

The licensing of nuclear installations

This document replaces the HSE publication 'Nuclear Site Licences under the Nuclear Installations Act 1965 (as amended) - Notes for Applicants' [HSG120], issued in 1994. This replacement document is published on HSE's website only, at www.hse.gov.uk/nuclear/. It will be reviewed and updated periodically.

With effect from 01 April 2007, the security activities of the Office for Civil Nuclear Security (OCNS) will be performed by the Health and Safety Executive (HSE) on behalf of the Health and Safety Commission. The operational nuclear safeguards work of the Department of Trade and Industry (DTI) will also be carried out by HSE with effect from the same date. The staff in both areas will transfer to HSE with their work. From 01 April 2007 the Nuclear Safety Directorate will be known as the Nuclear Directorate. These changes will be reflected in the next revision to this document.

Contents

Preface	4
Section 1: The law and the regulatory regime	5
The Health and Safety at Work Act	5
Reducing risks and ALARP	5
The Nuclear Installations Act	5
The nuclear site licence	6
Licence conditions	7
Operational methods	7
Assessment	7
Inspection	8
Sampling	8
Enforcement	8
Appeals	9
Other regulations relevant to the safety of nuclear sites	9
Other UK regulators	11
Regulation of defence-related nuclear sites	11
Nuclear Decommissioning Authority	12
Regulatory costs	12
International obligations	13
Section 2: The nuclear licensing process	14
Scope	14
First licensing	14
Relicensing	15
Licensable activities	15
Assessment of the safety case	16
The licensee's organisation	16
Safety management prospectus	17
Intelligent customer principle	18
The location	18

Applying for a site licence	18
Mandatory consultation	19
Discretionary consultation	20
Nuclear liability insurance	20
Public body notification	20
Justification	20
Public inquiry	21
HSE regulation post-licensing	21
Section 3: Delicensing	21
Background	21
The period of responsibility	22
The legal basis for ending the licensee's period of responsibility	22
Delicensing the whole site	23
Consultation	24
Partial delicensing	24
Retention of records	25
Annex 1: Regulatory powers available to HSE	25
General powers	25
Licence instruments	25
Annex 2: The licensed site boundary and map	27
Abbreviations	28
References	28

Preface

The safety of nuclear installations in the UK 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 site for specified activities. This document describes how the Health and Safety Executive regulates the design, construction, operation and decommissioning of any nuclear installation for which a nuclear site licence is required under the Nuclear Installations Act. Such installations include nuclear power stations, research reactors, nuclear fuel manufacturing and isotope production facilities, fuel reprocessing and the storage of radioactive matter in bulk.

Throughout this publication there are references to various bodies that are responsible for the development and implementation of the regulatory regime. The following description of the duties of each is provided to assist readers.

The Health and Safety Commission (HSC) was established by the Health and Safety at Work etc Act 1974 (HSW Act). Its 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 proposing new law and standards, conducting research, providing information and advice, and controlling explosives and other dangerous substances.

HSC is appointed by, and reports to, the Secretary of State for Work and Pensions, though it may report on specific matters to other Secretaries of State as appropriate. In particular, it advises the Secretary of State for Trade and Industry on nuclear safety matters relating to civil nuclear sites, and the Secretary of State for Defence on matters concerning the regulation of defence-related nuclear facilities.

In preparing proposals for health and safety law and standards, the HSC relies on the advice of the Health and Safety Executive. The HSC is also advised by the independent Nuclear Safety Advisory Committee (NuSAC). The functions of NuSAC are:

- to advise HSC on matters which are referred to it or which it considers require attention regarding nuclear safety policy and its implementation; and
- to advise the HSC on the adequacy and balance of its nuclear safety research programme.

HSC has general oversight of the work of the Health and Safety Executive and has power to delegate to HSE any of its functions. However the HSC is precluded from giving directions to HSE about the enforcement of the HSW Act in any particular case.

The Health and Safety Executive (HSE) is the corporate body appointed to enforce health and safety law under the general direction of HSC. It is the licensing authority for nuclear installations. HSE's staff are engaged in developing health and safety policy, inspecting the premises of duty holders and enforcing health and safety legislation, investigating work-related accidents and complaints, and providing information, guidance and advice on health and safety matters.

The Nuclear Safety Directorate (NSD) is a directorate within HSE. Its mission is: 'To secure effective control of health, safety and radioactive waste management at nuclear sites for the protection of the public and workers and to further public confidence in the nuclear regulatory system by being open about what we do.'

The Nuclear Installations Inspectorate (NII) forms the major part of NSD. It is to NII that the day-to-day exercise of HSE's licensing function is delegated.

Section 1: The Law and the regulatory regime

The Health and Safety at Work Act

1.1 The operators of nuclear facilities in the UK, 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). 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 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.

1.2 HSE's approach to enforcement is informed by the principles of *proportionality* in applying the law and securing compliance; *consistency* of approach; *targeting* of enforcement action; *transparency* about how it operates 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 [1].

1.3 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 duty holders guidance and advice, both face to face and in writing. This could include warning a duty holder 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.

Reducing risks, and the ALARP principle

1.4 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 that would be averted. In short, risks must be reduced to a level that is as low as reasonably practicable (ALARP [2]). This requirement and the way in which nuclear risks are regulated by HSE requirement is explained in *The tolerability of risks from nuclear power stations* [3], and *Reducing risks, protecting people* [4].

The Nuclear Installations Act

1.5 Relevant parts of the nuclear industry must also comply with the Nuclear Installations Act 1965 (as amended) (NIA65) which has three purposes:

- it requires the licensing of sites which are to be used for the operation of nuclear reactors (except for reactors which form part of a means of transport) and certain other classes of nuclear installations which may be prescribed (currently these are prescribed via the Nuclear Installations Regulations 1971: paragraph 2.8 of this document provides a summary);
- it provides for the control of the processes and the application of security measures associated with the enrichment of uranium and the extraction of plutonium or uranium from irradiated matter; and
- it sets up a special legal regime to govern the liability of the licensees towards third parties for certain kinds of damage (primarily nuclear damage) caused by nuclear materials on, or coming from, their sites.

