offices. ONR will advise the applicant on the required format of the submission (for example, number of copies, use of electronic media etc).

92 Although prospective nuclear power station operators may prefer the design to have completed the GDA process before submitting a site licence application it is also possible to apply directly for a site licence without the design having gone through a GDA, or the GDA process having completed.

93 Following an initial review of the licence application, ONR will provide an estimate of the timescale required to complete the licensing assessment. However, the exact timescale will be influenced by a number of factors, including:

- the adequacy of the licence application dossier;
- the quality of the licence applicant's safety documentation and how successfully it provides assurance that the site will be suitable for the proposed activities if the plant is adequately designed, constructed and operated;
- the development of the licence applicant's organisational structure and capability;
- the development of the licence applicant's licence compliance arrangements;
- when the applicant indicates that it will conclude its own review of its readiness to be granted the licence.

Depending on the factors above, and on the workload of ONR, typically it might be expected to take around a year from site licence application to the completion of the licensing process, subject to adequate and timely submissions from the applicant. ONR recovers its costs from the applicant using the power provided by section 24A of NIA65.

Step 4A – Assessment of the application

94 ONR's internal process for dealing with applications for licences for new nuclear sites is available on the ONR website.[39] The key stages are summarised below:

Assessment of the safety case

95 A site-specific PCSR does not need to be in place when the nuclear site licence is granted (see paragraphs 61–63). However, the applicant will be expected to have agreed with ONR a schedule of safety case submissions leading up to the granting of the licence and, subsequently, to support licence instruments to permission construction to proceed from one stage to the next. The safety documentation for power reactors may draw upon a generic safety case for which ONR has issued a DAC but will need to include additional information relating to site-specific aspects of the application.

96 Generally, the applicant will have maintained a dialogue with ONR throughout the development of the safety case so that submissions can be made as aspects of the design reach the point where their safety can be assessed. ONR's assessment of these submissions may indicate where ONR considers that further analysis or design modifications are necessary before ONR permissions the relevant activity. To help assess the applicant's submissions ONR may seek independent data and advice from external sources.

97 ONR's expectations for safety cases are set out in SAPs SC1 to SC8.[10] ONR has also published its internal guidance on its expectations for safety cases, including for PCSR, in TAG T/AST/051.[12]

Assessment of the licence applicant's organisation

98 ONR will seek assurance that the applicant has suitable and sufficient organisational structures, resources and competencies to lead and manage for safety effectively by applying SAPs MS1 to MS4 on "Leadership and management for safety" and the suite of supporting assessment guides set out on the ONR website. The licensee will also need to demonstrate that its management system and arrangements for complying with the nuclear site licence conditions are adequate and that they are being implemented effectively before the licence is granted.

Assessment of the site

99 ONR will apply SAPs[10] ST1 to ST7, which set out the key safety factors by which it judges the acceptability of any proposed site.

Decommissioning strategies, plans and programmes

100 SAP DC1 requires that facilities should be designed and operated so that they can be safely decommissioned. Consequently, before granting a licence, ONR will need to be satisfied that the licensee has developed adequate strategies, plans and programmes for the decommissioning of nuclear plant and facilities and for the treatment and disposal of radioactive wastes. Further guidance on ONR's expectations of licensees' strategies for decommissioning and radioactive waste management is in SAPs DC1 to DC8 and on the ONR website.

Waste management and disposal

101 The management of radioactive waste is a function potentially spanning all the stages in the lifecycle of a facility. Consequently, the minimisation and control of waste should be taken into account at all stages in the lifecycle of a facility, starting at the planning and design stage through operation, to decommissioning and site clearance. Related issues to be considered by ONR include the applicant's waste management strategy, waste characterisation, arrangements for segregation, passive safety (in relation to the form of the waste itself and its storage conditions), and the requirement for the keeping of records. Other relevant factors when considering radioactive waste management include the quantity of waste involved, the magnitude of radiological hazard, the potential for the hazard to be realised, the potential dose uptake and the cost. Further guidance can be found in SAPs RW1 to RW7 and on the ONR website.

102 Some new licensing proposals, such as those for waste management facilities and waste repositories, will have relevance to the NDA's strategic role in waste

management and disposal. ONR will expect the applicant to have consulted the NDA's Radioactive Waste Management Directorate in these cases.

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

Defining the site boundary

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

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

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

Security of tenure

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

Security requirements

106 ONR regulates nuclear security requirements at civil nuclear sites and associated premises. ONR will not grant a licence until it is satisfied that appropriate measures are in place to manage both physical and information security. The Nuclear

Industries Security Regulations 2003 prevent nuclear material being brought onto a site until an approved site security plan is in place. Prior to construction, ONR expects that a construction security plan will be in place that describes the arrangements to be progressively installed to deliver the requirements of the site security plan prior to nuclear material being delivered to site. Information is available on the ONR website.[16]

Safeguards

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

Step 4B – Consultation

Mandatory consultation with the environment agencies

108 NIA65 places a requirement on ONR to consult the appropriate environment regulator (Environment Agency in England and Wales, SEPA in Scotland) before granting a new nuclear site licence. This is to ensure that granting a new licence will not conflict with the relevant environment regulator's environmental protection responsibilities, or prejudice any legal process under the Radioactive Substances Act 1993, the Environmental Permitting (England and Wales) Regulations 2010, or other environmental legislation. The arrangements for this consultation are set out in Memoranda of Understanding between ONR and each agency.[18,19] ONR will not normally grant a licence unless it has been assured by EA or SEPA that they expect to be able to grant a permit under the Environmental Permitting (England and Wales) Regulations 2010 or a Radioactive Substances Act 1993 authorisation. The process for applications for new authorisations is given in EA's *The regulation of radioactive substances activities on nuclear licensed sites*.[40]

Public body notification

109 ONR has a discretionary power under section 3(3) of NIA65 to direct a licence applicant to serve notice on certain public bodies local to the site in question. The intention of public body notification[41] is to ensure that relevant public bodies have an opportunity to comment and to suggest anything that, from the point of view of their own statutory responsibilities, ought to be provided for in the conditions

attached to the licence. Such bodies include local authorities, emergency services, river authorities, fisheries committees, statutory water undertakings, national parks authorities, where appropriate, and other public or local authorities.

