





Guidance

How we regulate radiological and civil nuclear safety in the UK (webpage)

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Foreword

Following the discovery of ionising radiation [footnote 1], and its uses for industrial, research and medical purposes, the United Kingdom (UK) has had a long history of utilising its benefits and protecting against its potential harms. The UK was one of the first countries to develop a legislative framework for radiological safety [footnote 2], in the form of the Radioactive Substances Act 1948 which enabled arrangements to be put in place to control the use of radioactive substances and irradiation apparatus in medicine, industry and research and the transport of such substances and apparatus.

As a pioneer of nuclear technology, the UK opened the world's first commercial nuclear power station at Calder Hall in 1956. The aftermath of a fire in 1957 in Pile 1 on what is now the Sellafield site led to the development of the UK's first nuclear regulator, the Inspectorate of Nuclear Installations in the then Ministry of Power. Since the 1950s regulation has evolved, incorporating best practice domestically and internationally, and the UK now has a comprehensive regulatory framework for radiological and civil nuclear safety.

Our regulatory framework for radiological and civil nuclear safety comprises regulatory bodies across England, Scotland, Wales and Northern Ireland (NI) and can be broken down into the following broad areas:

- occupational exposures
- civil nuclear safety
- public exposures and environmental protection
- medical and non-medical exposures
- consumer products and radiation
- transport of radioactive material (RAM)
- emergency preparedness and response (EP&R)

The UK government and the devolved administrations work together and with bodies including the International Atomic Energy Agency (IAEA) [footnote 3], the International Commission on Radiological Protection (ICRP) [footnote 4], the Western European Nuclear Regulators Association (WENRA) [footnote 5], the Heads of the European Radiological Protection Competent Authorities (HERCA) [footnote 6], and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) [footnote 7]. This enables us to share our regulatory experience and support the continuous development of international safety standards to help ensure we continue to implement good practice.

We also participate in the IAEA's expert peer reviews, as well as providing our own experts for overseas missions. Additionally, we work closely with the Nuclear Energy Agency of the Organisation for Economic Cooperation and Development (OECD-NEA)[footnote 8], and the Radioactive Substances Committee of the Convention for the Protection of the Marine Environment of the North-East Atlantic (the OSPAR Convention)[footnote 9].

The UK left the European Union (EU) and the European Atomic Energy Community (Euratom) [footnote 10] on 31st January 2020. We are committed to putting in place all the necessary measures to ensure that the UK can continue to operate as an independent and responsible nuclear State. Given the potential of the civil nuclear sector - the combination of its key role in meeting our net zero target (https://www.gov.uk/government/news/uk-becomes-first-major-economy-to-pass-net-zero-emissions-law) and in providing low-carbon energy to Great Britain (GB), its specialist skills, and wider work with ionising radiation- there is strong mutual interest in ensuring that the UK and Euratom continue to work closely together in the future, for example through WENRA and HERCA, which include both EU and non-EU States.

The purpose of this document is to provide an overview of the UK's existing regulatory framework for radiological and civil nuclear safety, including the relevant legislation. It also sets out how we maintain our framework for safety and demonstrate regulatory transparency. It does not, however, introduce any new policies, or make changes to existing ones. A summary of the UK's policies on radiological and civil nuclear safety is set out in chapter 2.

We are publishing this document to provide those with an interest in how the UK regulates radiological and civil nuclear safety access to this information in one place.

This document was produced with input from the UK's regulators and in close cooperation with the devolved administrations. Together we strive to ensure that the UK's regulatory framework for radiological and civil nuclear safety is in line with international safety standards.

1. Introduction

This document sets out the UK's legislative and regulatory approach for radiological and civil nuclear safety. [footnote 11] It is intended to provide a guide to the UK's comprehensive safety framework in one place.

It should be noted that the regulatory regimes for some areas in the document overlap. For example, the Health and Safety at Work etc. Act 1974 (HSWA74) applies to occupational exposures wherever they occur and includes occupational exposures that are linked to medical and environmental exposures as well as occupational exposures at nuclear sites. Further information on these areas is set out in chapters 6, 7 and 8.

All legislation referred to in this document relates to legislation in force at the time of publication, unless otherwise stated.

Devolution

Health, the environment, and EP&R are devolved matters in the UK. [footnote 12] As a result, there are separate regulatory bodies covering these areas in England, Scotland, Wales and NI and distinct regulations for protecting people and the environment from radioactive substances. Although health and safety is reserved in relation to GB, it is an area where NI has competence. Further details on each of these devolved matters are set out in chapters 5, 7, 8 and 11 respectively.

The UK's framework is set by multiple government departments, the devolved administrations and regulatory bodies. This document outlines the responsibilities of the various departments and bodies involved across the UK. It was prepared working closely with all the departments, devolved administrations, and key regulatory and advisory bodies with an interest in those areas. A full list of contributing organisations is available at Annex D.

Scope of the document

The document covers the regulation of radiological and civil nuclear safety. It does not include the regulation of radioactive material used for defence purposes. The default position is that within the UK, the Ministry of Defence (MoD) is required to comply with all applicable health, safety and environmental protection legislation. Where defence and security activities conflict with legislative requirements the MoD has derogations, exemptions or disapplications from UK law [footnote 13], the MoD maintains departmental arrangements that produce outcomes that are – so far as reasonably practicable – at least as good as those required by UK legislation.

<u>Chapter 2</u> provides a summary of the UK's national policies for radiological and civil nuclear safety.

The UK's approach to regulation is set out in <u>chapter 3</u>. This provides details of each of the following aspects:

- safety as a top priority;
- justification (the justification principle is covered in more detail in <u>chapter</u>
 4);
- · optimisation;

- limitation (dose limits);
- the graded approach;
- the goal setting approach;
- independence of regulatory decisions; and
- stakeholder engagement

Chapters 5 to 11 cover the following areas in more detail:

- occupational exposures;
- civil nuclear safety;
- · medical and non-medical exposures;
- public exposures and protection of the environment;
- consumer products and radiation;
- transport of radioactive material (RAM); and
- EP&R.

<u>Chapter 12</u> sets out how the UK maintains its framework for radiological and civil nuclear safety and ensures its approach remains consistent with international good practice.

Finally, <u>chapter 13</u> shows how the UK maintains its regulatory transparency. This includes how regulators engage with stakeholders, including those that they regulate, the public and other interested parties.

2. Summary of UK policies on radiological and civil nuclear safety

Introduction

The UK has a well-established radiological and civil nuclear safety regime which demonstrates a long-term commitment to safety as a top priority. Its fundamental objective is to ensure an efficient and effective safety framework which protects the public and the environment from the harmful risks of ionising radiation. [footnote 1] The UK is committed to this objective, thereby avoiding undue burden on future generations whilst allowing the safe use of ionising radiation, the safe operation of the nuclear industry and managing the legacy of this work in accordance with the graded approach. Nuclear power also contributes to the government's leadership on sustainable development and the UK's 2050 net zero target

(https://www.gov.uk/government/news/uk-becomes-first-major-economy-to-pass-net-zero-emissions-law).

Set out below are the key elements of the UK's policy for radiological and nuclear safety:

Adherence to IAEA Fundamental Safety Principles

UK policy is consistent with the <u>IAEA's Fundamental Safety Objective and Fundamental Safety Principles</u>

(https://www.iaea.org/publications/7592/fundamental-safety-principles). These set out the basis for requirements and measures for the protection of people and the environment against radiation risks and for the safety of facilities and activities that give rise to those risks. Further details on how the UK implements the Fundamental Safety Principles is set out in Annex A.

Signatory to international conventions

The UK is a signatory to a number of international conventions that place legally binding obligations on contracting parties to effectively manage their domestic safety regimes and some require peer review to maintain international accountability. The UK was an early sponsor [footnote 14] and signatory of the relevant international legal instruments relating to nuclear and radiological safety including:

- The <u>Convention on Nuclear Safety (CNS)</u>
 (https://www.iaea.org/topics/nuclear-safety-conventions/convention-nuclear-safety)
- The Convention on Early Notification of a Nuclear Accident
 (https://www.iaea.org/topics/nuclear-safety-conventions/convention-early-notification-nuclear-accident#:~:text=The%20Convention%20on%20Early%20Notification,may%20result%20in%20an%20international)
- The <u>Convention on Assistance in the Case of a Nuclear Accident or</u> <u>Radiological Emergency (https://www.iaea.org/topics/nuclear-safety-conventions/convention-assistance-case-nuclear-accident-or-radiological-emergency)</u>
- The <u>Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (JoC)</u>
 (https://www.iaea.org/topics/nuclear-safety-conventions/joint-convention-safety-spent-fuel-management-and-safety-radioactive-waste)

These conventions provide an effective and credible legal framework agreed by the international community, which the UK values and has played a key part in formulating. The UK plays an active role in the CNS [footnote 15] and JoC [footnote 16] regular review meetings to support and facilitate enhancement of the international safety regime and works closely with other IAEA member states to ensure we learn from experiences and take advantage of good international practices.

Alignment with international safety standards

The UK is committed to maintaining high levels of safety and contributes its expertise to the development of relevant international safety standards. Safety standards developed by international bodies such as the IAEA and ICRP are widely regarded as international good practice. The UK actively contributes to these and adopts them into its laws, regulations, and guidance. In so doing, the UK continues to demonstrate full compliance with the obligations in the relevant Conventions. The UK recognises the IAEA's safety standards as the primary standards that its safety framework is measured against and routinely welcomes IAEA peer review missions. This independent benchmarking ensures the UK benefits from sharing good practice and learning across IAEA member states, demonstrating our commitment to high safety standards. Further information on IAEA peer review missions is set out in chapter 12.

Commitment to maintaining a legal framework for safety

The UK has established a legal framework for safety that ensures all its regulators have sufficient financial and human resources to carry out their functions efficiently and effectively. Government departments and devolved administrations work with regulators to regularly review the UK's legal framework to ensure that it is effective and fit for purpose. The legal framework also gives regulators legal powers to take enforcement action and bring employers back into compliance. Enforcement action is made public to support learning and transparency. Regulators work closely with employers by providing guidance to ensure compliance with relevant regulations.

Effective coordination

To provide effective coordination of safety policy across a diverse range of stakeholders, the UK's government departments, devolved administrations and regulators routinely collaborate and share information and issues through the Radiological Safety Group (RSG) and other key coordination groups [footnote 17]. These forums support the consistent enforcement of the regulations where powers are devolved.

The RSG is chaired by the Department for Business, Energy and Industrial Strategy (BEIS) and consists of senior officials from the appropriate departments and regulatory bodies. It is designed to enhance collaboration and sharing of best practice to support key safety requirements including:

- monitoring and raising issues related to social and economic developments and their impacts on effective regulation and the government to regulator interface;
- the promotion of credible leadership and management for safety, including safety culture. The UK recognises the importance of a strong safety culture [see <u>Chapter 3</u>]. All regulators require employers to implement management systems that give due priority to safety; and
- discussing legislative and policy proposals across the UK's radiological and civil nuclear safety regime.

The RSG, and its sub-group the Radiological Safety Working Group, also consider how IAEA standards should be implemented into the UK's framework.

Providing international leadership

The UK takes its leadership role in radiological and civil nuclear safety seriously through its engagement and participation in the relevant international fora and organisations (e.g. IAEA, ICRP, OECD-NEA, UNSCEAR, OSPAR and the World Health Organisation (WHO)[footnote 18]) that cover radiological and nuclear safety. As one of the main contributors to the IAEA, both financially and through expert support, the UK works closely with like-minded IAEA Member States and partners to support the continuous improvement of the global safety regime, therefore enhancing the UK's domestic regulatory framework. The UK also proudly contributes towards achieving the UN Sustainable Development Goals (https://www.gov.uk/government/publications/implementing-the-sustainable-development-goals/implementing-the-sustainable-development-goals--2) as the key framework that ensures our efforts are tailored to wider development needs.

Commitment to research and development

The UK is internationally recognised for its leadership in research and the excellence of its scientific institutions. The UK government has made ambitious provisions for research and development (R&D). In March 2020, the Chancellor announced a record increase in public investment in R&D, committing to reaching £22 billion per year by 2024 to 2025 [footnote 19]. The UK's Nuclear Sector Deal (https://www.gov.uk/government/publications/nuclear-sector-deal) ensures that the UK's nuclear sector remains cost competitive with other forms of low-carbon technologies. It sets out the government's commitment to support the development of skills (the Nuclear Sector Skills Strategy

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attach_ment_data/file/415427/Sustaining_Our_Nuclear_Skills_FINAL.PDF)) to support the sector and the UK's commitment to investing in innovation. This includes £180 million for the Nuclear Innovation Programme (NIP)[footnote 20].

In November 2020, the <u>Ten Point Plan for a Green Industrial Revolution</u> (https://www.gov.uk/government/publications/the-ten-point-plan-for-a-green-industrial-revolution) announced further investment in the next generation of nuclear technology. Subject to value-for-money and future spending rounds, this commits up to £385 million in an Advanced Nuclear Fund. This will enable investment of up to £215 million into Small Modular Reactors to develop a domestic smaller-scale power plant technology design that could potentially be built in factories and then assembled on site and will unlock up to £300 million private sector match-funding. The Plan also commits up to £170 million for a research and development programme on Advanced Modular Reactors. Further information on enabling the regulation of new technologies is available in chapter 12.

The UK's <u>Nuclear Innovation and Research Office (NIRO)</u> (https://www.nirab.org.uk/about-us/about-niro) is responsible for providing advice to government, industry and other bodies on R&D and innovation opportunities in the nuclear sector under the guidance of the Nuclear Innovation and Research Advisory Board (NIRAB)) (https://www.nirab.org.uk/about-us/about-nirab).

3. The UK's approach to regulation

Every day in the UK, radioactive materials are used in a diverse range of processes including in energy generation, industrial, medical and research applications. These range from nuclear power plants to radiological techniques in, for example, cancer treatment and dentistry. Our key aim is to ensure that the necessary measures are in place to ensure the safety of the public, and the protection of patients, those that work with radiation on a

day-to-day basis, third parties affected by work carried out and the environment.

From the time that the UK started working with ionising radiation in an industrial and medical setting to the development of the first commercial power reactor in 1956, it has continued to develop and enhance its comprehensive legislative, regulatory and policy framework. This provides for the proportionate regulation of facilities and activities involving ionising radiation. The UK's framework applies to 30 GB licensed civil nuclear sites [footnote 21] as set out in Annex C. [footnote 22] It also applies to thousands of employers working with ionising radiation, handling radioactive waste and the transport of radioactive material across the UK.

The UK's approach incorporates the following aspects:

Safety as a top priority

For all uses of radioactive material the safety of the public, workers and patients is a top priority. This also applies to environmental protection, which provides protection to the public through the avoidance of environmental harm caused by radioactive material. The responsibility for radiological and nuclear safety rests with the employer. The UK legislative framework ensures that those who create the radiation risk must ensure that risks are removed or limited so far as reasonably practicable to ensure the safety of the public, patients and those who work with the radiation. This principle is enshrined in HSWA74 and the Health and Safety at Work (Northern Ireland) Order 1978 (HSW(NI)O78) and supports the development of a strong safety culture [footnote 23] across all sectors. The Act, the Order and the Ionising Radiations Regulations 2017 (IRR17) and the Ionising Radiations Regulations (Northern Ireland) 2017 (IRRNI17) that sit beneath them apply to all sectors. Protection of patients as a result of medical exposure is covered in more detail in chapter 7. Those that fail to meet their legal obligations in any sector may face enforcement action.

Justification

The IAEA Safety Fundamentals state that "Facilities and activities that give rise to radiation risks must yield an overall benefit." In the UK, the justification process under the Justification of Practices Involving Ionising Radiation Regulations 2004 (JoPIIRR) (as amended [footnote 24]) requires that before any new class or type of practice involving ionising radiation can be introduced, the government must first assess it to determine whether the

individual or societal benefit outweighs the health detriment it may cause. Further information on justification is set out in chapter 4.

Optimisation [footnote 25]

The optimisation principle requires that those who create the risk must demonstrate that they have done everything reasonably practicable to reduce it, balancing the level of risk posed by their activities against the cost and benefits of the measures needed to control that risk - whether in money, time or resources (or in the case of public exposures, the economic and societal benefits). Whilst the different regulatory regimes in the field of radiological protection in the UK use different terminology and have their own guidance on optimisation, they are all broadly equivalent.

These include reducing risks or exposure:

- as low as reasonably practicable (ALARP);
- so far as is reasonably practicable (SFAIRP)[footnote 26]; and
- as low as reasonably achievable (ALARA).