1.6 HSE is responsible for the first of those purposes, the licensing and inspection of sites, whilst the other two are the responsibility of the Secretary of State for Trade and Industry, for sites in England and Wales, and Scottish Ministers for Scotland. Taking each in turn:

Licensing

Apart from certain exemptions, no site may be used for the purpose of installing or operating a nuclear installation unless a licence has been granted by HSE and is in force. The sections of the NIA65 relating to the licensing and inspection of sites (sections 1, 3 to 6, 22 and 24A) are 'relevant statutory provisions' of the HSW Act. Thus these sections of pre-existing law 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 the NIA65. Undertaking such activities requires a permit granted by the Secretary of State for Trade and Industry, or the 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. This provision is not enforced by HSE, but by the Department of Trade and Industry for England and Wales, and Scottish Executive Ministers for Scotland. Further details are on the DTI website [5].

The nuclear site licence

1.7 The safety of nuclear installations in the UK is secured primarily through the nuclear site licence. Nuclear site licences are granted for an indefinite term and one licence may cover the lifetime of an installation from design, siting, construction, commissioning, operation, and modification through to eventual completion of decommissioning [6].

1.8 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 that may lead to the need to relicence a site include changes to the site boundary and changes to the types of prescribed activity for which the site is licensed. Before a replacement licence is granted, HSE considers the same evaluation criteria that it would for an initial licensing (see Section 2 of this document), but takes a proportionate approach and focuses particularly on those aspects of the licensing basis that are the subject of the change.

1.9 Each nuclear site licence is unique to its site. It may be varied by HSE to exclude any part of the site that the licensee no longer needs for licensable activities. Before granting a Variation HSE is required by the 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 3 of this guide).

1.10 A licence may be revoked by HSE or surrendered by the licensee. However, depending upon the circumstances, the licensee may be required to retain responsibility for certain aspects associated with the site. This 'period of responsibility' is ended only

when a new licence has been granted for the site or HSE has given written notice that in its opinion there has ceased to be any danger from ionising radiations from anything on the site (see paragraph 3.2). Before such a notice is issued HSE needs to be satisfied that the site has been decommissioned and adequately decontaminated.

Licence conditions

1.11 NIA65 allows HSE 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 or disposal of nuclear materials. HSE also has power to add, vary or revoke conditions, so providing scope for the licence to be tailored to specific circumstances and the phase of the installation's life.

1.12 HSE has developed a standard set of 36 conditions [7] which are attached to all nuclear site licences. For sites operated under contract to the Nuclear Decommissioning Authority and the Ministry of Defence, Licence Condition 3, 'Restrictions on dealing with the site', has been slightly modified. In the main, they require the licensee to make and implement adequate arrangements to address the particular issues identified. Each licensee can develop licence condition compliance arrangements that best suit its business whilst demonstrating that safety is being managed properly. Similarly, the arrangements made to comply with them may change as the facility progresses through its life from initial design to final decommissioning.

1.13 The licence conditions provide the basis for regulation by HSE. They do not relieve the licensee of the responsibility for safety. They are non-prescriptive and set goals that the licensee is responsible for meeting, amongst other things by applying detailed safety standards and safe procedures for the facility. The arrangements, which a licensee develops to meet the requirements of the licence conditions, constitute elements of a nuclear safety management system. HSE reviews the licensee's licence condition compliance arrangements to see they are clear and unambiguous and address the main safety issues adequately. Procedures which comply with site licence conditions are likely to satisfy other requirements under the HSW Act which relate to nuclear safety hazards, eg the Management of Health and Safety at Work Regulations 1999. However, this must be demonstrated rather than assumed to be the case.

Operational methods

1.14 Within HSE, the nuclear licensing function is delegated to the Nuclear Installations Inspectorate (NII), which therefore has the responsibility for granting licences and attaching appropriate Conditions. NII also makes judgements on the acceptability of responses made by licensees to the requirements of those Conditions.

1.15 NII's Inspectors are appointed under the HSW Act. They administer NIA65 and deal with nuclear and radiological safety issues at licensed nuclear sites. Non-nuclear health and safety aspects are also monitored and regulated either by NII 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, inspection of the implementation of the licensee's licence condition compliance arrangements and investigation of incidents and complaints.

Assessment

1.16 Assessment is the process by which NII's assessors, who are themselves 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 NII uses to judge a licensee's safety case, are expressed in HSE's Safety Assessment Principles for Nuclear Facilities (SAPs) [8].

1.17 A safety case is the totality of documented information and arguments developed by the licensee which substantiates the safety of the facility, 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 that is as low as reasonably practicable (ALARP). The safety case is not a one-off series of documents prepared to obtain a nuclear site licence but an 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 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 HSE's expectations of the scope and content of safety cases is available on the HSE website [9].

Inspection

1.18 Inspection at site, at the licensee's corporate headquarters and elsewhere, enables HSE to check compliance with licence conditions, safety cases and other legal requirements. It provides a basis for enforcement and other regulatory decisions. Inspectors also seek to advise and encourage the operators of plants to enhance safety where this is consistent with the ALARP principle. Nuclear licensed sites are subjected to a high level of inspection, 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. Much of the remaining time is spent reviewing the licensee's justifications of safety with other site inspectors and with technical assessors, and administering the nuclear site licence for the site.

1.19 Additionally, HSE 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.

Sampling

1.20 All inspection and assessment is done on a sampling basis, the size and scope of the sample being determined by, for example, the potential hazard of the activity and the findings from initial examinations. 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 accuracy of information supplied by the licensee, and on the readiness of the licensee to report matters which have safety significance to HSE.

Enforcement

1.21 All of HSE's enforcement powers are employed in accordance with HSE's Enforcement Policy Statement [1]. In exercising its licensing function HSE makes use of a number of controls derived from NIA65 and the licence conditions. These enable HSE 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 HSE agreement;
- notify the licensee that it requires certain information to be submitted, eg 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, eg form of waste material;
- issue agreements as a means of agreeing to particular plant or process modifications;
- direct the licensee to shut down particular operations;
- revoke a nuclear site licence.

1.22 The first three of these controls 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 HSE in advance of receiving the formal request, and will often be the subject of considerable discussion, during which the views of each side will be well aired, before HSE exercises its powers.

1.23 In addition, a licensee's licence condition compliance arrangements may provide mechanisms for HSE 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.

1.24 HSE may from time to time reject or refuse a licensee's formal application. On occasion HSE may deem it necessary to call on its power to issue a Direction to close down particular operations for safety reasons. HSE 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. Breaches of licence conditions are offences for which the licensee, and any other person having duties upon the site who causes the breach, may be prosecuted. HSE's enforcement powers are summarised in Annex 1.