110 In deciding whether to direct an applicant to undertake public body notification, the key factors considered by ONR are the significance of the development associated with the application, the related impact on public bodies' duties and activities associated with a site, and consistency with previous use of ONR's discretionary powers.

111 When this power is invoked, ONR will require the applicant to provide specified bodies with details of the proposed development and will allow the consultees up to three months to submit their comments to ONR. ONR will also consider and evaluate any comments submitted by other stakeholders.

112 ONR's discretionary power to direct a licence applicant to undertake public body notification does not apply in relation to licence applications for nuclear power stations.

Approved funded decommissioning programme

113 For new nuclear power stations, the Energy Act 2008 introduced a statutory requirement on nuclear site licence applicants, requiring them to have in place an approved funded decommissioning programme before first using the site for activities that need to be licensed. That programme will require operators to make adequate arrangements for covering the cost of decommissioning the site and managing any operational or decommissioning wastes. Before permitting the start of nuclear safety-related construction, ONR will seek confirmation from DECC that any requirements which are placed on the operator by the provisions of the Energy Act 2008 can be met.

Nuclear liability insurance

114 Under NIA65 section 19(1) the licensee is required to provide cover for third-party claims within the limits prescribed by the Act and for the arrangements to be approved by the Minister. DECC, or the Scottish Government for sites in Scotland, will review the adequacy of the licensee's section 19 cover, which may be provided by insurance, indemnity or other approved means. A nuclear site licence may, with the consent of the Secretary of State, include provision with respect to the time from which section 19(1) is to apply (section 3(5) of NIA65). For example, this may be linked to the point at which nuclear fuel is to be brought onto the site for the first time.

115 A licensee will commit a criminal offence if suitable third-party cover is not in place at any time when section 19(1) of NIA65 applies in relation to the relevant licensed site. Unless provision has been made for a deferral of cover as described above, usually cover must be in place when the new nuclear site licence comes into force. To avoid the risk of the licensee not having the legally necessary

cover in place, ONR will seek confirmation that a licence applicant has made appropriate arrangements for insurance cover by liaising with DECC or the Scottish Government before granting the licence. However, it is not ONR's responsibility to audit or validate the licence applicant's arrangements for liability cover.

Justification

116 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).

117 ONR will require the licence applicant to indicate whether any proposed activities involving radiation are already justified or if they are in the process of being so. Licence applicants should check whether there is an existing UK government decision on the Justification of the types of activity which are, or are to be, undertaken at the site.[25] For nuclear power stations, and most prescribed civil nuclear activities, the Secretary of State for Energy and Climate Change is the justifying authority.

Financial standing

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

Step 5 – Granting the licence

119 At the conclusion of its assessment of the licence application, and if relevant consultations have been completed, ONR will draft a report which sets out the findings of its assessment and makes a recommendation to the Chief Inspector of Nuclear Installations as to whether a nuclear site licence should be granted. ONR will also draft the nuclear site licence itself, which will be checked for factual accuracy with the applicant before it is granted.

120 The prospective licensee should formally inform ONR that it is ready to receive a licence and that it has satisfied itself that it will be compliant with all licence conditions when the licence is granted. A date at which the licence comes into force will be agreed. Subject to the Chief Inspector being content to grant the licence a paper copy of the licence, signed by HM Chief Inspector of Nuclear Installations or a nominated Deputy Chief Inspector, will be despatched to the applicant.

Step 6A – Regulation under the licence – Installation

121 Once the nuclear site licence has been granted, the licensee must comply with the relevant provisions of NIA65 and all the conditions that ONR has attached to the licence. During this period ONR's regulatory activities will focus on equipment procurement, construction, design modification and pre-commissioning issues and the development of the licensee's organisation.

122 Granting the licence does not, in itself, give the licensee permission to begin nuclear safety-related construction on the site, as ONR will ordinarily use the primary power provided by site licence condition LC19**(4) to specify that the licensee should not commence nuclear safety-related construction without a regulatory Consent. Throughout installation, ONR may employ LC19(4) to identify further "hold points" where ONR Consent is required before the licensee may proceed from one stage to the next. However, ONR expects the licensee to manage the installation process under its own arrangements and, in practice, the LC19(4) power is used sparingly. In addition, ONR expects that the licensee's arrangements, made under LC19(1), should also include the power for ONR to specify that progress from one stage to the next should not proceed without the agreement of ONR.

123 ONR expects the licensee to consider the adequacy of its organisational capability, as well as its technical readiness, when making a case for moving through the different stages of installation, whether the stage transition entails seeking a formal Consent or Agreement from ONR or involves only internal due process. The licence application will have included programmes for development of its organisational capability, and ONR will expect to see evidence that these are being implemented, monitored and managed accordingly. The licensee needs to build up the number of trained staff progressively through installation and commissioning in order to be ready for full operation.

124 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, and be able to demonstrate that it is an intelligent customer for any bought-in expertise and is in control of contractors working on the site.