For environmental protection, employers demonstrate that exposures are ALARA through the use of best practicable means (BPM) and best practicable environment option (BPEO) in Scotland and NI; and in England and Wales, use of best available techniques (BAT), which is broadly equivalent to a combination of BPM and BPEO [footnote 27].

Limitation (dose limits and dose constraints)

A dose limit is the total radiation dose to an individual that must not be exceeded. Dose constraints are part of the system of radiological protection and are informed by a risk assessment. They are a tool to help restrict, as far as is reasonably practicable, an individual's exposure to ionising radiation that might arise from a particular activity. These are especially useful at the planning stage and in relation to individuals who may be exposed to more than one source of radiation.

The IRR17 and IRRNI17 require that all employers must, in relation to any work with ionising radiation that they undertake, take all necessary steps to restrict radiation exposure so far as is reasonably practicable with an absolute duty not to exceed specified dose limits. Chapter 7 sets out further information on dose constraints in medical and non-medical exposures.

Graded approach

UK regulators take a graded approach when regulating. The use of a graded approach is intended to ensure that the necessary levels of analysis, documentation and actions are commensurate with, for example, the magnitudes of any radiological hazards and non-radiological hazards, the nature and the particular characteristics of a facility, and the stage in the lifetime of a facility.

Goal setting approach

In line with our wider approach to safety, the UK adopts an outcome-focussed, goal setting regime rather than the more prescriptive, standards-based regimes applied in some other countries. This means that UK regulations set out broad regulatory requirements, supported by relevant codes of practice and guidance, and it is for the employer to determine and justify how best to achieve them. This approach allows an employer to be innovative and to achieve the required high levels of radiological protection by adopting practices that meet its particular circumstances. It also encourages continuous improvement and the adoption of relevant good practices rather than simply meeting a prescribed standard. [footnote 28]

Independence of regulatory decisions

In line with international standards, UK regulatory bodies are set up to make independent, objective, regulatory decisions in line with applicable legislation and free from undue external influence e.g. from government and industry. Ministers can set direction, but they cannot overrule a regulatory decision. [footnote 29]

Stakeholder engagement

In the UK, regulators must pay careful attention to the <u>Regulators' Code</u> (https://www.gov.uk/government/publications/regulators-code), which provides a flexible, principles-based framework for regulatory delivery. This supports and enables regulators to design their service and enforcement policies in a manner that best suits the needs of businesses and other regulated entities. The Code states that "Regulators should have mechanisms in place to engage those that they regulate, the public and others to offer views and

contribute to the development of their policies and service standards". Further information on how regulatory bodies demonstrate compliance with the Regulators' Code is available in <u>chapter 13</u>. Chapter 13 also includes detailed information on how regulators engage with other interested parties.

These aspects incorporate relevant international best practice and safety requirements that have been set by international organisations such as the IAEA. <u>Chapter 12</u> sets out how the UK actively engages with the international community to support the development of robust safety standards.

4. The justification regime

As set out in chapter 3, the IAEA Safety Fundamentals state that "Facilities and activities that give rise to radiation risks must yield an overall benefit." i.e. the justification principle. The JoPIIRR regulations, which apply across the UK, provide the regulatory framework for enabling the determination of whether an existing or proposed practice involving ionising radiation is justified. This takes into account the expected individual and societal benefits and the potential risks, including potential detriment to health. Only practices that are justified may be authorised by the regulatory bodies, such as the environmental regulators.

There are three ways in which activities that are the subject of these Regulations can be considered 'existing'. These are listed in Annex 2 of the JoPIIRR guidance:

- If there is evidence to show that they were in existence prior to 13 May 2000 (the transposition deadline for the 1996 Basic Safety Standards Directive);
- Where a new class or type of practice is the subject of a positive justification decision, it becomes an existing class or type thereafter;
- For certain classes or types of practice that were only brought within the scope of JoPIIRR 2004 by the 2018 change to the definition of "practice", the relevant date for distinguishing between new and existing classes or types of practice is 6 February 2018.

Anyone seeking to undertake a new type of practice must make an application for a justification decision. The Justifying Authority (the relevant Secretary of State (SoS), the Scottish ministers, NI ministers, or Welsh ministers as appropriate) will then make a decision regarding whether it is a justified practice.

As a result of transposition of the 2013 Euratom Basic Safety Standards Directive (BSSD13), the SoS making the justification decision under

JoPIIRR cannot be the SoS proposing the activity. For example, the SoS for BEIS can no longer make the justification decision for new power reactors coming through the JoPIIRR process.

JoPIIRR covers a range of activities, some of which fall within devolved subject areas. However, to ensure consistency across the justification system, the UK government has to-date made single pieces of legislation covering all areas of the UK and all practices (including those that are devolved). The devolved administrations have to-date been content with that approach.

Classes and types of practice include nuclear reactor designs. Three of these, including the UK European Pressurised Water Reactor (EPR) currently under construction at Hinkley Point C, have been subject to regulatory justification decisions and have achieved a positive decision.

5. Occupational exposures

lonising radiation is used throughout the UK in a diverse range of occupations including: industrial; medical and dental; veterinary; mining, drilling and quarrying; research; and non-destructive testing, as well as at licensed nuclear sites. These activities bring real benefits to people living and working in the UK, but it is vital that we have the necessary protections in place to ensure the safety of the public and those that work with radiation on a day-to-day basis.

Relevant legislation

HSWA74 and HSW(NI)O78 set the national framework for health and safety and apply to all employers in the UK. Failure to comply with the legislation and associated regulations can result in enforcement action being taken, including fines, imprisonment and disqualification of company directors.

Under HSWA74 and HSW(NI)O78 employers have a duty to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all their employees. The legislation also imposes a duty on every employer to conduct their undertaking in such a way as to ensure, so far as is reasonably practicable, that those persons not in their employment who may be affected thereby are not exposed to risks to their health and safety.

The IRR17 regulations made under HSWA74, and IRRNI17 in NI, apply to all employers who work with ionising radiations. They also apply to work

with naturally occurring radioactive materials, including work in which people are exposed to naturally occurring radon gas and its decay products (further information on this is provided in chapter 8).

Any employer who undertakes work with ionising radiation must comply with IRR17/IRRNI17, including the completion of a suitable and sufficient radiation risk assessment. [footnote 30] Employers are expected to regularly review their radiation risk assessments to ensure that this remains up-to-date and fit for purpose. Some examples of updates are a change of process, the introduction of a modified machine, or a revision required as the result of an accident that had occurred. Advice on how to comply with the regulations is included in an <u>Approved Code of Practice (ACoP) and guidance (http://www.hse.gov.uk/pubns/priced/l121.pdf)</u>.

Minimising exposure to ionising radiation

Regulations under HSWA74/HSW(NI)O78 and IRR17/IRRNI17 require employers to restrict exposure to ionising radiation so far as is reasonably practicable. Exposures must not exceed specified dose limits. Restriction of exposure should be achieved first by means of engineering control and design features. Where this is not reasonably practicable, employers should introduce safe systems of work and only rely on the provision of personal protective equipment as a last resort. Before commencing a new activity involving work with ionising radiation an employer must make a suitable and sufficient assessment of the risk to any employee and wider public and identify the measures needed to restrict exposure. Depending on the type of work involving ionising radiation (as specified in IRR17 and IRRNI17) and the location it is to be carried out, employers must either notify, register, or gain consent(s) from the Health and Safety Executive (HSE) for work on GB non-nuclear premises, the Health and Safety Executive Northern Ireland (HSENI) for work in NI, or the Office for Nuclear Regulation (the ONR) for work on nuclear licensed premises.

Under IRR17 and IRRNI17 and the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR19) or the Radiation (Emergency Preparedness and Public Information) Regulations (Northern Ireland) (REPPIRNI19), every employer engaged in work with ionising radiation must consult an appointed Radiation Protection Adviser (RPA), who will advise the employer on how to best comply with the regulations. The individual RPA or the RPA body [footnote 31] selected must meet the criteria of competence as set out in the HSE Statement on radiation protection advisers (https://www.hse.gov.uk/radiation/rpnews/rpa.htm) and must have the relevant experience to make them suitable to provide the advice needed.

Occupational exposure regulators and relevant government departments

Regulators

Enforcement of occupational health and safety legislation in GB is divided between the Health and Safety Executive (HSE) (http://www.hse.gov.uk/), Local Authorities, the Office for Nuclear Regulation (the ONR) (http://www.onr.org.uk/) and the Office of Rail and Road (ORR) (https://orr.gov.uk/) [footnote 32]. Regulation of work with ionising radiation is carried out by each of these regulatory bodies for those activities/premises for which they are the enforcing authority. For example, HSE is the enforcing authority for manufacturing activities and industrial radiography, Local Authorities (LAs) regulate X-ray machines located in warehouses or museums and ORR regulates within the rail industry. Detailed information on the ONR's role is set out in Chapter 6.

In NI, the <u>Health and Safety Executive Northern Ireland (HSENI)</u> (https://www.hseni.gov.uk/) regulates occupational exposure and LAs have similar enforcing authority roles. HSE on request, can and do provide specialist health and safety support to HSENI, LAs and ORR, e.g. in support of investigations, which may include radiation.

Inspectors in all the above organisations carry out a range of functions including providing advice, review and assessment, inspection, investigation and enforcement in a proportionate way so that radiation exposure of employees and others, arising from work activities, is adequately controlled. Please refer to the Enforcement Policy Statement (EPS) and other relevant documentation, e.g. the Enforcement Management Model (EMM) for each regulatory body for more information. [footnote 33]

Government departments

The HSE is an executive non-departmental public body (NDPB) [footnote 34] of the Department for Work and Pensions (DWP) (https://www.gov.uk/government/organisations/department-for-work-pensions). It devises its own policy and legislative proposals and reports directly to DWP ministers [footnote 35]

HSENI is a non-departmental public body with crown status under the remit of the Department for the Economy (https://www.economy-ni.gov.uk/).

6. Civil nuclear safety

The Office for Nuclear Regulation (the ONR) regulates nuclear safety at 30 licensed civil nuclear sites [footnote 36] in the UK, including the existing fleet of operating reactors and decommissioning power stations. [footnote 37] The UK currently has eight operating nuclear power stations, which consist of 14 Advanced Gas-cooled Reactors (AGR) and one Pressurised Water Reactor (PWR) contributing around 17% of the UK's electricity generated in 2019. Alongside these nuclear sites, the UK has fuel cycle facilities and waste management and decommissioning sites.

While this chapter relates to civil nuclear sites, it should be noted that other areas of this document are also relevant to nuclear safety. For example, as set out in chapter 5 on occupational exposures, HSWA74 and IRR17 apply to nuclear sites, in addition to specific legislation governing nuclear safety at nuclear installations in England, Scotland and Wales. [footnote 38] Further information on the role of the environmental regulators on nuclear sites is available in chapter 8 (public exposures and protection of the environment).

Relevant legislation

The Nuclear Installations Act 1965 (NIA65) provides the legal framework for nuclear safety and nuclear third-party liability. The NIA65 sets out a system of regulatory control based on a robust licensing process administered by the regulator (the ONR). In addition to the nuclear site licensing regime, NIA65 requires that financial provision is in place to meet claims in the event of a nuclear incident, as required under international law on nuclear third-party liability.

NIA65 states that no site can be used for the purpose of installing or operating a nuclear installation (or other prescribed activities [footnote 39]) unless a nuclear site licence has been granted by the ONR and is currently in force. Only a corporate body, such as a registered company or a public body can hold a site licence and the licence is not transferable.

An important provision of NIA65 is that it requires the ONR to attach such conditions to a site licence as it considers necessary or desirable in the interests of safety and may attach such conditions to it at any other time. It is an offence under the law to not comply with a licence condition. There are 36 standard site licence conditions ranging from marking the site boundary to decommissioning. Licence holders must demonstrate compliance with the licence conditions in a manner appropriate to their particular operation, such as with a safety case to meet a stage in the plant's life, or with arrangements and procedures to meet a licence condition. [footnote 40] The ONR ensures compliance with site licence conditions through a programme of inspections on site, and the licence conditions are supported by a framework of Safety Assessment Principles (SAPs)

(http://www.onr.org.uk/saps/index.htm), Technical Inspection Guides (TIGs)

(http://www.onr.org.uk/operational/tech_insp_guides/index.htm) and Technical Assessment Guides (TAGs)

(http://www.onr.org.uk/operational/tech_asst_guides/index.htm).

The NIA65 also allows the ONR to recover costs associated with licensing and enforcement of the licence conditions from licence holders.

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

(http://www.onr.org.uk/eiadr.htm), as amended, require the potential environmental impacts of projects to decommission nuclear power stations and nuclear reactors (except research installations whose maximum power does not exceed 1 kilowatt continuous thermal load)

[footnote 41] to be assessed before the ONR grants consent for the decommissioning project to commence. Decommissioning projects that commenced prior to the regulations coming into force in 1999, do not require retrospective consent.

However, for all decommissioning projects, regardless of when they started, any changes or extensions to the project which may have significant adverse effects on the environment cannot commence until the ONR has made a determination. This will determine whether the project shall be made subject to an environmental impact assessment, under Regulation 13 of the EIADR.

The EIADR require that the ONR consults the public and other relevant stakeholders, including the appropriate environmental regulator and the local highway and planning authorities, during the EIADR application process. This will take into account the environmental impacts of the options being considered for a proposed decommissioning project.

Nuclear safety regulators and relevant government departments

Regulators

The Office for Nuclear Regulation (the ONR) (http://www.onr.org.uk/), established by the Energy Act 2013 (TEA13), is the UK's independent regulator for nuclear safety, security and conventional health and safety at nuclear sites and it is the enforcing body for all aspects of nuclear safety including emergency response. The ONR regulates nuclear safety at 30 licensed civil nuclear sites[footnote 42] in the UK including the existing fleet of operating reactors, fuel cycle facilities and nuclear installations undergoing decommissioning.[footnote 43]

The ONR seeks to maintain and, where appropriate, improve safety standards for work with ionising radiation at nuclear sites, through regulation

of compliance with both relevant legislation and nuclear site licence conditions. It does so by using a range of approaches including on-site inspections and assessment of submissions by licensees. In addition, the ONR sets clear expectations in respect of the standards and outcomes expected. The ONR also contributes to the development of national and international radiological and nuclear safety standards and guidance in its work with, for example, the IAEA, OECD-NEA and WENRA.

It has a range of enforcement powers which arise from both the TEA13 and HSWA74. The ONR's approach to enforcement decision making is set out in its Enforcement Policy Statement (EPS)

(http://www.onr.org.uk/enforcement.htm). This ranges from giving advice to instigating court proceedings (prosecution) or recommending proceedings in Scotland and is underpinned by its Enforcement Management Model (EMM) (http://news.onr.org.uk/2018/04/new-onr-enforcement-management-model/).

It should be noted that for nuclear licensed sites in England and Wales (those which have / use nuclear matter) the accumulation and storage of radioactive waste is regulated by the ONR and disposal is regulated by the environmental regulators. The ONR works closely with the EA, NRW and the Scottish Environment Protection Agency (SEPA) at nuclear sites. Further information on this is set out in Chapter 8.

The ONR also regulates the transport of nuclear and radioactive materials within GB and works with the international inspectorates to ensure that the UK's safeguard obligations are met. Further information on the transport of radioactive materials is available in chapter 10.

In addition, it works alongside the <u>Environment Agency (EA)</u> (https://www.gov.uk/government/organisations/environment-agency) and Natural Resources Wales (NRW) (<a href="https://naturalresources.wales/?lang=en) [footnote 44] in a process called Generic Design Assessment (GDA). The objective for GDA is to provide confidence that the proposed design is capable of being constructed, operated and decommissioned in accordance with the standards of safety, security and environmental protection required in GB.

For the Requesting Party for a GDA, this offers a reduction in uncertainty and project risk regarding the design, safety, security and environmental protection cases, so as to be an enabler to future licensing, permitting, construction and regulatory activities. [footnote 45]

Government departments

The Department for Work and Pensions (DWP)

(https://www.gov.uk/government/organisations/department-for-work-pensions) is responsible for ensuring that the ONR has access to the funds it needs to carry out its regulatory functions and purposes. DWP sponsorship of the ONR ensures the ONR's functional separation from the Department for Business, Energy and Industrial Strategy (BEIS)

(https://www.gov.uk/government/organisations/department-for-business-energy-and-industrial-strategy) which is responsible for establishing government policy in relation to the use of nuclear power, with BEIS ministers being responsible to Parliament for nuclear safety.[footnote 46]

7. Medical and non-medical exposures

Every day in the UK ionising radiation is used for the diagnosis and treatment of disease as well as for screening and research involving patients and individuals. This includes X-rays, radiotherapy and nuclear medicine. It is widely used in hospitals, dental surgeries, clinics and in research facilities such as universities and sports science institutes.

