

Chapter 2

Background

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2.1 Fundamentals

Overview

The need to assure the safety of workers and the public from ionising radiation is the dominant requirement for integrated management systems/quality assurance in the nuclear industry.

International and national expectations require licensees to establish and implement management systems which give due priority to safety; for nuclear installations and their Site Licence Companies this is manifested in UK law by Licence Condition 17 – “Management systems”.

International Atomic Energy Agency (IAEA) Requirements set out in GSR Part 2, which are identified as ‘expectations’ in UK’s Office for Nuclear Regulation (ONR) Inspection guidance, state that these should be Integrated Management Systems which prioritise Safety. Therefore, it is vitally important to understand what is meant in the nuclear context by Safety.

Application

Tier 1 and 2 contractors need to have a very strong understanding of the nuclear nuances, whilst Tier 3 and 4 contractors need to fully understand why requirements are likely to be placed via contractual requirements, and the implications of their products, including services, on safety.

Key Definitions

IAEA provide a full [glossary of definitions](#) applicable to the nuclear industry which, to ensure commonality of understanding by everyone, should form the basis of industry usage.

ISO also have a set of standards covering nuclear energy vocabulary:

- 12749-1: Not published
- 12749-2: 2013 – Radiological protection
- 12749-3: 2015 – Nuclear fuel cycle
- 12749-4: 2015 – Dosimetry for radiation processing
- 12749-5: 2018 - Reactors

Further to this see [A useful general glossary of nuclear terms with abbreviations](#) which is published by Burges Salmon LLP in conjunction with the nuclear industry.

The following definitions are so key to all understanding of integrated management systems / quality assurance that they deserve special repeating:

Nuclear safety

“The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards.”

“Often abbreviated to ‘safety’ in IAEA publications on nuclear safety. ‘Safety’ should be taken to mean ‘nuclear safety’ unless otherwise stated, in particular when other types of safety (e.g. fire safety, conventional industrial safety) are also being discussed.”

Protection and safety

“The protection of people against exposure to ionising radiation or radioactive materials and the safety of radiation sources, including the means for achieving this, and the means for preventing accidents and for mitigating the consequences of accidents should they occur.”

“Safety is primarily concerned with maintaining control over sources, whereas (radiation) protection is primarily concerned with controlling exposure to radiation and its effects. Clearly the two are closely

connected: radiation protection (or radiological protection) is very much simpler if the source in question is under control, so safety necessarily contributes towards protection.”

Whilst not disagreeing with these definitions the reader new to the subject needs to be aware that:

1. To achieve Safety requires understanding the source term and maintaining control in a proportionate manner. The 'source' can range from a small amount of radioactive material used for medical or industrial purposes, through to the large irradiated fuel inventory of a nuclear power station.
2. Radiological protection is about the appropriate use of time distance and shielding in an ALARP (As Low As Reasonably Practicable) environment.

'Safety' is sometimes further described by prefixes e.g. nuclear safety, radiation safety, radioactive waste safety or transport safety; care has to be taken to recognise these adjectives relate to activities and forms of material and are thus not mutually exclusive. However, 'protection' is primarily concerned with protecting humans against exposure, whatever the source, and so is always radiation protection.”

Radiation Protection (also radiological protection). The protection of people from the effects of exposure to ionizing radiation, and the means for achieving this.

Pre-2000 principles for nuclear safety and radiation protection had been technically compatible but expressed differently; as such a unified set of principles was developed which became that set out in [IAEA Safety Fundamentals \(SF-1\)](#) (see below).

The [ONR Safety Assessment Principles \(SAPs\)](#) provide the following definition: 'safety' refers to the safety of persons in relation to radiological hazards

Management System. A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner.

- The component parts of the *management system* include the organizational structure, resources and organizational *processes*. Management is defined (in ISO 9000) as coordinated *activities* to direct and *control* an organization.
- The *management system* integrates all elements of an organization into one coherent system to enable all of the organization's objectives to be achieved. These elements include the organizational structure, resources and *processes*. Personnel, equipment and organizational culture as well as the documented policies and *processes* are parts of the *management system*. The organization's *processes* have to address the totality of the *requirements* on the organization as established in, for example, IAEA *safety standards* and other international codes and standards.

In IAEA GSR Part 2 the following statement is made at the outset: "Management systems that are designed to fulfil the requirements of this Safety Requirements publication will integrate safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements. The management system supports the achievement of the fundamental safety objective of protecting people and the environment from harmful effects of ionizing radiation”.

Standards

Safety Fundamentals

IAEA Safety Fundamentals state: 'The fundamental safety objective is to protect people and the environment from harmful effects of ionising radiation.' This is met by implementing ten safety principles: 'Responsibility for safety – The prime responsibility for safety must rest with the person or organisation responsible facilities and activities that give rise to radiation risks.