125 The licensee needs to demonstrate how it will manage both conventional and nuclear safety during construction, and in particular how it satisfies itself that the construction and any work that is subcontracted will meet the design intent and will be conducted safely.

126 A schedule will need to be agreed for the submission of further safety documentation throughout the period of installation and on-site testing. ONR and the licensee may choose to agree licensing activity programmes for the different

** **LC19: "Construction or installation of new plant".**

topic areas, with specific programmes of work by the licensee to complete the necessary safety case submissions in the post-licensing period. In particular:

- the PCmSR must be acceptable to ONR before active commissioning starts;
- technical specifications, or operating rules deriving from the safety case, should be submitted to and agreed with ONR during the construction and before commissioning;
- it may also be necessary for the maintenance schedule to be submitted and agreed at this stage.

127 ONR is responsible for inspections and regulatory oversight of the plant. It will usually appoint a site inspector, and a programme of regulatory inspections will be introduced. Its expectations for licence condition compliance will be on a proportionate basis. Attention is drawn specifically to LC20 on "modification to design of plant under construction".

128 The inspections will need to satisfy ONR that all the issues arising from the assessment of the PCmSRs, the technical specifications and the maintenance schedule are resolved satisfactorily before proceeding to active commissioning or operation.

Step 6B – Regulation under the licence – Commissioning

129 When the appropriate licence instrument to permit the start of active commissioning has been issued, which for a nuclear power station will be linked to bringing nuclear fuel on site, commissioning may start. During this period the licensee must comply with all licence conditions[8] including, specifically, LC21 on "Commissioning". Well in advance, the licensee should agree with ONR a schedule for the submission of further safety documentation for the period of commissioning and on-site testing, leading to a POSR. Guidance on ONR's expectations for safety cases including the commissioning and pre-operational stages is given in T/AST/051.[12] The safety case for these later stages should evolve from the PCSR.

130 ONR can use powers provided by LC21(4) to Specify that ONR's Consent is required to progress from one stage to the next. As noted above, in practice these powers are used sparingly, and ONR expects the licensee to manage the commissioning process under its own arrangements. However, these arrangements, made under LC21(1), should include the power for ONR to specify that progress from one stage to the next should not proceed without the agreement of ONR.

131 Before active commissioning is started, adequate emergency arrangements should be in place and an emergency exercise must be completed before the licensee commences operations.

132 The POSR should include the commissioning results and report on any anomalies. Through its inspection and assessment processes ONR will need to be assured that all the issues arising from its assessment of the POSR and from commissioning are resolved satisfactorily before proceeding to operation.

133 At the end of satisfactory commissioning and agreement of the POSR, ONR will issue a licence instrument giving Consent to first criticality.

Step 6C – Regulation under the licence – Operation

134 When the POSR has been accepted and the appropriate licence instrument permitting operation has been issued, normal operation of the plant may start. The licensee will remain responsible for the safe operation and maintenance of the plant and for meeting all licence conditions for the life of the site, including the decommissioning phase.

Section 3: Relicensing

Need for relicensing

135 A nuclear site licence is granted for an indefinite period and, in principle, one licence could cover the entire lifecycle of the site from installation and commissioning, through operation and decommissioning to site clearance and remediation. In practice, for many sites a replacement licence will be required from time to time. Because a site licence is granted to a particular corporate body to undertake 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, that is:

- where there is to be a change of operator, since NIA65 section 3(1) precludes nuclear site licences being transferred between corporate bodies;
- if the incumbent licensee wishes to install and operate a type of prescribed installation which is not covered by its current licence;
- where the site boundary is to be extended.††

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

Proportionality

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

137 In practice, applications for replacement nuclear site licences are often driven by a change of site operator associated with a corporate or industry restructuring, or by relatively minor changes in the site boundary. In such cases, ONR will already have access to much of the evidence needed to support the granting of the replacement licence, such as safety cases and licence condition compliance arrangements where these are being taken forward unchanged. Organisations considering applying for a replacement licence for an existing site are advised therefore to seek pre-application advice by contacting the Head of ONR's Licensing function.

†† **Section 3(6) of NIA65 provides for the variation of a nuclear site licence to exclude part or parts of a site if certain criteria are satisfied but there is no parallel power to vary the licence to enlarge a licensed site.**

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

Relicensing for a change of operator

139 It is imperative that the safety of activities at a licensed nuclear site is not compromised by a loss of capability resulting from a change of operator. ONR anticipates that where it is proposed to transfer the operation of a licensed nuclear site from one corporate body to another, the new licensee will retain the majority of the existing personnel, at least initially, to ensure continuing access to essential expertise and corporate knowledge. Any corporate restructuring, including staff changes, can be managed subsequently under the new licence using the change management processes developed by the licensee and ONR's powers under LC36: "Organisational capability".[43]

140 It is nevertheless open to the licence applicant to seek to make substantial changes to organisation or resources as part of its basis for the licence application. However, this is likely to necessitate substantial, additional, pre-relicensing scrutiny by ONR to ensure that, when implemented, the new licensee's arrangements will maintain or improve standards of safety at the site. In these circumstances ONR may expect to see a period of shadow working as a precursor to the granting of the new licence.

141 During the 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 period of shadow working would enable ONR to assess and inspect the proposed new structures in practice and to take a view on their efficacy and the potential for adverse consequences for the management of nuclear safety. The new licence will not be granted unless and until this demonstration has been completed to ONR's satisfaction. Consequently, 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.