The UK's regulatory framework also takes into account what are termed as non-medical exposures using medical radiological equipment. Exposures are undertaken using medical radiological equipment which do not confer a health benefit to the individual exposed, such as health assessments for employment purposes and identification of concealed objects within the body.

Devolution

Health is a devolved matter in the UK. This means that there are different medical and non-medical exposure regulators in England, Scotland, Wales and NI and separate regulations for protecting people against medical and non-medical exposures in GB and NI. Information on the relevant legislation and regulators is set out in this chapter.

Relevant legislation

Protection of patients, individuals and carers and comforters for medical and non-medical exposures are covered by the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) in GB and the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 in NI.

The regulations aim to make sure that ionising radiation is used safely to protect patients from the risk of harm when being exposed. They set out the responsibilities of employers for radiation protection and the basic safety standards that employers must meet.

Responsibilities include:

- minimising unintended, excessive or incorrect medical exposures;
- justifying each exposure to ensure the benefits outweigh the risks: and
- optimising diagnostic doses to keep them 'as low as reasonably practicable' for their intended use.

The regulations apply to both the independent and public sectors (the NHS).

Under IR(ME)R, employers who undertake medical and non-medical exposures must appoint a Medical Physics Expert (MPE)[footnote 47] for advice on complying with the regulations.

Optimisation

Dose limits are not applicable to IR(ME)R, but dose constraints must be established for medical or biomedical research programmes where no direct medical benefit to the individual is expected, and for carers and comforters. Dose constraints are restrictions set on prospective doses of individuals which may result from a given radiation source.

The regulations require that the doses arising from exposures are kept as low as reasonably practicable other than in radiotherapy. In radiotherapy, the dose to the tissue not being targeted must be kept as low as reasonably practicable.

Diagnostic reference levels

Diagnostic Reference Levels (DRLs) are radiation dose levels, or for nuclear medicine the administered activity, for typical diagnostic examinations on standard size adults and children for broadly defined types of equipment e.g. computerised tomography (CT) scans, fluoroscopy or general radiography. These levels should not be exceeded where good and normal practices exist but must be reviewed when consistently exceeded.

Quality assurance of equipment

The employer must establish a programme of quality assurance for the safe performance of radiological equipment used for medical and non-medical

purposes. This includes frequency of testing and corrective actions required to improve inadequate or defective equipment.

Guidance

Guidance on compliance with IR(ME)R

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attach ment_data/file/720282/guidance-to-the-ionising-radiation-medical-exposure-regulations-2017.pdf) is produced by the Department of Health and Social Care (DHSC). There is also guidance written and established by all regulatory bodies for health for statutory notifications of significant accidental and unintended exposures (SAUE). In addition, the Royal College of Radiologists has produced guidance relating to radiology (https://www.rcr.ac.uk/publication/irmer-implications-diagnostic-imaging-interventional-radiology-diagnostic-nuclear-medicine) and radiotherapy (https://www.rcr.ac.uk/sites/default/files/guidance-on-irmer-implications-for-clinical-practice-in-radiotherapy.pdf).

Public Health England (PHE)^[footnote 48] and the medical societies have provided IR(ME)R guidance for diagnostic and radiotherapy exposures. Two documents, <u>Ionising Radiation (Medical Exposure) Regulations: Implications for clinical practice in radiotherapy</u>

(https://www.rcr.ac.uk/sites/default/files/guidance-on-irmer-implications-for-clinical-practice-in-radiotherapy.pdf) and lonising Radiation (Medical Exposure)
Regulations: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine
(https://www.rcr.ac.uk/publication/irmer-implications-diagnostic-imaging-interventional-radiology-diagnostic-nuclear-medicine) explain how regulations should be interpreted in clinical practice. The latter document also extends to research laboratories, universities and sports facilities where medical and non-medical exposures are undertaken.

Medical and non-medical exposure regulators and relevant government departments

Regulators

The <u>Care Quality Commission (CQC) (https://www.cqc.org.uk/)</u>, established by the Health and Social Care Act 2008, is the 'enforcing authority' in England under HSWA74 in relation to the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R). The CQC is an executive non-departmental

public body^[footnote 49]. CQC's sponsoring government department is the Department for Health and Social Care.

The CQC regulates all health and social care services in England. Part of CQC's role is to ensure that medical and non-medical use of ionising radiation is carried out in accordance with the regulations in order to minimise the risk to patients in hospitals, dentists, ambulances, and care homes.

In Wales, Welsh ministers have the function of ensuring compliance with IR(ME)R and this is exercised through Healthcare Inspectorate Wales (HIW) (https://hiw.org.uk/), an operationally independent part of the Welsh Government.

Healthcare Improvement Scotland (HIS)

(http://www.healthcareimprovementscotland.org/), established by the National Health Service (Scotland) Act 1978, has broad powers to inspect and monitor the quality of healthcare in the NHS and the independent sector. The Act allows Scottish ministers to delegate to HIS, by order, such of their functions relating to the health service as they consider appropriate, including ensuring compliance with IR(ME)R. Inspectors for IR(ME)R sit within HIS.

In NI, the <u>Regulation and Quality Improvement Authority (RQIA)</u> (https://www.rqia.org.uk/) is the designated regulatory body for inspection and enforcement under the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018. The RQIA is a non-departmental public body (NDPB) sponsored by the <u>Northern Ireland Department of Health</u> (https://www.health-ni.gov.uk/).

IR(ME)R provides relevant enforcement authorities with powers arising from the HSWA74 to enter premises, interview staff, and to access or obtain information for the purpose of checking compliance with the regulations, for investigating notifications of incidents relating to medical and non-medical ionising radiation, and to initiate enforcement action.

Government departments

The <u>Department for Health and Social Care (DHSC)</u> (https://www.gov.uk/government/organisations/department-of-health-and-social-care) is a ministerial department, supported by 15 arm's length bodies and a number of other agencies and public bodies. As part of its remit, it is responsible for radiological protection of those exposed to ionising radiation as part of their own medical diagnosis or treatment in England. DHSC is the sponsoring department for the CQC and <u>Public Health England (PHE)</u> (https://www.gov.uk/government/organisations/public-health-england) [footnote 50] and the <u>Medicines and Healthcare products Regulatory Agency (MHRA)</u> (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-

<u>regulatory-agency</u>) who became the UK's standalone medicines and medical devices regulator on 1 January 2021.

PHE is an executive agency [footnote 51] of the DHSC. It is the UK's primary authority on health protection and carries out research to advance knowledge about protection from the risks of radiation across all sectors. PHE provides expert advice to government, national regulators in Scotland, Wales and Northern Ireland, international organisations, the public and others.

PHE also provides the secretariat for the Administration of Radioactive Substances Advisory Committee (ARSAC). The committee advises the licensing authorities on the granting, amendment and renewal of licences to employers and practitioners for the administration of radioactive substances on people e.g. as part of medical treatment. ARSAC also provides general guidance and advice to the health departments and healthcare professionals on the use of radioactive substances in clinical medicine and research. [footnote 52]

The MHRA is an executive agency [footnote 51] of the DHSC. It regulates medicines, medical devices and blood components for transfusion in the UK. This includes medical radiological equipment.

Scotland: The <u>Population Health Directorate (https://www.gov.scot/about/how-government-is-run/directorates/population-health/)</u> of the Scottish Government has policy responsibility for public health protection aspects following a radiation event and for radon. The Scottish Government's <u>Healthcare Quality and Improvement Directorate (https://www.gov.scot/about/how-government-is-run/directorates/healthcare-quality-and-improvement/)</u> is responsible for the sponsorship of HIS in respect of medical exposures regulation.

Wales: Ensuring compliance with the IR(ME)R in Wales is a function of the Welsh ministers, discharged through HIW.

NI: The <u>Department of Health (Northern Ireland) (https://www.health-ni.gov.uk/)</u> has principal responsibility for the RQIA which is responsible for regulating medical radiological exposure (patients). RQIA inspections are undertaken with specialist advice from PHE^[footnote 53].

Funding for each of the regulatory bodies in this area comes from their sponsoring government departments.

8. Public exposures and protection of the environment

Radioactive substances exist naturally in the environment and people can be exposed to this low-level radioactivity in their homes, through food and drinking water and from the atmosphere.

As set out in this document, radioactive substances are widely used by hospitals, universities and industry as well as in the nuclear power and defence industries. These activities may release radioactivity into the environment and to ensure that people and the environment are protected from the harmful effects of radioactive substances, activities involving radioactive substances are regulated.

Devolution

Environmental regulation is a devolved matter in the UK. This means that there are different environmental regulators in England, Scotland, Wales and NI and different regulations for protecting people and the environment from radioactive substances.

Radioactive substances are regulated by:

- The Environment Agency (EA) in England,
- The Scottish Environment Protection Agency (SEPA) in Scotland,
- · Natural Resources Wales (NRW) in Wales, and
- The Northern Ireland Environment Agency (NIEA) in NI

Collectively we refer to these agencies as the 'environmental regulators'. Different regulations apply in different parts of the UK, but they all have the same purpose: to protect people and the environment from the harmful effects of radioactive substances.

The environmental regulators regulate planned uses of radioactive substances and radioactive contaminated land left from past practices.

Planned uses of radioactive substances

Planned uses of radioactive substances occur when an operator intends to use radioactive substances for a particular activity, e.g. generation of electricity using a nuclear reactor or assessing the integrity of pipework using a radioactive source. It also includes circumstances where the operator undertakes an activity that changes the way in which people may be exposed to radioactive substances, e.g. the accumulation of naturally occurring radioactive substances during the extraction of oil and gas.

Relevant legislation

The regulations for the planned use of radioactive substances are:

- The Environmental Permitting Regulations (England and Wales) 2016 (EPR16) for England and Wales;
- The Environmental Authorisations (Scotland) Regulations 2018 (EASR18) for Scotland; and
- The Radioactive Substances Act 1993 (RSA93) as amended [footnote 54] and the High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005 for NI.

If an operator wants to work with radioactive substances in a planned use, they need to be authorised under the relevant regulations to do so. This may involve making an application to the relevant environmental regulator who will assess the application and decide if the operator should be allowed to undertake that activity. If the regulator decides that the operator can undertake that activity, they will grant an authorisation [footnote 55] that will apply limits and conditions on the operator. It should be noted that for nuclear site licensees, the keeping and use of radioactive material and accumulation of radioactive waste is regulated by the ONR.

The environmental regulators carry out inspections to ensure that operators are complying with the limits and conditions applied to them and if the operator is not complying, the environmental regulators can take enforcement action to make the operator comply. If necessary, fines and in some cases, prison sentences, can be applied to the operator for non-compliance.

When an operator no longer wants to carry on the activity that has been authorised, they can apply to surrender their authorisation. The relevant environmental regulator will assess the environmental impact of ceasing the activity and ensure that the operator will leave their premises in a satisfactory state before surrender is granted.

There are some lower risk activities using radioactive substances that an operator can carry on without needing permission from the relevant environmental regulator, for example the management of low activity sealed radioactive sources [footnote 56], the use of low quantities of radioactive substances for medical and veterinary uses and the management of smoke detectors containing radioactive sources. For these activities, the operator must comply with the general requirements set out in legislation, but does not need permission from the environmental regulator to carry on the activity.

Radioactive contaminated land

Land may be contaminated with radioactive substances from past practices when the legislation and standards were not as strict as they are today, or it may be contaminated from accidents that involved the release of radioactive substances. If that land might cause harm to people, it is regulated under the Environmental Protection Act 1990 (EPA90) and associated regulations which provide a system for identifying land contaminated with radioactive substances and give the environmental regulators powers to require the land to be cleaned up.

Security of sealed radioactive sources on non-nuclear sites

The security of sealed radioactive sources on non-nuclear sites is regulated by the environmental regulators. The security requirements for sealed radioactive sources are based on standards set by the IAEA and are incorporated in UK requirements set by the National Counter Terrorism Security Office (NaCTSO). NaCTSO is a police unit that supports the government's counter terrorism strategy. Conditions in environmental permits require operators to comply with the NaCTSO requirements and the environmental regulators work with Police Counter Terrorism Security Advisers (CTSAs) who advise on the adequacy of protective security measures for sealed radioactive sources.

Orphan sources

An orphan source is a radioactive source that should be regulated by the relevant environmental regulator but for some reason is not. This could be because the operator has failed to comply with the legislation, or because the source has been lost, abandoned or stolen. The government has duties to ensure that people working where an orphan source might be found, for example scrapyards, are aware that they may encounter them and that they have appropriate guidance issued to them. The environmental regulators have duties to ensure that advice and technical assistance is available to anyone who finds an orphan source. The environmental regulators also have powers to dispose of an orphan source or other radioactive waste if there is no-one else to do it legally.

International waste shipments

Whilst international conventions expect radioactive waste to be disposed of in the country in which it was generated, there are occasions when waste is imported and exported for treatment in another country.

Following the UK's exit from the EU and the end of the transition period on 31 December 2020, the Transfrontier Shipment of Radioactive Waste and Spent Fuel (EU Exit) Regulations 2019 came into force to ensure the safe shipment of radioactive waste between countries. The Regulations lay down regulatory procedures for the supervision and control of shipments of radioactive waste and spent fuel between the UK and other countries in a manner consistent with the provisions of Article 27 of the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. The regulations provide procedures for shipments to be authorised, consented to and appropriately documented, and for notification of arrival of shipments at their destination.

The environmental regulators are the competent authorities for authorising shipments into and out of their respective parts of the UK.

Imports of Radioactive Sources from the EU

The Transfrontier Shipment of Radioactive Waste and Spent Fuel (EU Exit) Regulations 2019 also ensure that imports of sealed radioactive sources into the UK from the EU are controlled and documented.

They provide that before a shipment of sealed sources can take place from the EU into the UK, consignees are required to make a prior written declaration demonstrating that they comply with national requirements for their safe storage, use and disposal. Declarations are sent by the consignee to the relevant competent authority in the UK, which acknowledge receipt of the declaration. The consignee will then forward the declaration and acknowledgment to the source holder before a shipment of sealed sources can take place. These prior written declarations will last up for to three years and may cover more than one shipment.

The appropriate regulators are the environmental regulators for non-nuclear sites, and the ONR for nuclear licenced sites.

Public exposures and protection of the environment regulators and relevant government departments

Regulators

The responsibility for protecting people and the environment from the harmful effects of radioactive substances lies with the environmental regulators:

- the <u>Environment Agency (EA)</u> (https://www.gov.uk/government/organisations/environment-agency) in England;
- the Scottish Environment Protection Agency (SEPA) (http://www.sepa.org.uk/) in Scotland;
- Natural Resources Wales (NRW) (https://naturalresources.wales/?lang=en) in Wales; and
- the Northern Ireland Environment Agency (NIEA) (https://www.daera-ni.gov.uk/northern-ireland-environment-agency) in NI

The environmental regulators work jointly where possible to ensure that consistent guidance is applied across the UK. At nuclear sites, the environmental regulators work closely with the ONR to ensure effective and efficient regulation. For example, the environmental regulators and the ONR carry out joint inspections and also consult each other on regulatory decisions that could have an impact on each other's regulatory responsibilities.

Government departments

England: The <u>Department for Environment</u>, <u>Food and Rural Affairs (Defra)</u> (https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs) has the principal responsibility for environmental protections in England and is the sponsoring department for the EA.

Scotland: The Environment and Forestry Directorate of the <u>Scottish</u> <u>Government (https://www.gov.scot/about/how-government-is-run/directorates/environment-and-forestry/)</u> has policy responsibility for radioactive waste and nuclear decommissioning in Scotland other than on a nuclear licensed site (which is regulated by the ONR). The Directorate has principal responsibility for SEPA in respect of radioactive substances regulation.

Wales: The Environment and Rural Affairs Directorate of the Welsh Government (https://gov.wales/environment-climate-change) has policy responsibility for radioactive waste and decommissioning in Wales other than on a nuclear licensed site (which is regulated by the ONR) and contingency planning for a radioactivity emergency. It also has principal responsibility for NRW.

NI: The <u>Department of Agriculture</u>, <u>Environment and Rural Affairs (DAERA)</u> (https://www.daera-ni.gov.uk/) has responsibility for regulating the keeping, use and disposal of radioactive substances; regulating radioactive transport by road, rail and inland waterway; emergency planning and response. The

Northern Ireland Environment Agency (NIEA) is an Executive Agency within DAFRA

Radon

Radon is a radioactive gas that comes from the rocks and soils found everywhere in the UK. People can be exposed to radon by it entering buildings through cracks in the foundations, from building materials, water, natural gas and in underground environments such as mines, caves and tunnels. Long term exposure to radon increases the risk of lung cancer, especially when combined with tobacco smoking.

The Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018 require the government to set reference limits for indoor exposure to radon and require it to publish information on radon, its health risks, its measurement, and how radon levels may be reduced. The regulations also require the government to establish a national action plan that addresses the risks of buildings being penetrated by radon.

The UK National Radon Action Plan (NRAP)

(https://www.gov.uk/government/publications/uk-national-radon-action-plan) was published by PHE in December 2018. The NRAP describes the UK's radon strategy from all significant radon sources, the arrangements that are in place for action on radon including reference levels, communications, measurements and mitigation in homes and workplaces, and identifies new topics for consideration.

Regulators for radon

Regulatory responsibility for radon lies with:

- The <u>Health and Safety Executive (HSE) (http://www.hse.gov.uk/)</u> and local authorities
- Public Health England (PHE) (https://www.ukradon.org/about/) [footnote 57] is the primary resource for advice about radon in the UK.

Radioactivity in food

Food (references to food include feed) can be contaminated with radioactive substances present in the environment. Therefore, the impact on food is considered by the environmental regulators working together with the food safety regulators.

Responsibility for regulating food safety lies with the Food Standards Agency (FSA) in England, Wales and NI and with Food Standards Scotland (FSS) in Scotland. In the UK, the environmental regulators consult the FSA and FSS where relevant on food safety as part of the process for determining applications for the use of radioactive substances.

The FSA conducts radiological monitoring of food in England, Wales and Northern Ireland. In Scotland, the radiological monitoring of food and the environment is undertaken by SEPA which works closely with the FSS to develop a holistic monitoring programme for radioactivity in food and the environment.

The FSA, FSS and environmental regulators' food and environmental monitoring results are published annually in the joint Radioactivity in Food and Environment Report (RIFE)[footnote 58]. The FSA also publishes food monitoring data on its website.

Food may also be treated by exposure to ionising radiation in a process known as food irradiation. This may be used to reduce the presence of food poisoning and spoilage bacteria, to delay ripening or prevent the inadvertent transit of invasive insects.

A food irradiation facility must be authorised before it can treat food. The FSA in England, Wales and NI and the FSS in Scotland authorise and regulate food irradiation facilities. In addition, a food irradiation facility must be authorised by the appropriate environmental regulator for the use of radioactive substances.

Regulators for Food Safety

Regulatory responsibility for food safety lies with:

- the <u>Food Standards Agency (FSA) (https://www.food.gov.uk/)</u> in England, Wales and NI; and
- Food Standards Scotland (FSS) (https://www.foodstandards.gov.scot/) in Scotland.

The FSA and FSS work together with the environmental regulators to ensure food safety is considered when regulating the use of radioactive substances.

FSA in England, Wales and NI and FSS in Scotland authorise and regulate food irradiation facilities.

Radioactivity in drinking water

Responsibility for drinking water safety lies with the Drinking Water Inspectorates for England, Wales and NI and the Drinking Water Quality Regulator in Scotland. They regulate public supplies provided by water companies and licensed suppliers of water that is intended for human consumption including in cooking, drinking, food preparation and other domestic purposes as well as water used in food production undertakings.

Regulators for drinking water safety

Regulatory responsibility for drinking water safety lies with:

- the <u>Drinking Water Inspectorate (DWI) (http://www.dwi.gov.uk/)</u> in England and Wales,
- the <u>Drinking Water Quality Regulator (DWQR) (https://dwqr.scot/)</u> in Scotland, and
- the <u>Drinking Water Inspectorate (DWI) (https://www.daera-ni.gov.uk/topics/water/drinking-water)</u> in NI

9. Consumer products and radiation

Any business that makes, imports, distributes or sells consumer products in the UK is responsible for making sure that the products are safe for consumers to use. In the case of any potential hazard - including ionising radiation - a producer or seller of products is obliged to produce an assessment of the risks based on an expert assessment before offering a product for sale. This includes products which may contain small radioactive sources, such as smoke detectors.

Relevant legislation

As set out in <u>chapter 4</u>, the JoPIIRR regulations require that before any new class or type of practice involving ionising radiation can be introduced, the government must first assess it to determine whether the individual or societal benefit outweighs the health detriment it may cause.

The General Product Safety Regulations 2005 (GPSR) require all products to be safe in their normal or reasonably foreseeable usage and enforcement authorities have powers to take appropriate action when this obligation is not met. Since leaving the EU on 31 January 2020 the GPSRs, along with other EU-based product safety law, have been adopted into UK law and continue to apply to businesses providing consumer goods in the UK following the end of the transition period.

There are also specific regulations or guidance for some product sectors, setting out essential safety requirements. Where there is a crossover with the GPSR, the product-specific legislation will usually take precedence. For example, relevant building material [footnote 59] is covered by the Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018.

Demonstrating compliance with the relevant regulations

Manufacturers and importers placing products on the UK market need to demonstrate that they comply with relevant safety requirements. This involves:

- minimising the risks associated with the product
- generating and keeping records of associated technical documentation
- placing appropriate labelling on the product
- providing instructions on how to use it safely

The use of agreed standards covering aspects of the product or its production process – where these exist – is one way to demonstrate compliance.

Consumer products regulators and relevant government departments

Regulators

Local Authority Trading Standards (https://www.tradingstandards.uk/consumers/support-advice) in England, Scotland and Wales and Environmental Health services (https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/environmental-health) in NI provide advice and support to manufacturers and importers in their local areas. They are responsible for investigating allegations of non-compliance.

Trading Standards officers can buy or seize goods to check they are safe. They may enter premises to carry out inspections of goods or request that the business provides technical documents relating to products or its processes.

A business could face action if a product is found to be unsafe or causes harm to consumers; this could include legal action.

Under JoPIIR, Agency Agreements between the <u>Department for Business</u> and Industrial Strategy (BEIS)

(https://www.gov.uk/government/organisations/department-for-business-energy-and-industrial-strategy) and the Health and Safety Executive (HSE)
(http://www.hse.gov.uk/) and the Health and Safety Executive Northern Ireland (HSENI) (https://www.hseni.gov.uk/) respectively delegate powers (during HSE and HSENI's normal course of inspections e.g. of a factory producing of consumer products) to determine if any practices are being carried out that are not justified including the presence of radioactive substances in consumer products. [footnote 60]

Government departments

The Office for Product Safety and Standards (OPSS) (https://www.gov.uk/government/organisations/office-for-product-safety-and-standards) is an office within BEIS. The OPSS provides information to consumers, businesses and regulators on product safety and enforces a range of technical, environmental and product legislation.

Public Health England (PHE)

(https://www.gov.uk/government/organisations/public-health-england) [footnote 61] is an executive agency [footnote 62] of the Department of Health and Social Care (DHSC) (https://www.gov.uk/government/organisations/department-of-health-and-social-care). It is the UK's primary authority on health protection and carries out research to advance knowledge about protection from the risks of radiation across all sectors.

10. Transport of radioactive materials (RAM)

The widespread use of radioactive substances in the UK means that radioactive materials (RAM) are regularly transported around the UK and are also transported into and out of the UK. This includes radiopharmaceuticals needed for use in hospitals, sealed radioactive sources needed by the construction industry and in the non-destructive testing of North Sea oil rigs as well as the movement of spent nuclear fuel from operating and decommissioning nuclear reactors.

Unlike other areas of the UK's safety framework, some RAM transport regulations are prescriptive and apply internationally. This is to enable the safe transport of packages containing RAM across international borders.

The UK has developed specific transport regulations based on international agreements and IAEA safety standards [footnote 63].

The ALARP principle (see <u>Chapter 3</u>] still applies to transport regulations. The ONR's inspectors seek ALARP solutions and encourage continuous improvements to safety during their assessment and inspection activities.

Regulations for the safe transport of RAM by road, rail and inland waterway

The regulatory framework for the transport of radioactive materials by road, rail and inland waterway in the UK is set out in:

- Part 3 of the Energy Act 2013;
- the Energy Act 2013 (Office for Nuclear Regulation) (Consequential Amendments, Transitional Provisions and Savings) Order 2014 (SI 2014 No. 469);
- the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (as amended) [footnote 64];
- the Carriage of Dangerous Goods (Amendment) Regulations 2019;
- the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010 (as amended) [footnote 65];
- the Carriage of Dangerous Goods (Amendment) Regulations (Northern Ireland) 2019;
- the Health and Safety at Work etc. Act 1974 and the Health and Safety at Work (Northern Ireland) Order 1978; and
- The Ionising Radiations Regulations 2017 and the Ionising Radiations Regulations (Northern Ireland) 2017

As well as implementing international agreements for the International Carriage of Dangerous Goods by Road (ADR), International Carriage of Dangerous Goods by Rail (RID) [footnote 66] (and limited provisions of European Agreement Concerning the International Carriage of Dangerous Goods by Inland Waterways (ADN)), these regulations set out requirements for preparing for and responding to potential radiological emergencies during the transport of radioactive material. The regulations place duties upon everyone involved in the carriage of dangerous goods to ensure that they know what they have to do to minimise the risk of incidents and guarantee an effective emergency response.

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (as amended) and the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010 (as amended) were further amended in 2019. This implemented the EP&R elements of the BSSD13. [footnote 67]

RAM transport by sea

The principal legislation for RAM transport for British registered ships and all other ships while in UK territorial waters is contained within the Merchant Shipping Act 1995 (MSA95) and associated regulations:

- Merchant Shipping (Dangerous Goods and Marine Pollutants)
 Regulations 1997 (SI 1997 No. 2367);
- The Merchant Shipping Notice (MSN) 1893 (M) The Carriage of Dangerous Goods and Marine Pollutants in Packaged Form: Amendment 39-18[footnote 68]; and
- The Merchant Shipping (Carriage of Packaged Irradiated Nuclear Fuel etc.) (INF Code) Regulations 2000, (SI 2000 No. 3216) covers the regulatory requirements for ships carrying spent fuel. [footnote 69]

The above regulations are enforced by the Maritime and Coastguard Agency (MCA). Under MSA95, MCA surveyors appointed by the SoS for Transport have powers, under separate legislation to board ships, survey vessels and consider the stowage and segregation requirements to ensure that they comply fully with the requirements of the International Maritime Dangerous Goods (IMDG) Code. MSA95 also provides the MCA with the powers to detain ships and issue Prohibition Notices and Improvement Notices. Where necessary the MCA can prosecute owners/charterers/Masters etc. if they do not comply with the applicable legislation.

Although responsibility for the approval of the packaging or containment systems for the carriage of radioactive material lies with the MCA. The ONR can carry out this function on MCA's behalf under their Agency Agreement. [footnote 70] However, the ONR only approves higher hazard packages on behalf of the MCA i.e. those that legally require Competent Authority approval (e.g. Type B or fissile packages [footnote 71]). There are some packages e.g. Type A and below that do not require Competent Authority Approval. [footnote 72] Packaging not requiring Competent Authority approval is still required to comply with the applicable packaging requirements in the IMDG Code for the RAM being shipped.

The ONR also carries out a similar function of approving certain designs and shipments on behalf of the CAA and DAERA in respect of transport of RAM by air in the UK and by road in NI respectively under comparable agency agreements. [footnote 73]

The Merchant Shipping (Port State Control) Regulations 2011 and Merchant Shipping (Survey and Certification) Regulations 2015 provide a further framework for ship safety and provisions for inspections and surveys to be carried out on ships in UK waters.

RAM transport by air

The principal legislation for RAM transport for UK registered aircraft and all other flights, is contained within the Civil Aviation Act 1982 and associated regulations. These regulations apply to UK registered aircraft carrying dangerous goods whether the flight is wholly or partly within or wholly outside of the UK. All non-UK registered aircraft should have an approval, from the State of Operator [footnote 74], to carry dangerous goods by air, granted by the State of Operator. Additionally, they are required to comply with the UK regulations while flying in UK airspace.

The associated Regulations are:

- the Air Navigation Order 2016 (ANO) as amended;
- the Air Navigation (Dangerous Goods) Regulations 2002 (AN(DG)R);
- the Air Navigation (Dangerous Goods) (Amendment) Regulations 2017);
 and
- DOC 9284 International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI) as amended.

In addition, there are two EU regulations which regulate the transport of dangerous goods, including RAM, by air:

- Regulation (EU) No 965/2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (the Air Ops Regulation) as retained (and amended in UK domestic law) under the European Union (Withdrawal) Act 2018;
- Regulation (EU) No. 2018/1139 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency (The Basic Regulation) (and amended in UK domestic law) under the European Union (Withdrawal) Act 2018

The above regulations are enforced by the Civil Aviation Authority (CAA) and. under Section 60 of the Civil Aviation Act 1982 and the ANO (2016), an authorised person e.g. a CAA inspector or others that are authorised by the Competent Authority [footnote 75] has the right of access at all reasonable times to:

- a) any aerodrome for the purpose of inspecting the aerodrome;
- b) any aerodrome for the purpose of inspecting any aircraft on the aerodrome or any document which it or the authorised person has power to demand under this Order, or for the purpose of detaining any aircraft under the provision of this order;
- c) any place where the aircraft has landed, for the purpose of inspecting the aircraft or any document which it or the authorised person has power to demand under this Order and for the purpose of detaining the aircraft under the provisions of this Order;
- d) any equipment used or intended to be used in connection with the provision of a service to an aircraft in flight or on the ground; or
- e) any document or record which the authorised person has power to demand under this Order.

The CAA is tasked by the Department for Transport (DfT) to conduct audits and inspections concerning all activities associated with dangerous goods in air transport including acceptance, packing, marking, documenting, loading and carriage by the aircraft operator, shippers, ground handling agents and freight forwarders.

It is further tasked to investigate and enforce in respect of apparent breaches of aviation safety rules, including dangerous goods offences. Where necessary the CAA can prosecute shippers/freight forwarders/ground handling agents and suspend or revoke dangerous goods approvals if they do not comply with the applicable legislation.

Where a shipment is suspected to be in breach of the AN(DG)R it may also be in breach of the regulations applicable to surface transport i.e. road or rail when carried to or from the airport. In such circumstances the CAA collaborates with the ONR on any following investigation and enforcement.

Although responsibility for the approval of the packaging or containment systems for the carriage of radioactive material lies with the HSE, the ONR may carry out this function on CAA's behalf under an Agency Agreement (http://www.onr.org.uk/documents/2014/caa-aa.pdf). However, the ONR only approves higher hazard packages on behalf of the CAA i.e. those that legally require Competent Authority approval (e.g. Class 7 goods). There are some packages e.g. Type A and below that do not require Competent Authority approval. Packaging not requiring Competent Authority approval is still required to comply with the applicable packaging requirements in the ICAO TI for the RAM being shipped.

Transport regulators – radioactive material, and relevant government departments [footnote 76]

Regulators

The regulators for the transport of radioactive material - which includes spent nuclear fuel and radioactive waste - depends on the mode of transport and, in some cases, the location. The table below summarises the regulators and modes of transport.

Table 1: Competent authorities and enforcing authorities for radioactive material transport

Mode of transport	GB (England, Scotland and Wales)	Northern Ireland
Road, rail, inland waterways	The Office for Nuclear Regulation (the ONR) (for CDG09 and IRR17)	The Northern Ireland Environment Agency (NIEA) (for CDG(NI)10 by road)
	The ONR, although in practice, inland waterways are not used for transporting radioactive material in GB	Health and Safety Executive Northern Ireland (HSENI) for rail and inland waterways (under IRRNI17 and rail and inland waterway under CDG(NI)10). In practice rail and inland waterways are not used for transporting radioactive material in NI.
Sea	The Maritime and Coastguard Agency (MCA) (for Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997)	The Maritime and Coastguard Agency (MCA) (for Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997)
Air	The <u>Civil Aviation</u> <u>Authority (CAA)</u> (for Air Navigation (Dangerous Goods) Regulations 2002)	The <u>Civil Aviation Authority (CAA)</u> (for Air Navigation (Dangerous Goods) Regulations 2002)

Road, rail and inland waterway

The ONR is the regulatory body for road, rail and inland waterway RAM transport in GB. Inspection and enforcement powers for road, rail and inland

waterway transport derive from the TEA13 and HSWA74. The Health and Safety (Enforcing Authority) Regulations 1998 make the ONR the enforcing authority for IRR17 in respect of dutyholders transporting radioactive material.