1.25 As licensee activities may require prior regulatory permission before changes are implemented, nuclear licensing is described as a 'permissioning' regime. HSC's policy statement 'Our Approach to Permissioning Regimes' [10] explains the regulatory philosophy within which the nuclear licensing regime is operated.

Appeals

1.26 Nuclear site licensees, like all duty holders under the HSW Act, have the right of appeal to an industrial tribunal in respect of Improvement and Prohibition Notices. However, Section 44 of the HSW Act precludes the right of nuclear licensees to appeal over licensing decisions made 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 licensing decision may raise concerns with the site inspector and the relevant management in NII. 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 had been reached.

Other regulations relevant to the safety of nuclear sites

1.27 In addition to the HSW Act and NIA65 other legislation of particular relevance to nuclear installations includes:

Ionising Radiations Regulations 1999 (IRR99)

These Regulations and their associated Approved Code of Practice cover the general radiation protection of workers and the public from work activities involving

ionising radiations. They include a general duty to keep exposures as low as reasonably practicable and, among other requirements, set limits on such exposure. They implement, in part, the latest Euratom Basic Safety Standards Directive.

Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999 (EIADR)

The EIADR make the dismantling or decommissioning of nuclear power stations and most nuclear reactors subject to environmental impact assessment (EIA) and various procedural requirements. In carrying out the EIA, the licensee must submit an Environmental Statement (ES) to HSE, seeking consent for the work to commence. HSE consults on the ES with expert bodies (eg the environment agencies, nature conservation bodies, local authorities, and other relevant organisations) and considers submissions from members of the public, and other stakeholders. HSE may attach conditions to any consent in the interests of limiting the impact of a project on the environment. No decommissioning work on any part of a nuclear reactor site, even non-nuclear work, can begin until HSE has granted consent. HSE has delegated this role to the Nuclear Safety Directorate (NSD).

Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPPIR)

For nuclear licensed sites, REPPPIR establishes a framework of emergency preparedness measures to ensure that the population local to the site is:

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

The Regulations place obligations on the licensee to produce an 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 in whose area the site is based, 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 determined by HSE. 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. REPPPIR is enforced by HSE under the HSW Act.

Other legislation

1.28 Other relevant legislation is contained in the Management of Health and Safety at Work Regulations 1999 that require, among other things, a suitable and sufficient risk assessment, and in the other regulations made under the HSW Act, eg Provision and Use of Work Equipment Regulations; Lifting Operations and Lifting Equipment Regulations; Personal Protective Equipment at Work Regulations; Pressure Systems Safety Regulations; Control of Major Accident Hazards Regulations (as amended) and Dangerous Substances and Explosive Atmospheres Regulations. The latter requires a risk assessment for any substance identified in the Chemicals (Hazard Information and Packaging for Supply) Regulations. Nuclear operators must comply with these regulations in the same way as any other employer, and the 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.

1.29 Not all relevant legislation is covered by the HSW Act. Other examples include the Anti-Terrorism, Crime and Security Act 2001 and its subordinate

Nuclear Industry Security Regulations 2003, the Electricity Act 1989, the Environmental Protection Act 1990, the Radioactive Substances Act 1993, various planning acts and the Building Act 1984 and its subordinate Building Regulations.

Other UK regulators

1.30 The requirements for the protection of the environment and the authorisation of disposals of radioactive waste from nuclear licensed sites are the responsibility of the Environment Agency for England and Wales, and the Scottish Environment Protection Agency for Scotland. The Environment Act 1995 amended NIA65 to place a statutory obligation on HSE to consult the appropriate environment agency before:

- granting, varying or revoking a licence; or
- attaching, varying or revoking a licence condition, if it relates to or affects the creation, accumulation or disposal of radioactive waste within the meaning of the Radioactive Substances Act 1993.

1.31 In addition to statutory requirements for consultation, HSE, 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, and Memoranda of Understanding [11].

1.32 The Department for Transport is responsible for the enforcement of certain legislation concerning the transport of radioactive materials, other than transport on nuclear licensed or relevant (ie Crown) sites [12].

1.33 The Office for Civil Nuclear Security (OCNS) is the security regulator for the UK's civil nuclear industry. It is responsible for approving security arrangements within the industry and enforcing compliance [13]. OCNS also undertakes vetting of nuclear industry personnel with access to sensitive nuclear material or information. It works in close conjunction with policy officials in DTI's Nuclear Policy Directorate, with other government departments and agencies, and with overseas counterparts. OCNS reviews police numbers and tasking at licensed nuclear sites policed by the Civil Nuclear Constabulary (CNC).

Regulation of defence-related nuclear sites

1.34 Many defence-related nuclear sites are operated by contractors to the Ministry of Defence (MoD), who hold nuclear site licences granted by HSE. These include the privately owned and operated Devonport and Rosyth dockyards and the Barrow shipyard. The Atomic Weapons Establishment (AWE) sites at Aldermaston and Burghfield remain in MoD ownership, but are operated by a contractor who holds nuclear site licences. MoD Ministers account to Parliament on nuclear safety matters at all of these sites.

1.35 Activities undertaken on MoD controlled nuclear sites enjoy some specific 'Crown' exemptions from relevant legislation. NIA65 applies only to a limited extent to the Crown; MOD is not covered by the licensing requirements, and in any case NIA65 excludes any nuclear reactor comprised in a means of transport (ie submarines). But MoD is not exempt from the HSW Act, IRR99 or REPIR, and HSE regulates MoD under these and other legislation [14].

1.36 Where exemptions and disapplications exist it is MoD policy to ensure, where reasonably practicable, that standards are at least as good as those required by civil regulation. The MoD safety regulator for its nuclear programme is Defence Nuclear Safety Regulator (DNSR). They maintain a close and regular working liaison with HSE.

Nuclear Decommissioning Authority

1.37 The Nuclear Decommissioning Authority (NDA) was set up in April 2005 under the Energy Act 2004. It has an objective of ensuring that the nuclear sites within its portfolio are decommissioned and cleaned up safely, securely, cost-effectively and in ways that protect the environment. The NDA is funded by the Government and is responsible to the Secretary of State for Trade and Industry and to the Scottish Ministers.

1.38 The nuclear legacy inherited by the NDA represents about 85% of the UK's civil nuclear liabilities and includes:

- nuclear sites and facilities developed in the 1940s, 1950s and 1960s to support the Government's research programmes, and the wastes, materials and spent fuels produced by those programmes;
- the Magnox fleet of nuclear power stations built in the 1960s and 1970s and facilities at Sellafield used for the reprocessing of Magnox fuel, and all associated wastes and materials.