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

Table 2 Relicensing for a change of operator

Topic	Relevant paragraphs in Section 2
Applicant organisation status	66 to 69
Dual and joint licensing	70 to 71
Leadership: Duties of directors	72 to 74
Relationship with parent company	75
Organisation capability / safety management prospectus / nuclear baseline	76 to 80
Intelligent operator status / Design Authority	81 to 83

Relicensing for new activities

143 Where an existing site is to be relicensed to accommodate the introduction of an additional class of prescribed activity, ONR will scrutinise the developing design safety case to assess whether the proposed operations at the site will be adequately safe. ONR will also need assurance that the particular class of activity proposed is deemed to be justified within the meaning of the Justification Regulations 2004.[25]

144 Generally the incumbent licensee will have opened and maintained a dialogue with ONR throughout the development of the safety case.[12] As aspects of the design reach the point where their safety can be assessed submissions should be made to ONR. These submissions may be discussed and further analysis or design modifications may be necessary before ONR permissions the relevant activity. However, relicensing is not directly dependent upon complete finalisation of the safety case for the new activity as this could be taken forward as normal business under the new licence.

145 ONR will expect the licensee to have reviewed the potential impact of the proposed new activity on its organisational, resource and competence requirements. If additional needs are identified the licence applicant should submit, in support of the licence application, its programme for meeting those needs.

146 Similarly the licensee's suite of site licence conditions 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 compliance arrangements. These will be assessed in accordance with ONR's internal guidance to inspectors.[44]

Relicensing to bring additional land within the licensed site boundary[‡‡]

147 It is ONR's policy to ensure that a licensee has full rights of access to, and control of, the site so that it can satisfy the demands placed upon it by the licence and NIA65. In considering an application for an extension to the site boundary ONR will require evidence of security of tenure for, and full rights of access to, the area to be brought within the licensing regime. If the applicant does not own the area in question evidence is normally required in the form of a lease or some other legally binding contract or documentation setting out the relationship between the prospective licensee and the owner of the site.

148 The revised boundary of the licensed site must be defined clearly. The extent of the site must encompass all licensable activities and allow a sufficient margin for the maintenance of facilities, services, plants and buildings. The boundary should, so far as is practicable:

- be obvious and permanent, for example, ideally it should not cross water;
- avoid passing through a building and, in particular, avoid being three-dimensional, ie the boundary should be a simple vertical limit;
- encompass all underground workings.

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

[‡‡] **Section 3(6) of NIA65 provides for the variation of a nuclear site licence to exclude part or parts of a site if certain criteria are satisfied but there is no parallel power to vary the licence to enlarge a licensed site.**

Section 4: Delicensing

Delicensing and ending the licensee's period of responsibility

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

150 The period of responsibility is defined in section 5(3) of NIA65 as follows:

(3) 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 thereof, the period beginning with the grant of the licence and ending with whichever of the following dates is the earlier, that is to say:

- *the date when the Health and Safety Executive gives notice in writing to the licensee that in the opinion of the Health and Safety Executive there has ceased to be any danger from ionising radiations from anything on the site or, as the case may be, on that part thereof;*
- *the date when a new nuclear site licence in respect of a site comprising the site in question or, as the case may be, that part thereof is granted either to the same licensee or to some other person….*

151 Statutory period of responsibility is significant because:

- it can survive the termination of the licence. As noted above, section 5(1) of NIA65 allows that, at any time, the site licence can be revoked by ONR or surrendered by the licensee. However, the person who holds the period of responsibility has continuing obligations in relation to the licensed site placed on them by section 5(2) of NIA65, unless a new licence is granted to the same licensee or a new operator;
- in the absence of a licence and for the duration of the period of responsibility ONR is empowered under section 5(2) to "..give to the licensee such directions as [it] may think fit for preventing or giving warning of any risk of injury to any person or damage to property from ionising radiations from anything remaining on the site";
- it determines the period for which the licensee / ex-licensee has liability for injury or damage affecting third parties under the insurance provisions of NIA65 (see in particular sections 7 and 19 of NIA65, which are regulated by DECC and the Scottish Government).

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

Delicensing the whole site

152 Section 5(3) of NIA65 provides that, unless a replacement licence is being issued, the period of responsibility continues until such time as ONR notifies the licensee in writing that in its opinion there has ceased to be any danger from ionising radiations from anything on the site. Consequently, complete delicensing can only be achieved when ONR is able to make such a declaration in respect of the whole site.

Partial delicensing

153 A complementary power is provided by section 3(6) of NIA65 in relation to the variation of an existing nuclear site licence to exclude part of the site, as follows:

The Health and Safety Executive may from time to time vary any nuclear site licence by excluding therefrom any part of the licensed site:

- *which the licensee no longer needs for any use requiring such a licence;*
- *with respect to which the Health and Safety Executive is satisfied that there is no danger from ionising radiations from anything on that part of the site.*

In such cases the licence variation issued by ONR to exclude the appropriate part of the site will also invoke the power provided by NIA65 section 5(3)(a) to end the licensee's period of responsibility in respect of that part of the site.

Partial delicensing via relicensing

154 There is another mechanism by which a part or parts of a licensed site can be removed from both the licensing regime and the period of responsibility provisions of the Act. A site may need to be relicensed to accommodate a change to the licensing basis such as a change of the person operating the site, annexation of additional land into the site boundary, or the introduction of new types of prescribed activity which are not covered by the existing licence. It is open to the licensee to seek simultaneously to exclude from the area to be covered by the new licence an area (or areas) included within the existing site boundary. As with the other mechanisms, the licensee would have to demonstrate "no danger" in order to secure the termination of its period of responsibility for the area(s) in question (see NIA65 section 5(3)(a)).