The ONR recovers costs from industry for transport package approvals. For work not requested by the dutyholder, such as compliance inspections and spot checks, the ONR receives a funding grant from the DWP.

In NI, the NIEA is the enforcing authority for radioactive material by road while HSENI is the enforcing authority by rail and inland waterway. NIEA derives its inspection and enforcement powers from HSW(NI)O78 and the transport regulations beneath it. NIEA's powers are broadly similar to the ONR's transport powers.

The ONR regulates the transport of RAM between civil sites, or RAM being carried by road, rail and on some inland waterways, and material transported to other non-nuclear sites, such as hospitals.

Air

The <u>Civil Aviation Authority (CAA) (https://www.caa.co.uk/home/)</u> is tasked by the Department for Transport (DfT)

(https://www.gov.uk/government/organisations/department-for-transport) to enforce regulations for air transportation of dangerous goods. This covers shippers, freight forwarders, the designated postal operator, ground handling agents involved with processing cargo/mail or passengers and their baggage, security screening personnel and all UK commercial air transport (CAT) air operators (regardless of whether they transport dangerous goods as cargo). The majority of CAA's costs are recovered from those that it regulates via Statutory Charges Schemes.

In response to non-compliance, the CAA may issue a warning letter, audit finding or suspend/revoke a UK air operator's approval for the transport of dangerous goods by air. Serious one-off or repeated non-compliance can lead to criminal prosecution. In Scotland, these are conducted by the Procurator Fiscal.

Sea

The Maritime and Coastguard Agency (MCA)

(https://www.gov.uk/government/organisations/maritime-and-coastguard-agency) is directed by the Department for Transport (DfT)

(https://www.gov.uk/government/organisations/department-for-transport) to develop policy and enforce the requirements of the International Maritime Dangerous Goods Code (IMDG Code) for the safe transport of dangerous goods by sea. This covers shippers, carriers and freight forwarders and the MCA's remit also includes inspection and certification of ships, the certification of crews and the inspection of foreign flagged vessels whilst in UK ports, through a number of applicable SIs. The MCA is able to recover

costs for some of its activities from those that it regulates via Statutory Fee Regulations.

Under the Merchant Shipping Act 1995 (MSA95), the MCA and its surveyors appointed by the Secretary of State for Transport are assigned responsibility to inspect and if required can detain ships and issue Prohibition Notices and Improvement Notices if they do not comply with the Act and any applicable SIs.

The HSE has responsibility for the safety of dangerous goods (including Class 7^[footnote 77]) when they come into or out of a Port Area under the Dangerous Goods in Harbour Areas Regulations 2016. The exemption to this is any harbour which is, or forms part of a nuclear build site; there the ONR is the regulator [footnote 78]. The equivalent legislation for NI is the Dangerous Substances in Harbour Areas Regulations (Northern Ireland) 1991. NI does not have any nuclear sites or regulation by the ONR.

Government departments

The Department for Transport (DfT)

(https://www.gov.uk/government/organisations/department-for-transport) is responsible for the policy framework for the transport of dangerous goods, with the exception of Class 7 and is the sponsoring department for the Civil Aviation Authority (CAA) (https://www.caa.co.uk/home/) and the Maritime and Coastguard Agency (MCA)

(https://www.gov.uk/government/organisations/maritime-and-coastguard-agency).

The <u>Department for Business</u>, <u>Energy and Industrial Strategy (BEIS)</u> (https://www.gov.uk/government/organisations/department-for-business-energy-and-industrial-strategy) is responsible for the transport of radioactive material (Class 7 dangerous goods) by road, rail and inland waterways.

The Northern Ireland Environment Agency (NIEA) (https://www.daera-ni.gov.uk/northern-ireland-environment-agency) is an Executive Agency within the Department of Agriculture, Environment and Rural Affairs (DAERA) (https://www.daera-ni.gov.uk/).

11. Emergency preparedness and response (EP&R)

The UK has strong national arrangements for emergencies involving radioactive substances or nuclear material and maintains national level modelling and monitoring and scientific advisory capabilities to be used in the unlikely event of an emergency.

The central government's Concept of Operations (https://www.gov.uk/government/publications/the-central-government-s-concept-of-operations) sets out the UK arrangements for responding to and recovering from emergencies, irrespective of cause or location and requiring co-ordinated central government action. It describes how the UK central government response will be organised, the relationship between the central, regional and local tiers in England, and as the relationship between the UK central government and the devolved administrations in Scotland, Wales and Northern Ireland.

Relevant legislation

The Civil Contingencies Act 2004 (CCA) and <u>accompanying non-legislative measures</u> (https://www.gov.uk/government/publications/emergency-preparedness) deliver a single framework for civil protection in the UK. The CCA arrangements provide the underpinning approach to all emergency response activity in the UK, which is then enhanced with further specific arrangements, including regulation, for some emergency types (including civil nuclear).

The CCA establishes a clear set of roles and responsibilities for those involved in emergency preparedness and response at the local level. It identifies "Category 1 responders", who must assess the risk of an emergency occurring and maintain plans for dealing with that emergency. They include the GB environmental regulators (EA, NRW and SEPA), local authorities and the emergency services.

Emergency planning is at the heart of the civil protection duty on Category 1 responders under the CCA. The Act requires Category 1 responders to maintain plans for preventing emergencies, reducing, controlling or mitigating the effects of emergencies, and taking other action in the event of emergencies. Requirements also include: training key staff; exercising the plan to ensure it is effective; reviewing the plan periodically and keeping it up to date. Plans should draw on risk assessments and should have arrangements to warn, inform and advise the public at the time of an emergency.

Specific preparation for radiological emergencies

The CCA is the overarching piece of EP&R legislation in the UK. It delivers a single generic framework for civil protection in the UK. The act sets out clear roles and responsibilities for those involved in EP&R at a local level.

Emergency responders must prepare for and minimise the impact of all hazards.

Specific EP&R arrangements for GB sites using radioactive substances are set out in the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR19) to make appropriate arrangements for the unique characteristics of ionising radiation hazards and their potential consequences.

REPPIR19 defines a "radiation emergency" as a non-routine situation or event arising from work with ionising radiation that necessitates prompt action to mitigate the serious consequences—

- (a) of a hazard resulting from that situation or event;
- (b) of a perceived risk arising from such a hazard; or
- (c) to any one or more of—
- (i) human life;
- (ii) health and safety;
- (iii) quality of life;
- (iv) property;
- (v) the environment

REPPIR19 places duties on operators and Local Authorities to put in place proportionate plans onsite and offsite. The regulations require the operator to make a detailed evaluation of the hazards posed from their activities and the potential consequences, to provide sufficient information to the relevant Local Authority to allow a detailed emergency planning zone (DEPZ) to be determined.

For example, in the case of licenced nuclear sites, there are DEPZs around all the higher hazard nuclear sites in the UK. These zones (between 1 and 7km) are focused on having capabilities in place, maintained and ready to implement very quickly during an emergency. Capabilities in these detailed emergency planning zones include sheltering, evacuation, provision of stable iodine and communications.

For nuclear sites, REPPIR19 requires outline planning and sets default outline planning zones (OPZ) proportionate to the risk from the sites. For example, OPZs are set at 30km for operating nuclear power plants and 50km around Sellafield. In these zones, local planners should consider how arrangements in the DEPZ could be extended across the OPZ and, at a high level what could be required in a less likely, but more serious event and where to obtain it, rather than having the capabilities in place, maintained and ready to go.

In addition, the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG09) and the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010 set out requirements for emergency planning and response for transport radiological emergencies, as set out in chapter 10.

The National Resilience Capabilities Programme

In addition to requiring local preparedness, the Cabinet Office, specifically the Civil Contingencies Secretariat, runs the Resilience Capabilities

Programme (RCP) (https://www.gov.uk/guidance/preparation-and-planning-for-emergencies-the-capabilities-programme) which aims to continuously improve the UK's capability to respond to and recover from civil emergencies. It does this by understanding what capabilities are needed to deal with the consequences of emergencies, regardless of whether those emergencies are caused by accidents, natural hazards or man-made threats. The Programme then coordinates cross-government efforts to build capabilities.

Central government coordination

Where COBR is activated in response to a no-notice incident [footnote 80], its default strategic objectives are to:

- protect human life and, as far as possible, property and the environment;
- · alleviate suffering;
- support the continuity of everyday activity and the restoration of disrupted services at the earliest opportunity; and
- uphold the rule of law and the democratic process.

To achieve these strategic objectives, the UK government will undertake to:

react with speed and decisiveness;

- respect local knowledge and decision-making wherever possible, without losing sight of the national strategy;
- prioritise access to scarce national resources;
- use data and information management systems to gain a national picture and support decision-making, without overburdening front-line responders;
- base policy decisions on the best available science and ensure that the processes for providing scientific advice are widely understood and trusted;
- draw on existing legislation to respond effectively to the emergency and consider the need for additional powers;
- apply risk assessment methodology and cost benefit analysis within an appropriate economic model to inform decision-making;
- work with international partners to share information and request assistance if necessary; and
- explain policies, plans and practices by communicating with interested parties (including the public) comprehensively, clearly and consistently, in a transparent and open way that addresses national and local concerns while encouraging and listening to feedback.

Devolved administrations and emergency preparedness and response

Within Scotland and Wales, some matters are reserved to the UK government whilst others are devolved to the Scottish and Welsh governments. Whatever the cause of an emergency, whether it is a reserved matter or not, the consequences are always devolved, and the consequence response will be led by Scottish or Welsh Government ministers as appropriate.

Scotland

In Scotland, the CCA 2004 and the Civil Contingencies Act 2004 (Contingency Planning) (Scotland) Regulations 2005 reflect the Scottish Government's commitment to enhancing the UK's resilience and form Scotland's contribution to the legislative framework. They provide a clear single framework for civil protection involving key agencies to work within when planning for and dealing with emergencies.

<u>Preparing Scotland (https://www.readyscotland.org/ready-government/preparing-scotland/)</u> is the statutory guidance for the Contingency Planning (Scotland) Regulations 2005 and describes the Scottish emergency planning philosophy, structures and good practice that support local response and recovery following emergencies.

Dependant on the scale of the emergency, the Scottish Government may choose to activate the Scottish Government Resilience Room (SGoRR). This is the co-ordination centre for the Scottish Government's corporate response activity. SGoRR has connectivity to COBR and will be the route of communication between the UK government and the Scottish Government should the scale of the emergency require both to be active.

Wales

In Wales, The Welsh Ministers (Transfer of Functions) Order 2018 (TFO) transferred functions under Part 1 of the CCA 2004 to Welsh ministers which had previously been exercisable by a minister of the crown. These powers now permit Welsh Ministers to make regulations under certain areas of the Act, produce guidance and issue directions in relation to devolved services. There is currently a period of transition as the TFO provides that the Civil Contingency Act 2004 (Contingency Planning) Regulations 2005 will remain in place for Wales until the first regulations are made by the Welsh ministers under Section 2 or 4 of the Act. The First Minister has agreed to a full review of the governance of resilience in Wales to establish a structure around which the new regulations will be built which will provide a framework for emergency planning, response and recovery.

The Welsh Government is the lead government department for consequence management and recovery in Wales – this includes devolved emergency responders and agencies with a role in radiological response and recovery. The decision on whether to activate the Emergency Coordination Centre (Wales) (ECC(W)) will depend upon the nature and extent of any emergency in or affecting Wales. ECC(W) is the co-ordination centre for the Welsh Government's corporate response activity. ECC(W) would be the route of communication between COBR and any multi-agency Strategic Co-ordinating Groups established in Wales to manage the response to a radiological incident.

Northern Ireland

In NI, civil protection is largely a devolved matter, with functions being exercised by the NI departments. Some functions are not devolved and are delivered in NI by bodies that fall within the remit of the UK government.

The Northern Ireland Civil Contingencies Framework (https://www.executiveoffice-ni.gov.uk/publications/civil-contingencies-policy-branch-guidance-documents) sets out how NI public service organisations will discharge their civil contingencies responsibilities. The framework consolidates existing policy on civil protection in the public sector with developments arising from, among other things the CCA, guidance to GB government departments, the UK Capabilities programme and the changing social and political environment in which civil contingencies activities take place.

By working within this framework, it is expected that:

- public service organisations at NI regional, sub-regional and local levels will have a clear understanding of what is required of them in terms of civil protection and will be committed to fully playing their part in civil protection for Northern Ireland;
- organisations will work to the same set of policies, principles and standards, which they will apply flexibly depending on their functions and responsibilities;
- co-ordination will be facilitated by a shared approach. This shared approach will include a common system of risk assessment and contingency planning across the NI public services;
- communication will be encouraged as all organisations commit themselves to working together to achieve common goals;
- public service organisations will resource civil protection to the required level; and
- commitment will be visible and standards will be auditable and consistent between and within NI public sector organisations.

National modelling and monitoring capabilities

Since the Chernobyl disaster in 1986, the UK has maintained a network of gamma dose rate monitors. This network, known as RIMNET (https://www.gov.uk/government/collections/radioactive-incident-monitoring), currently consists of 96 fixed and 112 mobile gamma dose rate monitors. The fixed monitors are distributed geographically evenly across the UK and the mobile monitors are positioned along coastlines and around civil nuclear facilities.

The UK is in the process of updating the online network and information management system which supports these monitors. This will improve how emergency dose information is shared quickly and effectively.

The UK also has a modelling capability known as Joint Agency Modelling (JAM). This capability builds on lessons learned from the Fukushima disaster in 2011. JAM brings together modelling expertise from the Met Office, PHE^[footnote 81], the ONR, the environmental regulators and food standards agencies in the event of an emergency to provide advice on projected doses and compare predictions against protective action criteria.

Emergency planning regulators

Enforcement responsibility for the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR19) (except in Northern Ireland) is split between the Office for Nuclear Regulation (the ONR) (http://www.onr.org.uk/) for licensed civil nuclear sites falling in scope of REPPIR19 and the Health and Safety Executive (HSE) (http://www.hse.gov.uk/) for radiological sites falling in scope of REPPIR19 [footnote 82]. The Health and Safety Executive Northern Ireland (HSENI) (https://www.hseni.gov.uk/) is the enforcing authority in NI. The requirements in REPPIR19 and the equivalent regulations in NI, which cover provision of information to the public, planning for and the execution of a plan in the event of an emergency, require coordination and cooperation between those agencies that may have a role in an emergency response.

Following a nuclear or other radiological emergency, the <u>Food Standards</u> <u>Agency (FSA) (https://www.food.gov.uk/)</u> or <u>Food Standards Scotland (FSS) (https://www.foodstandards.gov.scot/)</u> may consider using emergency controls to protect the public. The aim of these controls will be to prevent unsafe food from entering the food chain, for example food that exceeds, or potentially exceeds, the Maximum Permitted Levels established by legislation. The FSA/FSS may advise the SoS or devolved administrations to issue statutory restriction orders made under the Food and Environment Protection Act 1985 (FEPA).

The enforcing authority for transport radiation emergencies for the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG09) (except in Northern Ireland) is the ONR. In Northern Ireland, the Northern Ireland Environment Agency (NIEA) (https://www.daera-ni.gov.uk/northern-ireland-environment-agency) regulates radioactive transport on roads under the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010. The requirements in CDG09 and the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010 also cover provision of information to the public, planning for and the execution of a plan in the event of an emergency and require coordination and cooperation between all State agencies that may have a role in emergency response.

12. Maintaining the UK's framework for safety

The UK government and regulators maintain the framework for radiation protection and nuclear safety and work to ensure our approach remains consistent with international good practice. The framework is kept constantly under review with regards to safety, security, safeguards and the

transport of radioactive material to ensure that it remains world class. This chapter sets out the three main ways in which this is achieved.

International standards and conventions

The regulation of nuclear safety, security, safeguards and the transport of radioactive material operates within a global context of international law, obligations, standards and guidance. The UK supports a significant portfolio of international work with the IAEA, OECD-NEA and other standard-setting bodies which enables it to influence standard-setting globally, learn from relevant international good practice and maintain alignment with international obligations, standards and conventions. The UK is an active participant in standards development, providing technical expertise and research to promote high safety standards. Annex E of this document sets out further examples of areas where the UK supports the technical work of international agencies, working groups and committees.

The UK is committed to adopting international standards into UK laws, regulation and guidance. The UK's transposition of BSSD13 and the regulatory changes that were made to bring it into force have ensured that the UK remains in line with international safety standards. BSSD13 laid down minimum standards for occupational, medical, environmental, and public exposures as well as for emergency preparedness [footnote 83].