1.39 The NDA has contracted with the incumbent site licence companies (SLCs) – British Nuclear Group Sellafield Ltd, Magnox Electric Ltd, Springfields Fuels Ltd and the United Kingdom Atomic Energy Authority (UKAEA) – to deliver agreed near-term workplans. Over time the NDA will put the management of all of its SLCs out to competitive tender; its proposals for achieving this are set out in its strategy [15]. The existence of the NDA does not change the legal responsibilities of licensees for ensuring safety.

1.40 The relationships between the NDA and the regulators - HSE, EA, SEPA, OCNS, the Department for Transport - are of crucial importance. The regulators share the NDA's commitment to ensuring that decommissioning and clean up is driven forward safely, securely, cost-effectively and in ways which protect the environment. To set a framework for open, constructive and complementary working relationships, Memoranda of Understanding (MoU) have been established between the NDA and each regulator. Although the MoUs cannot override the statutory duties of any of the parties, mutual co-operation between NDA and the regulators should help to ensure that conflicting demands are minimised, synergies are exploited, the appropriate balance of precautions is attained, and public confidence in the process is maintained [16].

Financial liability and NDA sites

1.41 Section 21(1) of the Energy Act provides that the NDA has statutory financial responsibility for decommissioning, clean up and operations on sites that have been designated to it. This is also given contractual effect through the NDA's operating contracts with the SLCs, which provide that the costs of operating and cleaning up the sites fall to the NDA. Consequently, the cost of operating and cleaning up a site in compliance with the conditions attached to the nuclear Site Licence do not fall to the SLC but to the NDA. In turn, the NDA draws on state funds, subject to Ministerial approval. The NDA has published an explanatory statement on SLC funding on its website; a complementary statement from HSE is available on the HSE website [17].

Regulatory costs

1.42 Section 24A of NIA65 enables HSE to charge licensees for the expenses associated with its nuclear site licensing and inspection work (in this context the term 'licensee' includes applicants for licences as well as those who already hold

licences). The total costs are distributed between licensees in accordance with the amount of inspector time allocated against their sites.

1.43 HSE's charges may also include the cost of research and of nuclear safety studies commissioned to assist HSE and ensure that it has access to independent technical advice and information. These costs are allocated to licensees according to the nature of the work done under each contract.

International obligations

1.44 As a Member State of the European Union, the UK is bound by legislation relating to radioactive substances made under the Euratom Treaty. The UK became a signatory of the Treaty on its accession to the European Union in 1972.

1.45 The UK is also a Member State of a number of international organisations with an interest in radioactive substances. These include the OECD Nuclear Energy Agency (NEA), which contributes to the development of nuclear energy as a safe, environmentally acceptable energy source, and the United Nations International Atomic Energy Agency (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.

1.46 As an IAEA Member State, the development of the UK regulatory regime is influenced by the work of the Agency and the standards it promulgates. Additionally the UK is a signatory to two important international conventions [18].

The Convention on Nuclear Safety

The Convention on Nuclear Safety commits participating States to maintain a high level of safety at nuclear power stations by setting international benchmarks to which Member States subscribe. 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. It obliges participants to submit reports on the implementation of their obligations for 'peer review' both by written questioning and answering and at three-yearly review meetings. The HSE 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 obligations of the contracting parties include the establishment and maintenance of a legislative and regulatory framework to govern the safety of spent fuel and radioactive waste management and to ensure that individuals, society and the environment are adequately protected against radiological and other hazards. This involves, among other things, appropriate siting, design and construction of facilities and making provisions for ensuring their safety during their operation and after their closure. Like the Convention on Nuclear Safety, the Joint Convention requires participants to submit reports for 'peer review' at meetings held every three years. HSE also leads for the UK at these meetings.

Western European Nuclear Regulators' Association (WENRA)

1.47 The Western European Nuclear Regulators' Association is an informal association of chief nuclear regulators in the enlarged Europe. HSE has played an active role in the association since its inception. WENRA's objectives are to:

- build and maintain a network of chief nuclear safety regulators in Europe;

- promote exchange of experience and learning from each others' best practices;
- develop a common approach to nuclear safety and regulation, in particular, within the EU;
- provide the EU with an independent capability to examine nuclear safety and regulation in future applicant countries; and
- discuss and, where appropriate, express its consensus opinion on, significant safety and regulatory issues.

1.48 The members of WENRA are committed by the year 2010 to improve and harmonise their regulatory systems using as a minimum a series of agreed reference levels [19].

Section 2: The nuclear licensing process

Scope

2.1 This section outlines the process by which HSE considers applications for nuclear site licences. More detailed guidance for applicants for a nuclear site licence is available on the HSE website [20].

First licensing

2.2 Any organisation which proposes to install a nuclear installation within scope of NIA65 on a new site will need to apply for a nuclear site licence. Although no completely new site has been licensed in the UK since the 1970s, a number of sites which were originally exempt from the licensing provisions of NIA65 have more recently been brought into the licensing regime. These include the Atomic Weapons Establishment at Aldermaston and Burghfield, Devonport and Rosyth Royal Dockyards and the UKAEA sites at Dounreay, Harwell, Windscale and Winfrith. However, most licensing activity in recent years has involved the relicensing of existing sites.

New nuclear power stations

2.3 The UK Government's energy policy is set out in the report on the Energy Review, published in July 2006 [21]. In relation to power generation the Government believes that new nuclear power stations have a role to play in the future UK generating mix. The report also records that the Government had asked HSE to take forward proposals for a new, 'pre-licensing' design acceptance procedure. Under arrangements since developed by HSE and the other nuclear regulators, interested organisations may now request a regulatory Design Acceptance assessment of a potential nuclear power station design (or designs). Such an assessment would be non-site-specific and would give a potential applicant for a nuclear site licence a clear indication of the likelihood that such a design would be licensable at a suitable site in the UK.

2.4 HSE will apply the same principles when considering an application for a site licence for a nuclear power station that has been subject to the generic, Design Acceptance review. The subsequent licensing assessment might be a relatively simple process, referencing the Design Acceptance review as appropriate. In addition:

- any exclusions in the Design Acceptance review will need to be assessed;
- any proposed changes to the design would also need to be reassessed.

Guidance on HSE's Design Acceptance process has been developed and is available on the HSE website [22].