Overview

155 To sum up, depending on the stage in the lifecycle of the site and / or the business plans of the licensee, there are three mechanisms by which a licensee's period of responsibility for a site or part(s) thereof may be brought to a close. These are:

- for the whole site, by the issue of a notice under NIA section 5(3)(a);

- for part of the site:
  - by grant of a licence variation under section 3(6) to exclude part(s) of the site, and this will incorporate a statement confirming that the licensee's period of responsibility for the area(s) being excluded ends simultaneously; or
  - by the revocation of the existing licence and the granting of a new licence with a revised boundary configuration – to either the same licensee or a replacement licensee – and the simultaneous issue by ONR of a notice in writing, under section 5(3)(a) of NIA65, that the "no danger" criterion had been satisfied in respect of the area(s) being delicensed.

Interpretation of "no danger"

156 For the period of responsibility to be ended ONR must express an opinion that there has ceased to be any danger from ionising radiations from anything on the site. ONR has published a policy statement[45] setting out its criterion for judging when risks have been reduced sufficiently to satisfy the "no danger" requirement of NIA65. Essentially, on the basis of existing published guidance such as *Reducing risks, protecting people*[3] and *The tolerability of risks from nuclear power stations*,[4] ONR considers that an additional risk of death to an individual of one in a million per year, is "broadly acceptable" to society.

157 Applying this to nuclear licensed sites any residual radioactivity, above the average natural background, which can be satisfactorily demonstrated to pose a risk of death to the most exposed individual of less than one in a million per year is "broadly acceptable". For practical purposes, therefore, ONR uses this criterion to determine what is regarded as "no danger" for the purposes of sections 3(6)(b) and 5(3)(a) of NIA65. Compliance with this criterion will normally mean that ONR can delicense the site, thus removing it from regulatory control under NIA65.

Delicensing the whole site – Methodology of inspection and assessment

158 Although the period of responsibility can survive the surrender or revocation of the licence, ONR anticipates that in most cases licensees will seek to achieve a state of "no danger" as a precursor to delicensing, so that delicensing and the ending of the period of responsibility can be achieved simultaneously. Consideration of a licence applicant's case for demonstrating "no danger" will follow ONR's usual approach to making regulatory decisions involving assessment and inspection on a sample basis.

159 The licensee's application should be supported by an appropriate safety case which should provide a detailed demonstration of the work undertaken by the licensee to assess levels of radioactivity within the area concerned, and sets out the results obtained. This will include, but is not limited to:

- the history and use of the land;
- the identification of areas where radioactivity could contribute significantly to radiation exposure, now or in the future, and a demonstration of their remediation;
- documentation, records and results of radiological surveys and analyses of samples from the area to be delicensed for comparison with background data from the vicinity of the site;
- an assessment of dose and risk to the public following delicensing, based on conservative assumptions regarding future use of the site and exposure pathways, ie to demonstrate that any future use of the land represents no danger;
- in assessing the safety case ONR will be guided by its published guidance on the interpretation and implementation of the "no danger" criterion.[46]

Consultation

160 Section 5(1A) of NIA65 requires that: "the Health and Safety Executive shall consult the appropriate Agency before revoking a nuclear site licence…". The framework for this consultation is set out in memoranda of understanding (MoU) between ONR and the environment regulators, EA and SEPA.[16,17] ONR will write to the appropriate environment regulator site inspector at two stages seeking views on the proposed delicensing:

(a) immediately on receipt of the licensee's application, so the environment regulator's comments can be taken into account by ONR in planning its inspection and assessment programme in relation to the application;

(b) before implementing an in-principle decision to delicense the site, ie indicating that we are minded to proceed and giving the agency an opportunity to comment.

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

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

Partial delicensing

162 Section 3(6) of NIA65 empowers ONR to grant a variation excluding part of the site from the licensed area, simultaneously ending the licensee's period of responsibility for that part of the site. The following guidance relates to an application for a licence variation but can be applied also to a partial delicensing, effected in the course of a relicensing.

163 The licensee's demonstration of "no danger" should follow the guidance in paragraph 159 above. In addition, the licensee's case for delicensing should provide:

- details of the revised site boundary, and a map for attachment to the variation or new licence and identifying the area which is being delicensed as well as the new boundary of the licensed site (see Annex 3);
- a review of other matters of regulatory concern which may be affected by the partial delicensing. These could include, for example:
  - arrangements for marking the revised site boundary, and details of any actions required to address security considerations arising from the change, for example dialogue with ONR's security specialists;
  - consequences for working interfaces affecting activities on the licensed site, including supporting infrastructure and services, access etc;
  - the impact of the partial delicensing on the safety case for the remaining licensed area, and any plant thereon;
  - implications for the emergency arrangements for the licensed site;
  - whether the organisational changes associated with the release of part of a licensed nuclear site necessitate a submission under LC36.[§§]

164 Section 3(6A) of NIA65 requires ONR to consult EA or SEPA (as appropriate) before varying a nuclear site licence if the variation relates to or affects the creation, accumulation or disposal of radioactive waste, within the meaning of the Environmental Permitting Regulations 2010 or the Radioactive Substances Act 1993 (as the case may be). Consequently, ONR will consult the relevant agency as described in paragraph 160 above.

165 ONR will normally grant the variation if the "no danger" criterion is satisfied and the other issues outlined above are resolved to its satisfaction. However, ONR may want to ask the licensee to consider withdrawing, amending or deferring the proposed change if, for example:

- implementation is perceived to be potentially detrimental to the wider objectives of health, safety and waste management at the remaining operational site (for example, if it results in more complex operational interfaces and / or regulatory arrangements);

[§§] **LC36: "Organisational capability".**

- the relevant environment agency raised reasonable objections to the variation as a result of consultation under section 3(6A) of NIA65.