Regulators also take relevant international good practice and implement it into the UK domestic context. For example, the ONR has incorporated good practice identified by the IAEA and WENRA into its TAGs, TIGs, and SAPs which are benchmarked against the IAEA's <u>Safety Standards</u> (https://www.iaea.org/resources/safety-standards). These guides help employers determine what good compliance looks like in the context of their operations.

With regards to research relating to the health consequences associated with radiation, PHE contributes to the work of international organisations such as the IAEA, OECD-NEA, World Health Organisation, UNSCEAR and the European Council to advance global understanding in this area.

In addition, the UK contributes to the work of the ICRP. The ICRP provides authoritative advice and recommendations that are incorporated into radiological protection systems and standards worldwide, including in the UK.

The UK is also a full and proactive signatory to the CNS and the JoC. Both Conventions require the UK to submit reports showing how it has implemented its obligations under the Conventions. These reports are then

subject to international peer review. Feedback from the peer review process helps the UK to ensure an effective framework and maintain a high level of safety in its civil nuclear programme, as well as contributing to promoting nuclear safety worldwide.

In addition to the above, the UK is a signatory to the IAEA <u>Code of Conduct on the Safety and Security of Radioactive Sources</u>

(https://nucleus.iaea.org/sites/ns/code-of-conduct-radioactive-sources/Pages/default.aspx#:~:text=The%20Code%20of%20Conduct%20on,instrument%20issued%20by%20the%20IAEA.&text=The%20Code%20was%20published%20by,their%20support%20for%20the%20Code).

Enabling the regulation of new technologies

The UK government also maintains its framework for safety by ensuring that regulators can regulate new technologies, such as Advanced Nuclear Technologies (https://www.gov.uk/government/publications/advanced-nuclear-technologies), (otherwise known as small nuclear or small reactor technologies). These encompass a wide range of nuclear reactor technologies under development.

A key part of the UK's <u>Advanced Nuclear Technologies Framework</u> (https://www.cleanenergyministerial.org/publications-clean-energy-ministerial/advanced-nuclear-technologies-uk-framework) is the regulatory readiness workstream which aims to ensure that advanced reactor companies are ready to participate in the UK's formal regulatory processes and that the regulatory processes can accommodate them. To support this, the ONR and EA are reviewing guidance and processes to ensure they continue to be fit for purpose and accessible for small nuclear projects. They are also undertaking a significant programme of work to build capability and capacity to assess Advanced Nuclear Technologies.

In parallel with the BEIS <u>Advanced Modular Reactor (AMR) Feasibility and</u> Development (F&D) project

(https://www.gov.uk/government/publications/advanced-modular-reactor-amr-feasibility-and-development-project), the Clean Energy Ministerial (CEM) (https://www.cleanenergyministerial.org/about-clean-energy-ministerial) is investing up to £12 million to build capability and capacity to regulate Small and Advanced Modular Reactors.

International peer reviews

International peer reviews are another mechanism that supports the UK in maintaining its framework for nuclear safety and radiation protection. The IAEA offers its Member States a range of review services. The UK actively participates in these peer reviews in which an IAEA-led team of international experts compares current practices with IAEA standards. Provided below is further information on safety-specific peer reviews that the UK has hosted.

Integrated Regulatory Review Service (IRRS)

IRRS missions are important as they are the only independent review of IAEA Member States' regulatory infrastructure for radiological and nuclear safety. Missions take place at the invitation of the host country and consist of a comprehensive peer review of its regulatory infrastructure for safety against IAEA safety standards.

The most recent IRRS mission to the UK was conducted in 2019 and covered the following wide-ranging areas: responsibilities and functions of the government and regulatory bodies; how the UK participates in the global nuclear and radiation safety regime; management systems of the regulatory bodies, regulatory processes including authorisation, review and assessment, inspection, enforcement and the development of regulations and guides; emergency preparedness and response; and the interfaces with nuclear security.

During the 2019 mission the IAEA found that the UK is committed to strengthening its regulatory framework for nuclear, radiation, radioactive waste and transport safety. They identified strengths in the UK's regulatory authorities, including the competence of staff and the extensive regulatory guidance that has been developed for those legally responsible for nuclear and radiation safety. The IAEA's report, together with a government response is available on GOV.UK.

In addition to being reviewed by the IRRS, the UK supports and provides experts to take part in other countries' IRRS missions.

Operational Safety Review Team (OSART)

The focus of OSART missions is on identifying gaps between nuclear power plant operations and the requirements outlined in the IAEA Safety Standards. During an OSART mission, a team of international experts conducts in-depth reviews of operational safety performance at a nuclear power plant. They review the factors affecting the management of safety and the performance of personnel. The UK's most recent OSART mission

took place at the Torness nuclear power station in 2018 with the follow up mission in 2019.

13. Regulatory transparency

A key feature of the UK's framework is ensuring appropriate transparency. To support public confidence in the UK's regulatory framework, and in line with IAEA safety standards, UK regulators inform the public and other interested parties about the safety aspects (including health and environmental aspects) of facilities and activities and about regulatory processes.

Duty on regulators

In the UK, there are provisions in law which require regulators and employers to share information relating to radiological safety. For example:

- Under Section 92(1) of TEA13 the SoS made a <u>Direction requiring the ONR (http://www.onr.org.uk/documents/2017/direction-supply-of-information.pdf)</u> to share information on nuclear safety and to ensure that licence holders share information on nuclear safety.
- REPPIR19 sets out requirements in relation to the provision of information to the public in relation to possible radiation risks from GB nuclear licensed sites radiological sites and new nuclear build sites[footnote 85]. Further information on REPPIR19 is set out in chapter 11.
- Under the Environmental Permitting Regulations (England and Wales) 2016 (EPR16), EA and NRW publish public participation statements (PPS) [footnote 86]. SEPA publishes its PPS (https://www.sepa.org.uk/media/372006/public_articipation_statement.pdf) under the Environmental Authorisations (Scotland) Regulations 2018 (EASR18). The PPSs set out:
 - when the environmental regulators consult on permitting applications
 - how they consult on applications of high public interest
 - · how they publicise permitting applications
 - the timescales for consultation
 - how they record and publish permit decisions
 - how they develop and consult on standard rules for authorisations

Publication of enforcement action taken by regulators

Regulators use their judgement in deciding when to investigate or what enforcement action may be appropriate. In line with best practice, UK regulators make public any enforcement action taken. Further details can be found on regulators websites at the addresses within this document. [footnote Publicising enforcement actions primarily serves to provide a transparent mechanism by which regulators can inform the public and other interested parties about the actions they have taken. It can also provide a wider deterrent for non-compliance.

Independent monitoring

The UK regulates radioactive discharges to ensure that they do not harm the public or the environment. Independent monitoring is a key method of demonstrating transparency and retaining public trust. Below are some examples of independent monitoring conducted in the UK:

- The FSA, FSS and environmental regulators' food and environmental
 monitoring results are published jointly on an annual basis in the
 Radioactivity in Food and Environment Report (RIFE)
 (https://www.gov.uk/government/publications/radioactivity-in-food-and-theenvironment-rife-reports). The FSA also publishes food monitoring data on
 its website.
- People who live, work or carry out recreational activities near nuclear sites take part in regular <u>habit surveys</u> (https://www.food.gov.uk/search/research) which look at their habits and consumption patterns. This information helps work out how much radiation members of the public are exposed to from these sites.
- The National Dose Assessment Working Group (NDAWG) formerly brought together organisations that assess the public' exposure to radiation from the nuclear industry and other users of radioactive material, such as hospitals or universities and produced a <u>number of guidance notes and reports (https://srp-uk.org/resources/national-dose-assessment)</u>. The environment and food regulators, the ONR and PHE [footnote 88] continue to meet as the Practitioner Group on the Impact of Radioactivity in the Environment (PGIRE) to review NDAWG publications and consider any updates as required.

Engagement with stakeholders

Regulatory bodies actively engage with stakeholders, including the public and other interested parties. Examples of engagement range from

publishing regulatory reports, such as RIFE, to attending meetings with local communities with an interest in the environment and safety. [footnote 89]

Consultations relating to nuclear safety and radiological protection can be found on the government consultation pages on the GOV.UK website, devolved administrations' websites, regulators' websites and other relevant sites.

The EIADR require the ONR to consult the relevant regulatory authorities, including the appropriate environmental regulator and local highway and planning authorities, together with the public and any other interested parties. Consultation is carried out during the pre-application opinion process in order to inform the ONR's opinion on the scope of a proposed nuclear decommissioning project, and during the application for consent for the decommissioning project to commence. Further information on EIADR is set out in chapter 6.

Members of the public can request information held by public authorities including government departments and regulatory bodies under the Freedom of Information Act 2000 and the Freedom of Information (Scotland) Act 2002 as well as the Environmental Information Regulations 2004 and Environmental Information (Scotland) Regulations 2004. [footnote 90]

The government facilitates transparency through its engagement with Non-Governmental Organisations (NGOs) and with the public through forums and public consultations. The Nuclear Non-Governmental Organisation Forum brings together Government with key NGOs and regulatory stakeholders, ensuring there is regular and high-level contact between all parties on the issues that matter the most to NGOs, including safety.

Minutes of the forum's meetings (https://www.gov.uk/government/groups/non-governmental-organisation-forum) are published on the GOV.UK website.

The forum's main objectives are:

- to ensure clarity, transparency and openness in relation to the potential nuclear element of developing a low carbon energy sector;
- to allow the free and frank exchange of views between informed parties around the issues of new nuclear build, waste management, securing safe interim storage for waste; and
- to examine the implications of national policy statements, planning matters, justification and associated issues such as low-level radiation, research and development, the GDA process, Guidance for Regulatory Authorisations, security and those other items, at national and site level, that the meeting decides are germane to its task.

In addition, the <u>Regulators' Code</u> (https://www.gov.uk/government/publications/regulators-code), which came into effect in April 2014, provides a framework for how regulators in the UK

should engage with those that they regulate. The regulatory bodies demonstrate compliance with the Regulators' Code by having appropriate mechanisms in place to engage those they regulate, the public and others to offer views and contribute to development of policies and service standards. Before changing policies, practices or service standards, regulators need to consider the impact on business and engage with business representatives. [footnote 91] Regulatory bodies publish their respective Regulators' Code Self-Assessment Reports to provide an update and show progress on how well their activity aligns with the Code. [footnote 92]

Duty on the UK to share information internationally

The UK has a duty to share information internationally. Under the Convention on Environmental Impact in a Transboundary Context (the Espoo Convention), the UK is required to notify and consult other IAEA States on all major projects under consideration that are likely to cause a significant adverse transboundary impact, including new nuclear power stations. Similarly, under the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (the Aarhus Convention) the UK is required to make necessary provisions so that public authorities (at national, regional or local level) are able to participate in environmental decision-making.

Annex A: 10 fundamental IAEA principles in the policy and strategy of the UK

The IAEA has developed Fundamental Safety Principles which provide the basis for requirements and measures for the protection of people and the environment against radiation risks and for the safety and facilities that give rise to those risks. The table below sets out how the UK applies the IAEA safety principles in the UK context.

IAEA Fundamental Safety Principles

No 1: Responsibility for safety

The prime responsibility for safety must rest with the person or organisation responsible for facilities and activities that give rise to radiation risks.

UK context: HSWA74 and the equivalent legalisation in NI place a duty on employers to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all their employees and other persons. This legislation and associated regulations establish the roles and responsibilities for both employers and employees, requiring safety management and a safety culture.

For nuclear installations, the prime responsibility for safety rests with the licensee, as defined in the Nuclear Installations Act 1965. For radioactive substances activities in Scotland authorised by SEPA, the prime responsibility for safety is assigned to the authorised person, as defined in EASR18.

No 2: Role of government

An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.

UK context: There are stringent laws covering all aspects of radiological safety, encompassing occupational, medical, environmental and nuclear, all overseen by regulatory bodies that are independent in their regulatory decision making.

The UK government, and its officials, is obligated to regularly review legislation and regulations and consider whether they remain fit for purpose for achieving their intended objectives. For example, TEA13 is due for its post-implementation review (PIR) in 2021.

No 3: Leadership and management for safety

Effective leadership and management for safety must be established and sustained in organisations concerned with, and facilities and activities that give rise to, radiation risks.

UK context: The MHSWR place general duties in this area, supported by HSE-issued guidance on leadership and management in Plan, Do, Check, Act: an introduction to managing for health and safety (https://www.hse.gov.uk/pubns/indg275.htm) (INDG275) and Managing for health and safety (https://www.hse.gov.uk/pubns/books/hsg65.htm) (HSG 65). HSWA and IRR17 also place duties on employers to ensure the effective management of safety.

For nuclear sites, <u>licence condition 17</u>

(http://www.onr.org.uk/operational/tech_insp_guides/ns-insp-gd-017.pdf) requires that the licensee shall establish and implement management systems which give due priority to safety. This is supported by guidance within the SAPs.

Conditions in authorisations granted by the environmental regulators require employers to put in place and implement appropriate management

arrangements. The management arrangements should show how, with the appropriate individual and collective attitudes and behaviours, environmental safety is directed and controlled.

No 4: Justification of facilities and practices

Facilities and activities that give rise to radiation risks must yield an overall benefit.

UK context: The Justification of Practices Involving Ionising Radiation Regulations 2004 as amended sets out that practices that involve exposure to ionising radiation are only permitted if the economic, social and other advantages of the practices in question outweigh the health detriment they can cause.

No 5: Optimisation of protection

Protection must be optimised to provide the highest level of safety that can reasonably be achieved.

UK context: Different regulatory regimes in the field of radiological protection in the UK use different terminology and have their own guidance on optimisation, namely: reducing risks as low as reasonably practicable (ALARP); so far as is reasonably practicable (SFAIRP); as low as reasonably achievable (ALARA). For environmental protection, employers demonstrate that exposures are ALARA through the use of best practicable means (BPM) and best practicable environment option (BPEO) in Scotland and Northern Ireland; and in England and Wales, use of best available techniques (BAT), which is broadly equivalent to a combination of BPM and BPEO. The key principle of all of the above require those that create the risk to demonstrate that they have done everything reasonably practicable to reduce risks, balancing the level of risk posed by their activities against the measures needed to control that risk whether in money, time or resources.

No 6: Limitation of risks to individuals

Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.

UK context: The IRR17 Regulation 12 and Schedule 3 provide a framework of dose limitation for all persons, including employees and the public. All employers have a duty to ensure that no dose limit is exceeded in any calendar year.

IRR17 Regulation 9 requires that all employers must, in relation to any work with ionising radiation that they undertake, take all necessary steps to restrict radiation exposure so far as is reasonably practicable to employees and other persons. Dose constraints can be set to support dose limitation. REPPIR19 also sets out requirements relating to limitation of risks to individuals.

Similar requirements are set out in IRRNI17 and REPPIRNI19 and apply within NI.

EASR18 Schedule 8 defines the legal duties of SEPA regarding the limitation of public exposures due to radioactive substances activities in Scotland. Schedule 8 paragraphs 26 and 27 of EASR18 specifically require SEPA to ensure public exposures are below dose limits and dose constraints and paragraph 28 requires SEPA to estimate doses to the public from radioactive substances activities.

NIEA applies similar dose limit requirements through the Radioactive Substances (Basic Safety Standards) Regulations (Northern Ireland) 2003. Under IR(ME)R, every medical exposure must be justified as showing a sufficient net benefit (including the direct health benefits to the individual and society) to outweigh the potential detriment of the exposure.

No 7: Protection of present and future generations

People and the environment, present and future, must be protected against radiation risks.

UK context: The Environment Act 1995 and associated regulations (EASR18 and EPR16) provide an integrated approach to protecting and improving the environment through its application to environmental protection, flood defence, water resources, fisheries, recreation and conservation.

While RSA93 only relates to radioactive substances, an integrated approach is still in place due to the nature of the agencies i.e. all environmental regulators have a much wider remit than radiation. Through their regulation of radioactive waste, the environmental regulators ensure protection of people and the environment from radioactivity released into the environment. This includes assessment of impacts arising from the disposal of solid radioactive waste into long term disposal facilities where the impact on people and the environment may not occur for many generations. The Wellbeing of Future Generations (Wales) Act 2015 focusses on improving the social, economic, environmental and cultural well-being of Wales. The Act requires public bodies in Wales to think about the long-term impact of their decisions, to work better with people, communities and each other, and to prevent persistent problems such as poverty, health inequalities and climate change. These public bodies include NRW and HIW.

No 8: Prevention of accidents

All practical efforts must be made to prevent and mitigate nuclear or radiation accidents.