Relicensing

2.5 A nuclear site licence is granted for an indefinite period and that licence can cover the entire life-cycle of a site from installation and commissioning through operation and decommissioning to site clearance and remediation. In practice, a new licence may be required from time to time to accommodate certain changes to the basis on which the existing licence was granted. Because a site licence is granted to a named corporate body, to undertake specified 'prescribed' activities in a defined location, the circumstances which necessitate relicensing include:

- the introduction of new types of prescribed activity at the site (for example if land within the boundary of an existing licensed site was to be used to install a new nuclear power station);
- the operation of the site being transferred to a different corporate body; and
- proposals to extend the site boundary.

2.6 So the three key elements which determine licensability are:

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

The main issues to be considered in assessing an application for a licence are set out below. They apply to both the initial licensing of a new site and the relicensing of an existing site. In the latter case the depth of the assessment of a particular topic will be proportionate to the degree of change in that area.

Licensable activities

2.7 NIA65, together with the Nuclear Installations Regulations 1971 (SI 1971/381), require 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 used in a means of transport), or any other installation which may be prescribed.

2.8 In addition to nuclear power stations, installations currently prescribed in the Nuclear Installations Regulations 1971 are those used for:

- manufacturing fuel elements from enriched uranium or plutonium;
- producing alloys or chemical compounds from enriched uranium or plutonium;
- processing irradiated nuclear fuel except where this is just 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;
 - manufacturing rigs incorporating enriched uranium or plutonium for subsequent irradiation in a reactor; and
 - installing a sub-critical nuclear assembly in which a neutron chain reaction can be maintained.

2.9 So the licensing regime encompasses not only nuclear power stations but also research reactors, fuel manufacturing and isotope production facilities, fuel reprocessing and the bulk storage of certain types of radioactive materials.

2.10 Other types of installation may be prescribed from time to time, and intending applicants should familiarise themselves with the provisions of the current versions of both the Nuclear Installations Act 1965 and the associated Nuclear Installations Regulations [23]. Any queries regarding the prescribed status of a proposed installation can be made to HM Chief Inspector of Nuclear Installations at Redgrave Court, Merton Road, Bootle, Merseyside L20 7HS.

Assessment of the safety case

2.11 Where a new site is to be licensed, or where an existing site is to be relicensed to accommodate the introduction of an additional class of prescribed activity, HSE will scrutinise the developing design safety case to assess whether the operations at the site will be adequately safe [9].

2.12 The applicant will generally maintain dialogue with HSE throughout the development of the safety case and as aspects of the design reach the point where their safety can be assessed, submissions are made to HSE. These submissions may be discussed and further analysis or design modifications may be necessary before HSE permissions the relevant activity. To help assess the applicant's submissions HSE may seek independent data and advice from external sources. Major submissions may include:

- a reference design (an initial statement of design and the safety criteria to be applied);
- a preliminary safety report (intended to show, in principle, the means by which the reference design can meet the applicant's safety criteria);
- a pre-construction safety report (a more comprehensive statement on safety analysis);
- proposed research and development work in support of the safety case;
- proposals for quality assurance (the means for ensuring that design, manufacture, inspection and construction are carried out reliably to the required standard); and
- a contract design (the design intended for construction).

2.13 In all cases, the licence applicant will need to demonstrate to the satisfaction of HSE that it has an adequate safety case for the activities which it proposes to undertake, and that it has made and can implement suitable licence condition compliance arrangements (see paragraph 1.11).

Decommissioning strategies, plans and programmes

2.14 Before granting a licence HSE 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 HSE's expectations of licensees' strategies for decommissioning and radioactive waste management is available on the HSE website [24].

The licensee's organisation

2.15 NIA65 specifies that no person shall use any site for the licensable activities described in the previous section unless a nuclear site licence is in force for that site. NIA65 also states that a licence can be granted only to a corporate body and is not transferable. It follows that the licensee must be a company which is also a user of the site.

2.16 It is important that no doubt exists about the identity of the corporate body which has legal responsibility for the safe operation of an installation and absolute liability for injury to persons or damage to property. For this reason it is HSE's policy to avoid granting more than one licence for the same site, or granting the same licence to multiple corporate bodies.

Safety management prospectus

2.17 NIA65 places the responsibility for the safety of a nuclear installation on the licensee. Before granting a licence, therefore, HSE must be satisfied that the applicant will be using the site for licensable activities and will have an adequate management structure, capability and resources to discharge the obligations and liabilities connected with holding that licence. The type of organisation and level of resource will need to be commensurate with the risk posed by the operations on the site.

2.18 HSE expects an applicant to develop and submit a safety management prospectus demonstrating its commitment to health and safety. The safety management prospectus will form part of the licensee's safety case, and should provide a clear statement about the company, its structure and how it proposes to operate. HSE envisages that the management prospectus will cover the following items:

- the corporate safety policy statement;
- a review of the licence applicant's proposals against the HSE SAPs for Leadership and Management for Safety;
- a demonstration that the licence applicant's organisational structure, resources and competencies are suitable to manage nuclear safety (the organisational 'baseline');
- precise definition and documentation of duties;
- integration of health and safety responsibilities into job functions;
- arrangements for maintaining the availability of adequate staff resources;
- arrangements for the provision of appropriately trained, experienced staff to ensure adequate in-house expertise;
- arrangements for, and anticipated extent of, the use of contractors;
- details of the applicant's relationship with associated corporate bodies, such as its parent company and the Nuclear Decommissioning Authority. Among other things, the licence applicant will need to demonstrate that it will have unfettered day to day control of safety-related activities on the site;
- lines of authority leading to adequate control of activities, whether those activities are to be undertaken by the licensee's own staff or contractors;
- the basis for corporate health and safety standards;
- the way in which the licensee will meet its regulatory responsibilities under the appropriate legislation, eg NIA65, IRR99 etc;
- arrangements for providing key functions important to health and safety including:
 - safety case production (including modifications);
 - independent assessment of safety cases;
 - independent advice to line management, eg Nuclear Safety Committee, Board advisory groups;
 - internal safety audit, inspection and review;
 - effective challenge in decision making processes;
- details of performance indicators to monitor health and safety effectively;
- details of any incentive arrangements related to health and safety performance; and
- leasing arrangements for land and/or facilities.

The licensee must continue to maintain licensing requirements throughout the duration of the licence and must therefore keep the safety management prospectus under review and revise it when significant changes occur (see also Licence Condition 36).