1. 'Role of government – An effective legal and governmental framework for safety, including an independent regulatory body, must be established and sustained.
2. '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.
3. 'Justification of facilities and activities – Facilities and activities that give rise to radiation risks must yield an overall benefit.
4. 'Optimisation of protection – Protection must be optimised to provide the highest level of safety that can reasonably be achieved.
5. 'Limitation of risks to individuals – Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm.
6. 'Protection of present and future generations – People and the environment, present and future, must be protected against radiation risks.
7. 'Prevention of accidents – All practicable efforts must be made to prevent and mitigate nuclear or radiation accidents.
8. 'Emergency preparedness and response – Arrangements must be made for emergency preparedness and response for nuclear or radiation incidents.
Comment: In considering incidents the arrangements should be proportionate to the potential consequences. UK terminology used for licensed sites refers to Incidents and On-Site or Off-site Emergencies.
9. 'Protective actions to reduce existing or unregulated radiation risks – Protective actions to reduce existing or unregulated radiation risks must be justified and optimised.'

For each principle, further guidance is provided, which when considered requires the implementation of effective management systems.

Basic Safety Standards (BSS)

IAEA

The IAEA published the first 'basic safety standards' in 1962, and subsequently it has been revised; in processes that involved many international bodies. The revised BSS was published in July 2014 as [General Safety Requirements Part 3](#) in the IAEA Safety Standards Series.

The BSS introduces five Requirements for Protection and Safety; the fifth of which is 'Management for protection and safety': "The principal parties shall ensure that protection and safety is effectively integrated into the overall management system of the organizations for which they are responsible". Because they are so underlying all that we are about in nuclear quality, the full text of Requirement 5 is reproduced at Annex A to this Section

European Union

The European Union (EU) under the EURATOM treaty has also laid down basic standards. In December 2013 the European Council revised their [standard, Council Directive 2013/59/EURATOM¹](#) in line with IAEA. Within the UK, The Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018 (2018 No 482) significantly implements the Directive. There are other Regulations relating to contaminated land that also apply parts of the Directive.

¹ Within the Directive both 'quality assurance' and 'quality control' are defined.

Safety

Nuclear safety

Within the UK, nuclear activity (other than in means of transport) can only be undertaken on a licensed, permitted or authorised site.

As part of the ONR licensing a series of Licence Conditions (LCs) are prescribed. One of these is LC17 - Management Systems.

Defence sites which do not fall within licensing are 'authorised' by the Defence Nuclear Safety Regulator (DNSR) using conditions closely linked to the ONR LCs

Whilst accumulation and storage of nuclear materials are Licensable/Authorised activities, nuclear waste can only be disposed of by means 'authorised' by the EA, Natural Resources Wales or SEPA. For further information see [Radioactive substances regulation for nuclear sites](#)

Radiological safety

Within the UK the principal legislation, applying generally, not just to nuclear licensed sites, is the Ionising Radiation Regulations (IRRs).

Hazard and risk (definitions taken from ONR SAPs)

Understanding of the definitions and relationship of these two terms lies behind all regulatory approaches to safety.

Hazard	The potential for harm arising from an intrinsic property or disposition of something to cause detriment. See also external hazards.
Hazard potential	The propensity for the harm from a hazard to be realised.
External hazard	External hazards are those natural or man-made hazards to a site and facilities that originate externally to both the site and the process, i.e. the duty holder may have very little or no control over the initiating event.
Internal hazard	Internal hazards are those hazards to plant and structures that originate within the site boundary and over which the duty holder has control over the initiating event in some form.
Risk	Risk is the chance that someone or something is adversely affected in a particular manner by a hazard.

Note The UK Court of Appeal ² held that the term 'risk' in s.3, HSWA, means the possibility of danger rather than actual danger.

Link to safety case

The safety case is a fundamental suite of documentation which sets out the justification for nuclear safety. As such it inherently has to link to the management systems that have a prime function of delivering safety. This emphasises the issue that quality and management systems are about more than standard compliance but are about 'product' outcome.

See ONR references: [LC14 safety documentation](#); [Licence Condition 23 - Operating rules](#) and [NS-TAST-GD-051 The purpose, scope and content of safety cases](#)

² Court of Appeal – R v Board of Trustees of the Science Museum [1993] 3 All ER 853

Annex A- Text of IAEA GSR Part 3 Requirement 5 2014

The principal parties shall ensure that protection and safety are effectively integrated into the overall management system of the organizations for which they are responsible.

Protection and safety elements of the management system

2.47. The principal parties shall demonstrate commitment to protection and safety at the highest levels within the organizations for which they are responsible.