166 ONR will publish on its website the project assessment report which led to the recommendation to grant a licence revocation or variation on the grounds of "no danger".

Retention of records

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

Annex 1: Regulatory powers available to ONR

1 ONR's enforcement powers under the Health and Safety at Work etc Act include:

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

Prohibition Notice – The HSW Act provides (section 22) for an inspector, if 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 the HSW Act may lead to a criminal prosecution.

Licence Instruments

2 In addition to general HSW Act powers, ONR has specific powers under conditions attached to nuclear site licences for the control of licensees' activities and to undertake enforcement action aimed at bringing about improvements in operational safety, to direct that operations be carried out, or to direct that operations be halted.

Primary powers

3 The licence conditions provide for six primary powers comprising "Consent", "Approval", "Direction", "Notification", "Specification", and "Agreement", which may be used as follows:

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

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

approved arrangements; failure to do so would infringe the licence condition and would be an offence.

Directions – A Direction is issued by ONR when it requires the licensee to take a particular action. For example, Licence Condition 31(1) gives ONR the power to direct a licensee to shut down any plant, operation or process. Such a Direction would relate to a matter of major or immediate safety importance.

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

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

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

Derived powers

4 A number of the licence conditions require the licensee to "make and implement adequate arrangements…". The arrangements are the licensee's responsibility but they may provide mechanisms for ONR to permission activities via licence instruments issued under these "derived" powers. Since licensee's arrangements can differ, the derived powers can be different from licensee to licensee. Licence instruments issued under derived powers consist of:

Agreement – An agreement issued by ONR permissions a licensee, in accordance with the licensee's own arrangements, to proceed with a specified course of action. For example, LC22‡‡‡ requires a licensee to have adequate arrangements to control modifications to safety-related plant. Such arrangements will reflect the fact that some modifications have more safety significance than others. They will often state that for high category modifications which could, if inadequately conceived or implemented, have serious nuclear safety implications, the modification cannot be carried out without the agreement of ONR.

¶¶ **LC30: "Periodic shutdown".**
*** **LC21: "Commissioning".**
††† **LC23: "Operating rules".**
‡‡‡ **LC22: "Modification or experiment on existing plant".**

For many major activities, such as new build or complex modifications, the project is divided into stages with hold points at which ONR wishes to exert its regulatory control by explicitly "agreeing" before a stage can start. Although there are primary powers which provide for such staged regulatory control by "Consent", there are situations in which it is more proportionate to use the derived power of agreement.

Acknowledgement – An acknowledgement issued by ONR informs the licensee, in accordance with the licensee's own arrangements, that ONR either intends to take no further formal action on a topic, or notifies that it intends to examine the licensee's proposals for ensuring safety. For example, under LC22 the licensee's arrangements will require the licensee to submit safety case documentation related to the more safety significant modifications. In such a case ONR may consider the modification of such safety significance that it judges it necessary to examine the proposal. In this case ONR will acknowledge receipt and notify the licensee of intention to examine the safety documentation for the modification, either at this or a later stage. ONR may however consider the modification does not warrant further examination and simply acknowledge receipt of the safety documentation. The licensee is then able to proceed with the proposed modification in accordance with its arrangements.

Specification – A further derived power is one "specifying", in accordance with the licensee's own arrangements, that ONR agreement is needed to implement a modification when that would not normally be required within the arrangements, ie we are intervening. This is typically used where we are not content with the licensee's category of modification or judge the matter such that intervention is warranted.

Note: If the licensee fails to comply with its own arrangements, and does something else which is considered to be inadequate, enforcement action may be taken for failure to implement adequate arrangements under the licence condition.

All of the enforcement powers are employed in accordance with HSE's *Enforcement policy statement*.[1]

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

1 The Nuclear Decommissioning Authority (NDA) is a non-departmental public body which was set up in April 2005 under the Energy Act 2004. Its purpose is to ensure that the licensed nuclear sites designated to it by the Secretary of State are decommissioned and cleaned up safely, securely, cost effectively and in ways that protect the environment. The NDA is responsible for 19 designated civil public sector sites operated under 18 nuclear site licences – almost half of the licensed sites in the UK – including Sellafield, Dounreay, Harwell and the magnox-class power stations. It is therefore important to understand the NDA's role and duties.

2 Legally the NDA can hold nuclear site licences. However it has opted to fulfil its Energy Act duties by contracting out the operation of the sites to site licensee companies (SLC), which hold the nuclear site licences, and appointing parent body organisations (PBO) to provide management and direction to each SLC. The SLC directors nominated by the PBO are part of the SLC corporate body and have duties to it under the Companies Act. Other PBO nominees may be seconded into "lead team" positions in the SLC. Providing the terms of the secondment are appropriate those secondees effectively have contracts of employment with the SLC and thereby become "employees" of the SLC for the purposes of the HSW Act.[47]

3 The NDA is an employer conducting an undertaking whose primary functions encompass the operation and decommissioning of prescribed installations on licensed nuclear sites, and the processing and management of hazardous material including nuclear wastes. It owns licensed nuclear sites and the assets and liabilities on those sites. So, in addition to its responsibilities to its own employees under HSW Act section 2 and the relevant statutory provisions, it has duties under HSW Act section 3 and section 4 to persons who are not their employees, ie:

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

HSW Act section 4(2): *"It shall be the duty of each person who has, to any extent, control of premises to which this section applies or of the means of access thereto or egress therefrom or of any plant or substance in such premises to take such measures as it is reasonably practicable for a person in his position to take to ensure, so far as is reasonably practicable, that the premises, all means of access thereto or egress therefrom available for use by persons using the premises, and any plant or substance in the premises or, as the case may be, provided for use there, is or are safe and without risks to health."*

4 A decided case on the extent of an employer's duties under the HSW Act section 3, Regina v Associated Octel,[48] is relevant to the NDA's relationship with its SLCs. Following an unsuccessful appeal to the House of Lords by Associated Octel

it was held that whether a work activity is part of the conduct of an employer's undertaking is a question of fact. It does not depend on whether the employer engages employees or independent contractors – such as the SLCs in the case of the NDA – to carry out that work or whether control is exercised over the activity. If the work itself is part of the undertaking, a duty is owed under HSW Act section 3(1) to ensure that it is done without risk – subject to reasonable practicability. What is reasonably practicable will be determined on a case-by-case basis.