Intelligent customer principle

2.19 HSE expects a licence applicant to have the capability within its own organisation, in terms of staffing and expertise, to understand the safety case for all the nuclear facilities on the site and the limits under which it must be operated. The licensee will need to understand the safety significance of any bought-in expertise and take responsibility for its implementation. This requirement is known as the Intelligent Customer capability [25].

2.20 The need for the licensee to be in day to day control of the site does not rule out the use of contractors for certain functions. However, the licensee, as the Intelligent Customer, is expected to oversee and take responsibility for their activities, including ensuring that the contractor's staff are sufficient and competent to carry out their nuclear safety duties. The use of contractors or consultants must not compromise the licensee's chain of command or its ability to control the activities on the site [26].

The location

2.21 The nuclear site licence applicant will need to identify the site on which it proposes to build a nuclear power station or other installation; there are three main aspects to this on which it must be able to satisfy HSE. These are:

- the design safety case must show that each 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 REPPPIR. 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, which relates to population density in the vicinity of proposed sites and is intended to limit the number of people that might be affected in the unlikely event of a major radiation release.

2.22 It is important that the 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:

- be obvious and permanent, eg ideally it should not be across water;
- avoid, so far as is practicable, passing through a building and in particular, avoid being three-dimensional, ie the boundary should be a simple vertical limit; and
- wherever practicable, encompass all underground workings.

2.23 It is HSE'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 HSE 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.

Applying for a nuclear site licence

2.24 Applications for nuclear site licences should be made to Her Majesty's Chief Inspector of Nuclear Installations (see paragraph 2.10 for the address), copied to the Head of NII's Nuclear Site Licensing Unit. The supporting evidence required will usually include:

- a safety management prospectus;
- a description of the installation or activities to be licensed;
- an indication of the status of activities at the site in relation to the Justification of Practices Involving Ionising Radiation Regulations 2004 (Justification is considered later in this section, see paragraphs 2.36 and 2.37);
- a map of the site and, for a new site, its location with details of population type and density around the proposed site. Annex 2 provides a specification for the site map which will form part of the nuclear site licence;
- details of the ownership of the site or arrangements for its leasing;
- licence condition compliance statements and top tier arrangements;
- the submission or review of adequate safety cases;
- a statement of decommissioning arrangements;
- details of emergency arrangements; and
- terms of reference for the Nuclear Safety Committee (Licence Condition 13).

2.25 Where pre-existing facilities and operations are being brought into the licensing framework it may also be necessary to include engineering substantiation. This entails verifying that a design was fit for purpose at inception and was properly realised, and that it remains fit for purpose in the face of factors - such as in-service degradation, or potential inadequacies in the control of modifications, which could raise questions about the facility's continuing safety.

2.26 Recent applications for new licences have mostly arisen from relatively minor changes in the site boundary or a change of site operator associated with a corporate restructuring. In such cases HSE may already have access to some of the supporting evidence, which may not need to be resubmitted. Organisations considering making such an application may therefore find it helpful to obtain pre-application advice by contacting NII's Nuclear Site Licensing Manager.

Proportionality

2.27 The licensing process involves HSE's assessment of the applicant's case for the grant of a new nuclear site licence. While HSE will consider all relevant aspects of the licence applicant's case, it will adopt a proportionate approach to the licensing process, in line with the HSC Enforcement Policy Statement [1]. For an existing site this means that the main assessment effort will be focused on those areas where changes are taking place or which are judged to be potentially important for other reasons.

2.28 Following an initial assessment by the Nuclear Site Licensing Manager (and, for relicensing applications, the relevant NII site inspector), and taking account of the extent of the changes which need to be assessed, HSE will be able provide an estimate of the timescale required for the processing of the licence application.

Mandatory consultation

2.29 NIA65 places a requirement on HSE to consult the appropriate environment agency (EA 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 agency's environmental protection responsibilities, or prejudice any legal process under the Radioactive Substances Act 1993 (RSA93) or other environmental legislation. The arrangements for this consultation are set out in Memoranda of Understanding between HSE and each agency [11].

Discretionary consultation

Nuclear liability insurance

2.30 Under NIA65 section 19(1) the licensee is required to provide cover for third-party claims within the limits prescribed by the Act in accordance with arrangements approved by the DTI (or the Scottish Executive for Scotland). The DTI (or the Scottish Executive) will review the adequacy of the licensee's section 19 cover, which may be provided by insurance, indemnity or other approved means. This will usually be done when a new site is licensed, when there is a new licensee, or when there is a change to the insurance status of the site. (See section I 6(1) of NIA65 and the Nuclear Installations (Prescribed Sites) Regulations 1983 (SI 1983/919).)

2.31 By section 19(5) of the NIA65 the licensee would be committing a criminal offence if suitable third-party cover was not in place when a new site licence came into force. To reduce the likelihood of the licensee being placed in this position, it is HSE's practice to seek confirmation that a licence applicant has made appropriate arrangements for insurance cover by liaising with DTI or the Scottish Executive. However, it is not HSE's responsibility to audit or validate the licence applicant's arrangements for liability cover.

Public body notification

2.32 HSE 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 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.

2.33 In deciding whether to Direct an applicant to undertake public body notification, the key factors considered by HSE 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 HSE's discretionary powers.

2.34 When this power is invoked, HSE will require the applicant to provide specified bodies with details of the proposed development and will allow the consultees up to 3 months to submit their comments to HSE. HSE will also consider and evaluate any comments submitted by other stakeholders.

2.35 The provision in NIA65 for public body notification does not apply in relation to licence applications for nuclear power stations. As explained below, for proposed new power stations the applicant must seek a consent from the DTI Secretary of State, with the provision for there to be a public inquiry to examine the case for the development. Such arrangements obviate the need for HSE to consider directing the applicant to undertake public body notification.

Justification

2.36 Justification is a principle of radiation protection embodied in successive European Basic Safety Standards Directives [27]. 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 statute by the Justification of Practices Involving Ionising Radiation Regulations 2004 (SI 2004/1769).

2.37 HSE will require the licence applicant to indicate whether any proposed activities involving radiation are justified. 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 [28]. For nuclear power stations and most prescribed civil nuclear activities, the Secretary of State for Trade and Industry is the Justifying Authority, from whom a decision on justification should be sought prior to submitting a site licence application to HSE.

Financial standing

2.30 While it is beyond HSE's remit to judge the financial standing of licence applicants, HSE will invite interested Government Departments and agencies to draw to its attention anything relating to the licence applicant's financial standing which they consider HSE should take into consideration before granting a licence.