UK context: HSWA74 places a duty on all employers in all sectors 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 every employer to conduct their undertaking in such a way as to ensure, so far as is

reasonably practicable, that those persons not in their employment who may be affected thereby are not thereby exposed to risks to their health and safety. The equivalent legislation in NI is the HSW(NI)O78.

REPPIR19 also reinforces this in Regulation 4(4) (a) prevention of radiation emergency.

Similar requirements are set out in IRRNI17 and REPPIRNI19 and apply within NI.

The IRR17 and IRRNI17 requires that all reasonably foreseeable radiation accidents are identified by the employer and steps taken to reduce the likelihood of these accidents happening and limit their consequences. IR(ME)R requires employers to undertake a study of the risk of accidental or unintended exposures for radiotherapy.

IR(ME)R requires the employer to establish a procedure to ensure that the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced as far as reasonably practicable

IR(ME)R requires the employer to establish a system for recording analysis of events involving accidental or unintended exposures proportionate to the risks posed by the practice.

No 9: Emergency preparedness and response

Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.

UK context: The CCA establishes a clear set of roles and responsibilities for those involved in emergency preparedness and response at the local level. It identifies "Category 1 responders", who must assess the risk of an emergency occurring and maintain plans for dealing with that emergency. These include local authorities and emergency services.

IRR17 Regulation 13

(http://www.legislation.gov.uk/uksi/2017/1075/regulation/13/made) requires contingency plans for reasonably foreseeable accidents to be drawn up. REPPIR19 establishes a framework for the protection of the public through emergency preparedness for radiation emergencies with the potential to affect the public and workers, from premises (transport operations are now covered in CDG09). It also ensures the provision of information to the public: in advance in situations where a (REPPIR) radiation emergency might arise; and in the event of any kind of radiation emergency (however it may arise).

REPPIR19 requires coordination and cooperation between all agencies that may have a role in emergency response. The equivalent legislation in NI is IRRNI17, REPPIRNI19 and the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2010 which have corresponding requirements.

No 10: Protective actions to reduce existing or unregulated radiation risks

Protective actions to reduce existing or unregulated radiation risks must be justified and optimised.

UK context: The UK has in place provisions for the detection, recovery, management, control, disposal and financial security of orphan sources. These provisions are there to optimise orphan source management as a whole, which incorporates practices to facilitate their management. The UK has arrangements in place to manage the decommissioning of nuclear sites and de-licence those where the radiation hazard has been removed.

UK legislation also provides a system for the identification of land contaminated with radioactivity from historic activities or the after-effects of emergencies, the assignment of responsibility and the arrangements to require remediation where that radioactive contaminated land presents unacceptable radiation risks to the public.

Annex B: Overview of the UK legislative framework

The tables below outline key legislation relating to radiation protection and nuclear safety. All legislation is 'as amended' and was correct at time of publication.

Table 3: Legislative framework for occupational exposures

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodies Regulator
Health and Safety at Work etc. Act 1974 (HSWA74)	Ionising Radiations Regulations 2017 (IRR17)	HSE and HSENI Guidance including:	Department for Work and Pensions (DWP)	Health and Safety Exe (HSE)
,	Radiation (Emergency Preparedness	Ionising Radiations Regulations	` ,	The Office Nuclear Regulation [footnote 93]
	and Public Information) Regulations	2017 – Guidance for Notifications,		Local autho

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodies Regulator
	2019 (REPPIR19)	Registrations and Consents		Office of Ra
		Approved Code of Practice (ACoP) to IRR17 and IRRNI17 ACoP to REPPIR19		
Health and Safety at Work (Northern Ireland) Order 1978 (HSW(NI)O78)	lonising Radiations Regulations (Northern Ireland) 2017 (IRRNI17)	Ionising Radiations Regulations (Northern Ireland) 2017 – Guidance for Notifications, Registrations and Consents	Department for the Economy	

Table 4: Legislative framework for nuclear safety

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodies: Regulato
Nuclear Installations	Nuclear Installations	The ONR's guidance	DWP	The ONF
Act 1965	Regulations 1971	guidance	Department	
(NIA 65)	(NIR) made under NIA 65		for Business, Energy and Industrial	
Energy Act	The Nuclear		musmai	

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodies: Regulato
2013 (TEA13)	Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999 (EIADR)		Strategy (BEIS)	

Table 5: Legislative framework for public exposures and environmental protection

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodie Regulato
Environmental Protection Act 1990	The Ionising Radiation (Basic Safety Standards)	EA, NRW, SEPA, NIEA Guidance	Department for Environment, Food and	Environm Agency (I
Environment Act 1995	(Miscellaneous Provisions) Regulations	Defra Guidance on Environmental	Rural Affairs (Defra)	
Radioactive Substances Act 1993	2018[footnote 94]	Permitting The ONR's	Welsh Government	
(RSA93)	Environmental Permitting	guidance	Scottish Government	
Food Standards Act 1999	(England and Wales) Regulations 2016 (EPR16)		Department of Agriculture,	
Food Safety Act 1990	[footnote 95]		Environment and Rural	
The Town and Country	Environmental Authorisations (Scotland)		Affairs (DAERA)	
Planning Act 1990 (TCPA)	Regulations 2018 (EASR)		Food Standards	

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodie Regulato
	Radioactive Contaminated Land (Scotland) Regulations 2007 The Transfrontier Shipment of Radioactive Waste and Spent Fuel (EU Exit) Regulations 2019		Agency (FSA) Food Standards Scotland (FSS) BEIS	
	The Radioactive Substances (Basic Safety Standards) Regulations (Northern Ireland) 2003 [footnote 97]			
	The Radioactive Contaminated Land Regulations (Northern Ireland) 2006 [footnote 98]			
	The			

Radioactive Substances Exemption

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodie Regulato
	Northern Ireland) Order 2011			
	The Radioactive Substances (Modification of Enactments) Regulations (Northern Ireland) 2018			
	Waste and Contaminated Land (Northern Ireland) Order 1997 1997 and the Hazardous Waste Regulations (Northern Ireland) 2005			
	EIADR			

Table 6: Legislative framework for medical and nonmedical exposures

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodies: Regulator
Health and	lonising	DHSC	Department for Health	Care Quality
Safety at	Radiation	guidance on		Commission

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodies: Regulator
Work etc. Act 1974 (HSWA74)	(Medical Exposure) Regulations	the IR(ME)R 2017 regulations	and Social Care (DHSC)	(CQC) Healthcare
	2017	0		Inspectorate
	(IR(ME)R)	Significant accidental	Welsh Government	Wales (HIW)
	lonising	and	•	Healthcare
	Radiation (Medical Exposure)	unintended exposures (SAUE)	Scottish Government	Improvement Scotland (HIS)
	Regulations (Northern	guidance	Department of Health	Regulatory
	Íreland) 2018	IR(ME)R guidance for diagnostic and radiotherapy	Northern Ireland (DHNI)	and Quality Improvement Authority (RQIA)

Table 7: Legislative framework for transport of radioactive materials

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodies: Regulator
For road, rail and inland	Road, rail and inland		DWP	The ONR
waterways in GB:	waterways:		BEIS	Maritime and
TEA13	The Carriage		DAERA and	Coastguard
110)4/474	of Dangerous		Department	Agency
HSWA74	Goods and Use of		for the Economy	(MCA)
For road, rail	Transportable		-	Civil
and inland	Pressure		Department	Aviation
waterways	Equipment		for Transport	Authority
in NI: Health and Safety	Regulations 2009		(DfT)	(CAA)
at Work			DfT	

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodies: Regulator
(Northern Ireland) Order 1978) Sea: Merchant Shipping Act 1995 (MSA95)	The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010		DfT	
Air: Civil Aviation Act 1982	Ionising Radiations Regulations 2017			
	Ionising Radiations Regulations (Northern Ireland) 2017 (IRRNI17)			
	Sea: The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997			
	Merchant Shipping (Carriage of Packaged Irradiated Nuclear Fuel etc.) (INF Code) Regulations 2000			

Acts of

Framework: Framework: Framework: **UK bodies:** UK bodies: Regulations Guidance Government parliament Regulator department Air: The Air **Navigation** Order 2016; The Air Navigation (Dangerous Goods) Regulations 2002; Regulation (EU) No 965/2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European **Parliament** and of the Council (the Air Ops Regulation) as retained (and amended in **UK** domestic law) under the European Union (Withdrawal) Act 2018; and

Regulation

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodies: Regulator
	(EU) No. 2018/1139 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency (The Basic Regulation) as retained (and amended in UK domestic law) under the European Union (Withdrawal)			

Table 8: Legislative framework for emergency preparedness and response (EP&R)

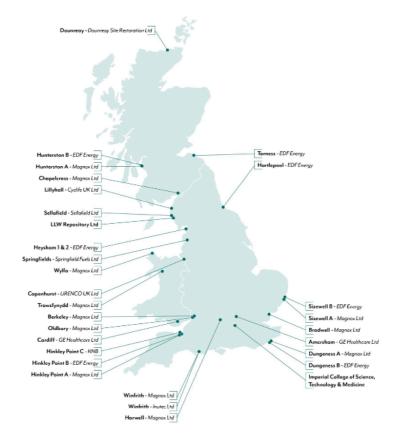
Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodie Regulato
Civil Contingencies Act 2004 (CCA)	Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR19)	EA, SEPA, NRW and NIEA emergency response guidance HSE guidance	HSE and the ONR are the enforcing authorities for REPPIR19 as it only goes up to the point of transition to	The requiments in REPPIR and REPPIR coordinat and cooperati

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodie Regulato
	Radiation (Emergency Preparedness and Public Information) Regulations (Northern Ireland) 2019 The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 as amended The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010 as amended The Food and Feed (Maximum Permitted Levels of Radioactive Contamination) (Amendment) (EU Exit) Regulations 2019	The ONR's guidance Cabinet Office Guidance UK and Scottish Government guidance, including "Preparing for and responding to energy emergencies" and "Preparing Scotland" and PHE [footnote 100] guidance	recovery. From recovery onwards, it becomes Defra and EA BEIS, HSE and MOD are the policy owners of REPPIR19 as it covers 3 sectors. Civil nuclear is BEIS lead, defence nuclear is MOD lead and radiological is HSE lead. The ONR is the enforcing authority for transport radiation emergencies under CDG09 in GB. In Northern Ireland, the NIEA regulates radioactive transport on roads under the Carriage of Dangerous Goods and Use of Transportable	between State agencies that may have a roin emergent response

Framework: Acts of parliament	Framework: Regulations	Framework: Guidance	UK bodies: Government department	UK bodie Regulato
		Pressure Equipmer Regulatio (Northern Ireland) 2		S

Annex C: Map of UK civil nuclear sites – generating, decommissioning and new build power plants

Does not include defence sites.



Annex D: list of UK government departments and regulatory bodies [footnote 101]

UK government departments:

- Department for Business, Energy and Industrial Strategy (BEIS)
- Department for Environment, Food and Rural Affairs (Defra)
- Department for Health and Social Care (DHSC) and Public Health England [footnote 102] (PHE), an Executive Agency of DHSC
- Department for Transport (DfT)
- Department for Work and Pensions (DWP)
- Equivalent government departments in devolved administrations

Regulators:

- Care Quality Commission (CQC)
- Civil Aviation Authority (CAA)
- Drinking Water Inspectorate (DWI) (England and Wales)
- Drinking Water Inspectorate (DWI) (Northern Ireland)[footnote 103]
- Drinking Water Quality Regulator for Scotland (DWQR)
- Environment Agency (EA)
- Food Standards Agency (FSA)
- Food Standards Scotland (FSS)
- Health and Safety Executive (HSE)
- Health and Safety Executive Northern Ireland (HSENI)
- Healthcare Improvement Scotland (HIS)
- Healthcare Inspectorate Wales (HIW)
- Local Authorities [footnote 104]
- Maritime and Coastguard Agency (MCA)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Natural Resources Wales (NRW)
- Northern Ireland Environment Agency (NIEA)
- Office for Nuclear Regulation (the ONR)
- Office of Rail and Road (ORR)
- Regulatory and Quality Improvement Authority (RQIA)
- Scottish Environment Protection Agency (SEPA)

Annex E: examples of areas where the UK supports the technical work of international agencies, working groups and committees

The table below outlines some of the key forums and working groups in which the UK actively participates in relation to radiation protection and nuclear safety.

Table 9 Relevant key forums and working groups

UK participation **Forum** International Atomic The UK supports the drafting of IAEA safety and **Energy Agency** security guidance – for example, within ENVIRONET. (IAEA) The UK is part of the core group that is responsible for the Definition of Environmental Remediation End States (DERES) project. The ONR, with input from the environmental regulators, provides UK representation and actively participates at the IAEA's Commission on Safety Standards (CSS). The UK attends and actively contributes to: - Radiation Safety Standards Committee (RASSC) Nuclear Safety Standards Committee (NUSSC) - Transport Safety Standards Committee (TranSSC) - Emergency Preparedness and Response Standards Committee (EPReSC) - Standing Advisory Group on Safeguards Implementation (SAGSI) - Nuclear Security Guidance Committee (NSGC) - Waste Safety Standards Committee (WASSC) The UK inputs to negotiating the annual IAEA Resolution on Nuclear Safety.

Security Network.

The UK attends the IAEA Global Nuclear Safety and

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UK participation

The UK contributes to IAEA peer review and advisory missions to Member States (IRRS, IPPAS and ARTEMIS etc.).

The UK is a full and proactive signatory to the CNS^[footnote 105] JoC^[footnote 106]. As a Contracting Party to the CNS and Joint Convention the UK is required, on a triennial basis, to submit a National Report for international peer review on the activity undertaken to give effect to the obligations of the Convention.

International Civil Aviation Organisation (ICAO)

The UK, represented by the CAA, is an active member of the International Civil Aviation Organisation (ICAO), which facilitates cooperation between countries to develop and maintain international standards for aviation safety and security, including requirements for the safe carriage of dangerous goods by air.

International Maritime Organisation (IMO)

The UK, represented by the MCA, is an active member of the International Maritime Organisation, which facilitates cooperation between countries to develop and maintain International Requirements and Guidance to ensure the safe carriage of cargoes and persons, the safety of ships and their crews and the protection of the environment.

International Commission on Radiological Protection (ICRP)

The UK contributes to the work of the ICRP. The ICRP provides authoritative advice and recommendations that are incorporated into radiological protection systems and standards worldwide.

Nuclear Energy Agency (OECD-NEA)

The UK attends and contributes to the OECD-NEA Steering Committee, standing committees and working groups on a variety of research and regulatory topics.

The UK is an active member of the OECD-NEA's Standing Technical Committees:

- the Committee on Radiological Protection & Public Health (CRPPH) which is responsible for, amongst other matters, studying the societal issues that **Forum**

UK participation

influence radiation protection, providing representation from EA, the ONR and PHE. The Committee uses its findings to help link national policy to the needs of the public, workers and the environment.

- the Committee on the Safety of Nuclear Installations (CSNI) which is responsible for NEA programmes and activities that support maintaining and advancing the scientific and technical knowledge base of the safety of nuclear installations.
- the Committee on Nuclear Regulatory Activities (CNRA) which is responsible for NEA programmes and activities concerning the regulation, licensing and inspection of nuclear installations with regards to both technical and human aspects of nuclear safety.
- the Radioactive Waste Management Committee (RWMC) which assists member countries in the development of safe, sustainable and broadly acceptable strategies for the management of all types of radioactive waste and spent nuclear fuel.
- the Committee on Decommissioning of Nuclear Installations and Legacy Management (CDLM) which supports the efforts of the member countries to develop strategies to manage nuclear legacy sites and installations.
- the Nuclear Law Committee which provides advice on nuclear law in relation to safety and other relevant issues.

Heads of the European Radiological Protection Competent Authorities (HERCA) The UK is represented on the HERCA Board of Heads, and together with representatives from the environmental regulators, CQC and PHE attend and contribute to HERCA working groups.

- The UK plays an active role in HERCA, both chairing and contributing to a number of the Working Groups.
- The UK attends and contributes to HERCA workshops dedicated to Emergency Arrangements and cross-border issues, protection during medical exposures and to the protection of people and the environment from natural radiation sources e.g. radon and naturally occurring radioactive material (NORM) wastes and Research and Industrial Sources and Practices.

Forum	UK participation		
United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)	The UK attends and contributes to main meetings and participates on working groups covering a variety of research topics.		
World Health Organisation (WHO)	ganisation Protection.		