5 Hence it is legitimate for the NDA to exercise a degree of direction and oversight over its contractors, the SLCs. The extent of that oversight and direction is a matter for the NDA to determine. However, it is clear that the more involved the NDA becomes in the way a site is managed the more will be expected of it to meet its duties under the HSW Act.

Annex 3: The site boundary and map

1 The boundary of the licensed site must encompass the licensable activities. It is important that no doubt exists in the definition of the licensed site. The boundary should be obvious and permanent and avoid, so far as is practicable, passing across water, through a building or being three-dimensional.

2 The nuclear site licence will define the licensed site boundary by reference to a map submitted by the prospective licensee. The map to be attached to the site licence must:

- be produced on A3 paper;
- have the scale and Ordnance Survey grid lines clearly marked;
- cover the whole of the licensed site, and identify its boundary in colour (usually red);
- carry an unambiguous licensee's drawing reference and revision number;
- be clearly titled and dated;
- provide an Ordnance Survey grid reference (in the form AB 123456) for a significant point on the site or its boundary;
- show grid north, preferably using a rose-cross type identifier.

3 The aim is to define the site clearly so that there can be no doubt as to its limit. Such clarity will assist the application of the nuclear site licence conditions and in establishing the extent of a licensee's absolute liability for occurrences on a site. Applicants considering using GPS data to define the site boundary may find it helpful to refer to guidance on the Ordnance Survey website.[49]

4 Copies of nuclear site licences are provided to the Department of Energy and Climate Change. The maps attached to the licences may be used by DECC to fulfil its obligation (see NIA65 section 6) to maintain a publicly-available list of licensed nuclear sites, including a map or maps showing the position and limits of each site. Consequently the licence applicant should consider security implications when determining the level of detail of the installations on the site to be represented on the site map. The applicant may wish to seek advice from ONR on this point (the Ministry of Defence for defence-related sites).

Delicensed areas

5 Any person who may have suffered harm as a consequence of activities on a licensed nuclear site is entitled to make a claim for compensation for up to 30 years after the date of the occurrence which gave rise to the claim (see NIA65 section 15). Consequently any area(s) of a licensed site which are being delicensed, or which have previously been delicensed (whether through a licence

Variation under section 3(6) of NIA65 or through an earlier relicensing) should remain identifiable over that period. This should be achieved by delineating the area delicensed by marking its boundary on the map in a distinctive manner. For example, if the licensed boundary is marked in red, by marking the delicensed area's boundary in green.

References

1 *Enforcement policy statement* HSE41(Rev1) Health and Safety Executive February 2009 http://www.hse.gov.uk/pubns/hse41.pdf

2 *Regulators' Compliance Code* Department for Business, Innovation and Skills http://www.bis.gov.uk/policies/better-regulation/improving-regulatory-delivery/implementing-principles-of-better-regulation/the-regulators-compliance-code

3 *Reducing risks, protecting people – HSE's decision-making process* HSE Books 2001 ISBN 978 0 7176 2151 4 www.hse.gov.uk/risk/theory/r2p2.pdf

4 *The tolerability of risks from nuclear power stations* www.hse.gov.uk/nuclear/tolerability.pdf

5 HSE's ALARP suite of guidance http://www.hse.gov.uk/risk/theory/alarp.htm

6 Technical assessment guide for inspectors *ONR Guidance on the demonstration of ALARP* T/AST/005 Issue 4 Rev 1 HSE January 2009 http://www.hse.gov.uk/foi/internalops/nsd/tech_asst_guides/

7 A register of companies holding nuclear site licences with details of their sites is available at www.hse.gov.uk/nuclear/licensees/pubregister.pdf

8 The standard nuclear site licence conditions www.hse.gov.uk/nuclear/silicon.pdf

9 *Our approach to permissioning regimes* http://www.hse.gov.uk/enforce/permissioning.pdf

10 *Safety assessment principles for nuclear facilities* HSE 2006 (Revision 1) http://www.hse.gov.uk/nuclear/saps/saps2006.pdf

11 Index to technical assessment guides http://www.hse.gov.uk/foi/internalops/nsd/tech_asst_guides/

12 *Technical assessment guide on the purpose, scope, content of safety cases* T/AST/051 HSE 2002 http://www.hse.gov.uk/foi/internalops/nsd/tech_asst_guides/tast051.pdf

13 The Health and Safety (Fees) Regulations 2010 http://www.legislation.gov.uk/uksi/2010/579/contents/made

14 Ionising Radiations Regulations 1999 (IRR99) http://www.hse.gov.uk/radiation/ionising/index.htm

15 Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999 (EIADR 99) http://www.hse.gov.uk/nuclear/eiadr.htm

16 Guidance relating to the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR) http://www.hse.gov.uk/radiation/ionising/reppir.htm

17 OCNS and regulation of civil nuclear security http://www.hse.gov.uk/nuclear/ocns/

18 Environmental Permitting Guidance, Radioactive Substances Regulation Defra http://www.defra.gov.uk/publications/files/pb13632-ep-guidance-rsr-110909.pdf