Public inquiry

2.38 Having proposed a site for the installation of a nuclear power station, the applicant would also need to seek consent to proceed from the Secretary of State for Trade and Industry (or from the Scottish Ministers for developments in Scotland) under section 36 of the Electricity Act 1989 and make a submission in accordance with planning regulations. This may result in the Secretary of State (or the Scottish Ministers as appropriate) calling a Public Inquiry, at which the applicant would be invited to put the case for the installation of the station, and to which local and other stakeholders may make representations. HSE will not usually grant a licence to allow the construction to begin on a new nuclear power station until section 36 consent has been given.

HSE regulation post-licensing

2.39 Once a licence has been granted to allow installation of new facilities, HSE's regulatory activities will focus on equipment procurement, construction, installation and commissioning issues and the development of the licensee's organisation. 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 in the control of contractors working on the site.

2.40 Throughout procurement, construction, installation and commissioning, HSE will often use the powers provided by the site licence conditions to apply a number of regulatory hold-points. Hold-points are agreed between the regulator and the licensee and are linked to defined activities requiring HSE's consent before they may proceed. Hold-points provide regular 'review points' during the project, and are vital for both licensee and regulator, as they give a formalised framework for resolving concerns before they become critical.

Section 3: Delicensing

Background

Delicensing and ending the licensee's period of responsibility

3.1 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 HSE 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 for licensable activities without a licence being in force would be an offence under section 1 of NIA65. However, the surrender or revocation of the licence period does not of itself end the licensee's period of responsibility. The implications of this are explained below.

The period of responsibility

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

'(3) ... 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 [HSE] gives notice in writing to the licensee that in the opinion of [HSE] 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, ...'

3.3 This 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 HSE or surrendered by the licensee. However, the person who holds the PoR has continuing obligations in relation to the licensed site placed on him or her 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 HSE is empowered under section 5(2) to '... give to the licensee such directions as [HSE] 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'; and
- it determines the period for which the licensee/ex-licensee has liability for injury or damage affecting third parties under the insurance provisions of the NIA65 (see in particular sections 7 and 19 of NIA65, which are regulated by DTI and the Scottish Executive).

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

3.4 It is clear from section 5(3) of NIA65 that, unless a replacement licence is being issued, the PoR continues until such time as HSE notifies the licensee in writing that in its opinion there has ceased to be any danger from ionising radiations from anything on the site.

3.5 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 [HSE] may from time to time vary any nuclear site licence by excluding therefrom any part of the licensed site:

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

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

3.6 Therefore HSE's section 5(3) power to end the period of responsibility relates to cases where the whole site is being removed from the nuclear regulatory regime, whilst NIA65 section 3(6) caters for partial removal.

3.7 Relicensing a site offers another means by which parts of the site may be removed from the licensing regime and the PoR provisions of NIA65. As described in Section 2 of this document, 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. 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.

3.8 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 PoR for a site or part thereof may be brought to a close. These are:

- for the whole site, by the issue of a notice by HSE under NIA65 section 5(3)(a);
- for part of the site:
- by grant of a licence variation by HSE under section 3(6) to exclude part of the site; or
- by the revocation of the existing licence and the granting of a new licence - with a revised boundary configuration - to either the same or a replacement licensee and the simultaneous issue by HSE 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'

3.9 For the period of responsibility to be ended, HSE must express an opinion that there has ceased to be any danger from ionising radiations from anything on the site. HSE has published a policy statement setting out its criterion for judging when risks have been reduced sufficiently to satisfy the 'no danger' requirement of NIA65 [29].

Delicensing the whole site

Methodology of inspection and assessment

3.10 Although the PoR can continue after the surrender or revocation of the licence, HSE 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 PoR can be achieved simultaneously. Consideration of a licence applicant's case for demonstrating 'no danger' will follow the HSE's normal approach to making regulatory decisions: HSE assesses and inspects on a sample basis, involving consultants and HSE's legal advisors and policy function where appropriate.

3.11 The licensee's application will need to 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 the results obtained. This will include:

- history and use of the land;

- identification of areas where radioactivity could contribute significantly to radiation exposure, now or in the future, and an assessment of reasonably practicable methods for 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.

Consultation

3.12 Section 5(1A) of NIA 65 requires that:

‘[HSE] shall consult the appropriate Agency before revoking a nuclear site licence ...’

The framework for this consultation is set out in the Memoranda of Understanding (MoU) between HSE and the environment agencies, EA and SEPA [11]. In accordance with the MoUs, HSE will take full and meaningful account of any environmental issues raised.

3.13 There is no statutory requirement on HSE to consult anyone other than the environment agencies in relation to an application for delicensing. HSE will decide the outcome of the application on the basis of its own reasoned assessment of the facts of the case. However, HSE encourages licensees to ensure that, wherever possible, the local community is kept fully informed via local Stakeholder Groups meetings, newsletters etc. Licensees are encouraged also to engage with other stakeholders such as the Department of Trade and Industry, the Scottish Executive, the Ministry of Defence (for defence-related sites), and any other public bodies having duties in relation to the site.

Partial delicensing

3.14 Section 3(6) of NIA65 empowers HSE 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. However, the following guidance can be applied also to a partial delicensing effected in the course of a relicensing.

3.15 The licensee’s demonstration of ‘no danger’ should follow the guidance given in paragraph 3.11 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 2 to this guidance);
- a review of other matters of regulatory concern which may be affected by the partial delicensing. These include, for example:
 - arrangements for marking the revised site boundary, and details of any actions required to address security considerations arising from the change, eg dialogue with the Office of Civil Nuclear Security;
 - 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 nuclear facilities in that area;
 - implications for the emergency arrangements for the licensed site; and
 - whether the organisational change associated with the release of part of a licensed nuclear site necessitates a submission under Licence Condition 36.

3.16 As with whole site delicensing, HSE will consult the relevant environment agency as described in paragraph 3.13.

3.17 HSE would normally expect to grant the licence variation if the 'no danger' criterion is satisfied and the other issues outlined above are resolved to its satisfaction. HSE 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 site (eg if it resulted in more complex operational interfaces and/or regulatory arrangements); or
- the relevant environment agency raised objections to the variation as a result of consultation under section 3(6A) of NIA65.

Retention of records

3.18 Any person who believes they 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 refers). Consequently, upon delicensing and/or the ending of the period of responsibility for all or part of a licensed site, HSE will expect the licensee to make secure arrangements for relevant records to be retained for that period.