In addition, the FSA supports the technical work of several Codex Alimentarius Commission (CAC) committees including the committee dealing with food contaminants which includes radioactive contamination of food. The CAC was established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

- lonising radiation occurs as either electromagnetic rays (such as X-rays and gamma rays) or particles (such as alpha and beta particles). It occurs naturally (e.g. from the radioactive decay of natural radioactive substances such as radon gas and its decay products) but can also be produced artificially. <u>Further information</u> (https://www.hse.gov.uk/radiation/ionising/protection.htm).
- 2. For the purpose of this document "safety" means the safety of the public, those working with ionising radiation, third parties affected by the work being carried on, patients and the environment.
- 3. The IAEA is an autonomous inter-governmental organisation founded by the United Nations (UN) General Assembly in 1957. Its purpose is to foster research and development in the peaceful uses of nuclear energy and the exchange of scientific and technical information, to establish and administer safeguards against the diversion to military purposes of nuclear materials intended for use in civil nuclear programmes and to establish or adopt health and safety standards.
- 4. The ICRP is an independent body of experts which provides guidance on a range of topics relating to the protection of humanity against radiation.
- 5. WENRA is a voluntary association of nuclear regulators who work together to develop common approaches to civil nuclear safety and provide a network for regulators exchange experience and discuss significant safety issues.
- HERCA is a voluntary association in which the Heads of Radiological Protection Authorities work together in order to identify common issues

- and propose practical solutions for these.
- 7. UNSCEAR's remit within the United Nations is to assess and report levels and effects of exposure to ionising radiation.
- 8. The OECD-NEA was created in 1956 and facilitates co-operation among countries with advanced nuclear technology infrastructures.
- 9. OSPAR is the mechanism by which 15 Governments and the EU cooperate to protect the marine environment of the North-East Atlantic. The 15 governments are Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the UK.
- 10. The Treaty of the European Atomic Energy Community (Euratom) gave the European Community the task of establishing uniform safety standards to protect the health of workers and the general public.
- 11. This document does not set out the approach for the regulation of radioactive materials for defence purposes, although some of the legislation referred to in this document is applicable to defence.
- 12. Further information on the <u>devolution of powers to Scotland, Wales and NI (https://www.gov.uk/guidance/devolution-of-powers-to-scotland-wales-and-northern-ireland).</u>
- 13. A disapplication means that a law or article does not apply to the MoD. An exemption from an aspect of law can be granted by the Secretary of State for Defence in exceptional circumstances. Derogations from particular provisions of legislation may be sought by the MoD, normally during the drafting process and are a lessening of a statutory requirement for justifiable practical or operational reasons.
- 14. The UK played a key role in developing and adopting these legal instruments.
- 15. See the <u>UK's report on compliance with the CNS</u>

 (https://www.gov.uk/government/publications/compliance-with-the-convention-on-nuclear-safety-obligations-7th-national-report)
- 16. See the UK's report on compliance with the JoC
- 17. Examples of other coordination groups include the Radiological Substances Policy Group, the Medical Radiation Liaison Group, the Competent Authority Strategic Management Group (CASMG) and the Transport Competent Authorities Co-ordination Group.
- 18. The WHO is a key player in establishing patient safety recommendations in radiology.
- 19. Department for Business, Energy and Industrial Strategy, <u>UK Research</u> and <u>Development Road Map (https://www.gov.uk/government/publications/uk-research-and-development-roadmap/uk-research-and-development-roadmap)</u>, 1 July 2020.

- 20. Further information on <u>funding for nuclear innovation</u> (https://www.gov.uk/guidance/funding-for-nuclear-innovation)
- 21. There are no nuclear sites in Northern Ireland. This number does not include any defence-related sites.
- 22. The map shows only civil nuclear sites and does not include any defencerelated sites.
- 23. The IAEA defines safety culture as: "the assembly of characteristics, attitudes and behaviours in individuals, organizations and institutions which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance."
- 24. As amended by the Justification of Practices Involving Ionising Radiation (Amendment) Regulations 2018.
- 25. The optimisation principle only applies to people, whereas the environment simply has to be protected.
- 26. ALARP is a tool for demonstrating SFAIRP.
- 27. Further information on <u>the principles of optimisation</u> (https://www.gov.uk/government/publications/rsr-principles-of-optimisation)
- 28. Except with regards to the transport of radioactive material which is based on standards developed by the IAEA. The IAEA transport regulations are prescriptive and apply internationally to enable the safe transport of packages in an integrated manner across international borders.
- 29. In Northern Ireland, the Department of Agriculture, Environment and Rural Affairs (DAERA) has powers under RSA93 to give direction to the Chief Radiochemical Inspector. However, the Chief Radiochemical Inspector is responsible for many of the functions covered by the relevant legislation rather than the departments, providing the necessary separation between day-to-day regulatory decision-making and government.
- 30. IRR17 works in parallel with the Management of Health and Safety at Work Regulations 1999 (MHSWR) that set out general requirements for risk assessment.
- 31. A list of RPA bodies recognised by HSE under IRR17 (https://www.hse.gov.uk/radiation/rpnews/bodieshse.htm)
- 32. The ORR is a non-ministerial department. A non-ministerial department is a government department in its own right but does not have its own minister. However, it is accountable to Parliament through its sponsoring ministers. A non-ministerial department is staffed by civil servants and usually has its own estimate and accounts.
- 33. Further information is available from regulatory bodies' websites at the relevant links throughout this document.

- 34. A non-departmental public body (NDPB) is a body which has a role in the processes of national government but is not a government department or part of one, and which accordingly operates to a greater or lesser extent at arm's length from ministers.
- 35. HSWA74 places a duty on the SoS for Work and Pensions to pay HSE such sums as are approved by HM Treasury and that they consider appropriate to enable HSE to perform its functions. Regulations also enables HSE to charge fees for certain functions.
- 36. This does not include defence-related sites.
- 37. This document does not set out the approach for the regulation of radioactive materials for defence purposes. As such, this does not include any defence-related sites licensed by ONR.
- 38. There are no civil nuclear installations in Northern Ireland, nor are any planned.
- 39. The Nuclear Installations Regulations (NIR) 1971 cover other prescribed installations in addition to those described in NIA65.
- 40. Further information on licensing (http://www.onr.org.uk/licensing.htm)
- 41. Further information on the <u>application of the EIADR</u> (http://www.onr.org.uk/eiadrguidance.pdf)
- 42. This does not include defence-related sites.
- 43. This document does not set out the approach for the regulation of radioactive materials for defence purposes. As such, this does not include any defence-related sites licensed by the ONR.
- 44. No new nuclear power stations are planned for Scotland and none are planned for Northern Ireland.
- 45. Further information on the GDA process (https://www.gov.uk/government/publications/new-nuclear-power-plants-generic-design-assessment-guidance-for-requesting-parties/new-nuclear-power-plants-generic-design-assessment-guidance-for-requesting-parties)
- 46. BEIS and DWP liaise regularly, hold Quarterly Accountability Reviews with the ONR and have a Memorandum of Understanding (MoU) in place to provide clarity about their working relationships with each other and the ONR. As the ONR is the UK's legally independent regulatory body for nuclear safety it provides advice to BEIS on nuclear safety matters when requested.
- 47. Under IR(ME)R the MPE must be formally appointed and recognised by a Competent Authority. The Department of Health and Social Care (DHSC), as the Competent Authority for medical exposures, has appointed RPA2000 to act as the authorised Assessing Body for recognition of MPEs under IR(ME)R. Further information (https://www.gov.uk/government/publications/medical-physics-experts-recognition-scheme)

- 48. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be formalised and operating from spring 2021. Further information (https://www.gov.uk/government/news/government-creates-new-national-institute-for-health-protection)
- 49. Executive agencies are clearly designated units of a central government department, administratively distinct, but remaining legally part of it. It has a clear focus on delivering specific outputs within a framework of accountability to ministers.
- 50. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be formalised and operating from spring 2021. Further information (https://www.gov.uk/government/news/government-creates-new-national-institute-for-health-protection)
- 51. Executive agencies are clearly designated units of a central government department, administratively distinct, but remaining legally part of it. It has a clear focus on delivering specific outputs within a framework of accountability to ministers.
- 52. <u>Administration of Radioactive Substances Advisory Committee</u>
 https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee)
- 53. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be formalised and operating from spring 2021. Further information (https://www.gov.uk/government/news/government-creates-new-national-institute-for-health-protection)
- 54. As amended by Radioactive Substances Act 1993 (Amendment) Regulations (Northern Ireland) 2011.
- 55. Sealed radioactive sources are used widely in medicine, industry and agriculture. The radioactive substance within a source is sealed within a protective container. Radioactive substances emit energetic particles or waves, which is called ionising radiation. Radiation from the sources is used for a specific purpose e.g. by doctors to treat cancer, by radiographers to check welds in pipelines, or by specialists to irradiate food to prevent it from spoiling.
- 56. The term that we use for this authorisation can vary between the different legislation it may be a permit, a registration or an authorisation but it has the same meaning.
- 57. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be

formalised and operating from spring 2021. <u>Further information</u> (https://www.gov.uk/government/news/government-creates-new-national-institute-for-health-protection)

- 58. References to food include feed
- 59. Radioactivity in Food and the Environment (RIFE) reports

 (https://www.gov.uk/government/publications/radioactivity-in-food-and-the-environment-rife-reports)
- 60. In this regulation "relevant building material" means building material that (a)emits gamma radiation; and (b)is of concern from a radiation protection point of view, taking into account the indicative list of types of building material in Annex XIII to the Basic Safety Standards Directive
- 61. The Health and Safety Executive (HSE) and the Health and Safety Executive Northern Ireland (HSENI) are the regulators for workplace products but not consumer products.
- 62. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be formalised and operating from spring 2021. Further information (https://www.gov.uk/government/news/government-creates-new-national-institute-for-health-protection)
- 63. Executive agencies are clearly designated units of a central government department, administratively distinct, but remaining legally part of it. It has a clear focus on delivering specific outputs within a framework of accountability to ministers.
- 64. There are separate such agreements for different types of transport as follows: road in GB and NI: United Nations Economic Commission for Europe (UNECE) European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR); Rail in GB: Intergovernmental Organisation for International Carriage by Rail (OTIF) Regulations concerning the International Carriage of Dangerous Goods by Rail (RID); Sea in UK: International Maritime Organization (IMO) International Maritime Dangerous Goods (IMDG) Code 2018 Edition incorporating Amendment 39-18; Air in UK: International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air.
- 65. As amended by the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011.
- 66. As amended by the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) (Regulations) (Northern Ireland) 2011
- 67. See footnote 65 for details of ADR and RID.
- 68. These further amendments were through the Carriage of Dangerous Goods (Amendment) Regulations 2019 and the Carriage of Dangerous

- Goods (Amendment) Regulations (Northern Ireland) 2019 respectively.
- 69. These requirements implement the International Maritime Organisation's (IMO) IMDG Code Amendment 39-18 directly by referencing it from within the legislation.
- 70. These Regulations give effect to the International Code for the Safe Carriage of Packaged Irradiated Nuclear Fuel, Plutonium and High-Level Radioactive Wastes on board Ships (the INF Code), and the International Convention for the Safety of Life at Sea (SOLAS) chapter VII Part D, Regulation 4.
- 71. The agreement Under Section 13(4) of HSWA74 (https://www.onr.org.uk/documents/2014/mca-aa.pdf)
- 72. Further information on <u>Type A and Type B packages</u> (https://www.energy.gov/sites/prod/files/2014/04/f14/rmem2_0.pdf)
- 73. The ONR would investigate failure of a package if it were associated with road, rail or inland waterway in GB but not any other transport mode.

 ONR has no enforcement powers in relation to transport in NI.
- 74. Civil Aviation Authority (http://www.onr.org.uk/documents/2014/caa-aa.pdf) and Health and Safety Executive Northern Ireland (http://www.onr.org.uk/documents/2014/transport-aa-northern-ireland.pdf)
- 75. The State of Operator is the International Civil Aviation Organisation (ICAO) State where the operator has their principle place of business or residence. Further information on the ICAO (https://www.icao.int/about-icao/Pages/default.aspx)
- 76. For the purpose of this document, "Competent Authority" means an organisation that has the legally delegated or invested authority, capacity, or power to perform a designated function.
- 77. This document does not set out the approach for the regulation of radioactive materials for defence purposes. As such, it does not include the regulation of the transport of radioactive material for defence purposes.
- 78. A <u>definition of the 9 classes of dangerous goods (https://www.vehicle-certification-agency.gov.uk/dangerousgoods/what-are-dangerous-g.asp).</u>
- 79. This document does not set out the approach for the regulation of radioactive materials for defence purposes. As such, it does not include the regulation of the movement of such goods into a harbour which is or forms part of an authorised defence site.
- 80. Further information on the <u>broad triggers for the activation of COBR</u>

 (https://www.gov.uk/government/publications/the-central-government-s-conceptof-operations). Annex B provides a chart indicating the characteristics of different levels of emergency and the likelihood of central government engagement according to the actual or potential spread of an emergency and its effect.

- 81. A no-notice incident is defined as an unexpected emergency.
- 82. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be formalised and operating from spring 2021. Further information (https://www.gov.uk/government/news/government-creates-new-national-institute-for-health-protection).
- 83. This document does not set out the approach for the regulation of radioactive materials for defence purposes. As such, it does not include the regulation of defence sites falling within the scope of REPPIR.
- 84. Following UK exit from EU and Euratom, the UK government has proposed a new civil nuclear relationship based on a comprehensive Nuclear Cooperation Agreement (NCA) between Euratom and the UK.
- 85. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be formalised and operating from spring 2021. Further information (https://www.gov.uk/government/news/government-creates-new-national-institute-for-health-protection)
- 86. This document does not set out the approach for the regulation of radioactive materials for defence purposes. As such, it does not include the regulation of defence sites falling within the scope of REPPIR.
- 87. For example, see Environmental permits: when and how we consult (https://www.gov.uk/government/publications/environmental-permits-when-and-how-we-consult).
- 88. There are a small number of exceptions e.g. where there are human rights issues or there would be a risk of disproportionate negative impact on the organisation's stakeholders or the public.
- 89. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be formalised and operating from spring 2021. Further information (https://www.gov.uk/government/news/government-creates-new-national-institute-for-health-protection)
- 90. For example, the ONR and the UK environment agencies regularly attend scrutiny meetings for local communities with an interest in the environment and safety e.g. the West Cumbria Sites Stakeholder Group (WCSSG). The WCSSG consists of six working groups which provide a forum for discussion about the nuclear industry in Cumbria. Similar working groups operate within other UK regions.
- 91. <u>Guidance on how to make a request under the Freedom of Information Act or the Environmental Information Regulations (https://www.gov.uk/make-a-freedom-of-information-request) or in Scotland (https://www.gov.scot/about/contact-information/how-to-request-information/)</u>

- 92. An example of this is HSE's consultation on revisions to the IRR regulations and on the ACOP that supports REPPIR (https://consultations.hse.gov.uk/hse/reppir-2019/).
- 93. Regulators' Code Self-Assessment Reports should be available from the relevant regulators' websites at the addresses throughout this document
- 94. The ONR is the regulator for nuclear dutyholders and all transport dutyholders for IRR17. It operates a graded approach for work on nuclear premises). Transport regulations apply internationally to enable the safe transport of packages containing radioactive material across international borders.
- 95. Made under s 2(2) of the European Communities Act 1972.
- 96. The EPR16 were made under the Pollution Prevention and Control Act 1999, the Water Act 2014, the European Communities Act 1972 and the Regulatory Enforcement and Sanctions Act 2008.
- 97. These regulations were made under the Regulatory Reform (Scotland) Act 2014.
- 98. These regulations were made under the European Communities Act 1972.
- 99. These regulations were made under the Northern Ireland Act 1974.
- 100. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be formalised and operating from spring 2021. Further information (health-protection)
- 101. This document does not set out the approach for the regulation of radioactive materials for defence purposes. As such, the below list does not include the Ministry of Defence (MoD) or the Defence Nuclear Safety Regulator (DNSR)
- 102. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be formalised and operating from spring 2021. Further information (health-protection)
- 103. The Drinking Water Inspectorate (DWI) is a unit within the Northern Ireland Environment Agency (NIEA).
- 104. Local authorities are responsible for enforcing health and safety legislation on premises where they are the enforcing authority.
- 105. The Joint Convention compels contracting parties to achieve and maintain the highest possible level of safety in the management of spent

fuel and radioactive waste in accordance to the Articles of the Convention.

106. PHE and NHS Test and Trace, as well as the analytical capability of the Joint Biosecurity Centre (JBC) have been brought together to form the National Institute for Health Protection (NIHP). The organisation will be formalised and operating from spring 2021. <u>Further information</u> (https://www.gov.uk/government/news/government-creates-new-national-institute-for-health-protection)

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