19 The Statement of Intent between HSE and EA http://www.hse.gov.uk/nuclear/sofi.pdf

20 Memorandum of Understanding (MoU) between HSE and EA on matters of mutual concern at licensed nuclear sites in England and Wales http://www.hse.gov.uk/nuclear/nucmou.pdf

21 MoU between HSE and SEPA on matters of mutual concern at licensed nuclear sites in Scotland http://www.hse.gov.uk/aboutus/howwework/framework/mou/sepa-nuclear.pdf

22 Regulation of Weapons and Naval Programme Activity G/INS/004 http://www.hse.gov.uk/foi/internalops/nsd/inspection/gins004.pdf

23 Nuclear safeguards http://www.hse.gov.uk/nuclear/safeguards/

24 The texts of the Nuclear Safety Convention and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management, and the UK's reports on their implementation, can be found at www.hse.gov.uk/nuclear/legal.htm

25 Guidance on the Justification Regulations, including their application to new nuclear build http://www.decc.gov.uk/en/content/cms/what_we_do/uk_supply/energy_mix/nuclear/new/reg_just/reg_just.aspx

26 National Policy Statement for Nuclear Power Generation (EN-6): http://www.decc.gov.uk/assets/decc/11/meeting-energy-demand/consents-planning/nps2011/2009-nps-for-nuclear-volumeI.pdf http://www.decc.gov.uk/assets/decc/11/meeting-energy-demand/consents-planning/nps2011/1943-nps-nuclear-power-annex-volII.pdf

27 Guidance on generic design assessment for new nuclear build http://www.hse.gov.uk/newreactors/guidance.htm

28 *Leading health and safety at work* http://www.hse.gov.uk/pubns/indg417.pdf

29 *Function and content of a safety management prospectus* T/AST/072 HSE May 2009 http://www.hse.gov.uk/nuclear/operational/tech_asst_guides/tast072.htm

30 *Function and content of the nuclear baseline* T/AST/067 HSE July 2008 http://www.hse.gov.uk/nuclear/operational/tech_asst_guides/tast065.htm

31 *Licensee use of contractors and intelligent customer capability* T/AST/049 September 2009 http://www.hse.gov.uk/nuclear/operational/tech_asst_guides/tast049.htm

32 *Training and assuring personnel competence* T/AST/027 HSE http://www.hse.gov.uk/nuclear/operational/tech_asst_guides/tast027.htm

33 *Maintaining the design integrity of nuclear installations throughout their operating life: A report by the International Nuclear Safety Advisory Group* INSAG-19 International Atomic Energy Agency 2003 http://www-pub.iaea.org/MTCD/publications/PDF/Pub1178_web.pdf

34 Technical assessment guide for inspectors Licensee Design Authority capability http://www.hse.gov.uk/nuclear/operational/tech_asst_guides/tast079.pdf

35 HSE Technical Inspection Guides (TIG) corresponding to the nuclear site licence conditions http://www.hse.gov.uk/foi/internalops/nsd/tech_insp_guides/

36 Licence Condition 11, Emergency Arrangements, and the associated Technical Inspection Guide http://www.hse.gov.uk/nuclear/operational/tech_insp_guides/tins11.htm

37 Nuclear Emergency Planning Liaison Group: Consolidated guidance http://www.decc.gov.uk/en/content/cms/meeting_energy/nuclear/safety_and_sec/emergency_plan/neplg/guidance/guidance.aspx

38 Licence Condition 13, Nuclear Safety Committee http://www.hse.gov.uk/foi/internalops/nsd/tech_insp_guides/tins013.pdf

39 *The processing of licence applications for new nuclear sites* INS/036 HSE September 2009 http://www.hse.gov.uk/nuclear/operational/inspection/ins037.htm

40 RSR RGN 2: The regulation of radioactive substances activities on nuclear licensed sites http://publications.environment-agency.gov.uk/pdf/GEHO0310BSGF-E-E.pdf

41 ND guidance to inspectors: Public body notification http://www.hse.gov.uk/foi/internalops/nsd/assessment/ins034.htm

42 *The processing of applications for replacement licences for existing licensed nuclear sites* INS/037 HSE http://www.hse.gov.uk/nuclear/operational/inspection/ins037.htm

43 *Management of organisational change* T/AST/048 HSE http://www.hse.gov.uk/nuclear/operational/tech_asst_guides/tast048.pdf

44 ONR compliance inspection – Technical Inspection Guides HSE www.hse.gov.uk/foi/internalops/nsd/tech_insp_guides/index.htm

45 *HSE criterion for delicensing nuclear sites* www.hse.gov.uk/nuclear/delicensing.pdf

46 *Guidance to inspectors on the interpretation and implementation of the HSE policy criterion of no danger for the delicensing of nuclear sites* http://www.hse.gov.uk/nuclear/delicenceguide.pdf

47 *Status of workers and contracts of employment* HSE Enforcement Guide http://www.hse.gov.uk/enforce/enforcementguide/investigation/status-intro.htm

48 Abstract of decided case Regina v Associated Octel Company Ltd http://www.publications.parliament.uk/pa/ld199697/ldjudgmt/jd961114/octel01.htm

49 *A guide to co-ordinate systems in Great Britain (An introduction to mapping co-ordinate systems and the use of GPS datasets with Ordnance Survey mapping)* Ordnance Survey August 2010 http://www.ordnancesurvey.co.uk/oswebsite/gps/docs/A_Guide_to_Coordinate_Systems_in_Great_Britain.pdf

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