Annex 1: Regulatory powers available to HSE

General powers

A1.1 HSE's general enforcement powers under the Health and Safety at Work Act are:

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

Prohibition notice – (section 22 HSW Act) an inspector, if of the opinion that activities are being carried out which risk causing serious personal injury, to serve a notice with immediate effect to prohibit the activity. HSE can also serve deferred prohibition notices.

Prosecution – contraventions of the provisions of the HSW Act may lead to a criminal prosecution.

Licence instruments

A1.2 HSE has specific powers under the nuclear site licence conditions for the control of licensees' activities, and may undertake enforcement action which is aimed at bringing about improvements in operational safety, or to require that operations are carried out or halted. HSE has delegated these powers to NII.

Primary powers

A1.3 The licence conditions provide for six primary powers which may be used as follows:

Consents - A Consent is required before the licensee can carry out any activity identified in the licence or any other activity which HSE may specify. For example, a Consent from HSE is required before a reactor is allowed to be started up again following a periodic shutdown. In order to grant a Consent the licensee must satisfy HSE that the proposed action is safe and that all procedures necessary for control are in place.

Approvals - An Approval is used to 'freeze' or 'fix' a licensee's arrangements and other key elements of its safety management system. This may include 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 HSE so specifies, the licensee is required to submit the arrangements etc to HSE for approval. Once approved, the arrangements cannot be changed without HSE'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. For example, for nuclear power stations HSE generally approves operating rules important to safety in order to ensure that licensees cannot change them without seeking HSE's agreement to the change.

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

Agreements - An Agreement issued by HSE allows a licensee to proceed with an agreed course of action. For example Licence Condition 30(2) enables HSE to agree the extension of a facility's operating period.

Notification - The standard licence conditions give HSE powers to request the submission of information by notifying the licensee of the requirement. For example, in Licence Condition 21(8) the licensee shall, if notified by HSE, submit a safety case and shall not commence operation of the relevant facility or process without the consent of HSE.

Specification - The standard licence gives HSE discretionary controls with regard to a licensee's arrangements and these are implemented through Specifications. For example, in Licence Condition 23(2), if HSE specifies, the licensee is required to refer operating rules to his Nuclear Safety Committee for consideration.

Derived powers

A1.4 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 HSE to permission activities via licence instruments issued under these 'derived' powers. Since licensees' 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 HSE permissions a licensee, in accordance with the licensee's own arrangements, to proceed with a specified course of action. For example, Licence Condition 22 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 such high category modifications which, if inadequately conceived or implemented, there could be serious nuclear safety implications, and the modification cannot be carried out without the agreement of HSE.

For many major activities, such as new build or complex modifications, the project is divided into stages with hold points at which HSE 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 HSE informs the licensee, in accordance with the licensee's own arrangements, that HSE 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 Licence Condition 22 the licensee's arrangements will require the licensee to submit safety case documentation related to the more safety significant modifications. In such a case HSE may consider the modification of such safety significance that it judges it necessary to examine the proposal. In which case HSE will acknowledge receipt and notify the licensee of intention to examine the safety documentation for the modification, either at this or a later stage. HSE may, however, consider the modification does not warrant further examination and simply acknowledges receipt of the safety documentation. The licensee is then able to proceed with the proposed modification.

'Specification' - A further derived power is one 'specifying' in accordance with the licensee's own arrangements that HSE 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.

Annex 2: The licensed site boundary and map

A2.1 A nuclear site licence defines the licensed site boundary by reference to a map submitted by the prospective licensee. HSE requires the map attached to the site licence to:

- be produced on A3 paper;
- identify the licensed site boundary in colour;
- be clearly titled and dated and carry an unambiguous licensee's drawing reference and revision number;
- show the scale and Ordnance Survey grid lines and provide grid reference for a significant point on the site or its boundary; and
- show grid north.

A2.2 The aim is to define the site clearly so that there can be no doubt as to its limit. This assists in the application of the nuclear site licence conditions and in establishing the extent of a licensee's absolute liability for occurrences on a site.

A2.3 NIA65 section 6 requires the DTI Minister to maintain a publicly-available list of licensed nuclear sites, including maps showing the position and limits of each site. Copies of nuclear site licences that are provided to DTI and may be used by DTI to fulfil these obligations. Licensees will need to seek the advice of the Office of Civil Nuclear Security (the Ministry of Defence for defence related sites) regarding the level of detail of the installations on the site appropriate for publicly available maps.

Delicensed areas

A2.4 Anyone who may have suffered harm due to activities on a licensed nuclear site is entitled to claim for compensation for up to 30 years after the date of the occurrence which gave rise to the claim (paragraph 3.18). Consequently, parts of a

site that have been delicensed need to remain identifiable over that period. Site licence maps therefore delineate delicensed areas by marking their boundaries in a distinctive colour.

Abbreviations

ALARP	As Low As Reasonably Practicable
CNC	Civil Nuclear Constabulary
DTI	Department for Trade and Industry
EA	Environment Agency
EIADR	Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999
EU	European Union
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HSW Act	Health and Safety at Work etc Act 1974
IAEA	International Atomic Energy Agency
IRR99	Ionising Radiations Regulations 1999
MoD	Ministry of Defence
MoU	Memorandum of Understanding
NDA	Nuclear Decommissioning Authority
NII	Nuclear Installations Inspectorate
NIA65	Nuclear Installations Act 1965 (as amended)
NSD	Nuclear Safety Directorate
NuSAC	Nuclear Safety Advisory Committee
OCNS	Office for Civil Nuclear Security
PoR	Period of Responsibility
REPPPIR	Radiation (Emergency Planning and Public Information) Regulations 2001
RSA93	Radioactive Substances Act 1993
SAPs	HSE's Safety Assessment Principles for Nuclear Facilities
SLC	Site Licence Company
SEPA	Scottish Environment Protection Agency
SFAIRP	So Far As Is Reasonably Practicable
TAG	Technical Assessment Guide
UKAEA	United Kingdom Atomic Energy Authority
WENRA	Western European Nuclear Regulators Association

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15. The Nuclear Decommissioning Authority's latest strategy document is available on its website: www.nda.gov.uk
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28. Guidance on Justification, and a register of justified practices, can be found on website of the Department for Environment, Food and Rural Affairs (Defra): www.defra.gov.uk/environment/radioactivity/government/legislation/justification.htm

29. *HSE Criterion for Delicensing Nuclear Sites*: www.hse.gov.uk/nuclear/delicensing.pdf

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