2.48. The principal parties shall ensure that the management system is designed and applied to enhance protection and safety by:

- (a) Applying the requirements for protection and safety coherently with other requirements, including requirements for operational performance, and coherently with guidelines for security;
- (b) Describing the planned and systematic actions necessary to provide adequate confidence that the requirements for protection and safety are fulfilled;
- (c) Ensuring that protection and safety are not compromised by other requirements;
- (d) Providing for the regular assessment of performance for protection and safety, and the application of lessons learned from experience;
- (e) Promoting safety culture.

2.49. The principal parties shall ensure that protection and safety elements of the management system are commensurate with the complexity of and the radiation risks associated with the activity.

2.50. The principal parties shall be able to demonstrate the effective fulfilment of the requirements for protection and safety in the management system

Safety culture

2.51. The principal parties shall promote and maintain safety culture by:

- (a) Promoting individual and collective commitment to protection and safety at all levels of the organization;
- (b) Ensuring a common understanding of the key aspects of safety culture within the organization;
- (c) Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, with account taken of the interactions between individuals, technology and the organization;
- (d) Encouraging the participation of workers and their representatives and other relevant persons in the development and implementation of policies, rules and procedures dealing with protection and safety;
- (e) Ensuring accountability of the organization and of individuals at all levels for protection and safety;
- (f) Encouraging open communication with regard to protection and safety within the organization and with relevant parties, as appropriate;
- (g) Encouraging a questioning and learning attitude, and discouraging complacency, with regard to protection and safety;
- (h) Providing means by which the organization continually seeks to develop and strengthen its safety culture.

Human factors

2.52. The principal parties and other parties having specified responsibilities in relation to protection and safety, as appropriate, shall take into account human factors and shall support good performance and good practices to prevent human and organizational failures, by ensuring among other things that:

(a) Sound ergonomic principles are followed in the design of equipment and the development of operating procedures, so as to facilitate the safe operation and use of equipment, to minimize the possibility that operator errors could lead to accidents, and to reduce the possibility that indications of normal conditions and abnormal conditions could be misinterpreted.

(b) Appropriate equipment, safety systems and procedural requirements are provided, and other necessary provision is made:

(i) To reduce, as far as practicable, the possibility that human errors or inadvertent actions could give rise to accidents or to other incidents leading to the exposure of any person;

(ii) To provide means for detecting human errors and for correcting them or compensating for them;

(iii) To facilitate protective actions and corrective actions in the event of failures of safety systems or failures of measures for protection and safety.

2.2 International and National Infrastructure

Scope and approach

The aim of this Section is to set out how international practices, commitments and in some cases law interact with the ways in which the UK nuclear industry is organised and the expectations that result. Details of the regulatory aspects are described in Chapter 3. Also provided are outlines of various international organisations operating in the nuclear arena which may be encountered; where these organisations have published quality/management systems related publications these are referred to.

Application

Tier 1 and 2 contractors need to have strong understanding of the international and UK industry picture, particularly regarding regulatory approaches and standard setting; whilst Tier 3 and 4 contractors should be aware of why requirements are likely to be placed via contractual requirements.

Introduction to International/National relationships

As described by the UK Department for Energy and Climate Change (DECC, since July 2016, part of the Department for Business, Energy and Industrial Strategy, BEIS)³ "The potential human, environmental and economic consequences of a serious release of radioactive material could be greater by orders of magnitude than those of an accident in another high hazard sector. Furthermore, the impact could extend far beyond national borders." Because of such widespread significance International organisations and agreements have been formed.

Between 1955 and 1959 the USA concluded agreements with 42 countries, whilst by 1968 the USSR had concluded nuclear co-operation agreements with 26 countries. In doing so, both major powers encouraged the establishment of regional / international organisations of their agreement states, in parallel to the overarching body which became the International Atomic Energy Agency (IAEA).

³ DECC –ONR legislative reform order explanatory section 12 – March 2010 -

In October 2018 there were 451 nuclear power stations in operation worldwide with 58 reactors under construction, across 30 countries⁴; some 60 countries were indicating interest in considering the introduction of nuclear power.

IAEA is the principal international organisation publishing standards; these are followed by many but not necessarily all states having nuclear industries. The IAEA produce a tiered set of publications related to Safety (including Transport), Security and Safeguards. IAEA Fundamental Safety Principles (See Section 2.1 for detail) No 5 'Leadership and management for safety' states – "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".

[IAEA Standard for Management systems, GS-R-3](#) published in 2006 is applicable at Regulatory/Operator – Licensee level. In 2016 IAEA replaced GS-R-3 with [GSR Part 2 Leadership and Management for Safety](#). Guidance to support this publication at June 2018 was scheduled to be published in Q4/2022, so in the UK the ONR have not yet been advising use of it to Site Licence Companies, although this is expected to change.

BEIS has the main Government lead on Generation and Waste Treatment/Storage whilst the Department for Environment, Food and Rural Affairs (DEFRA)/Welsh Assembly/Scottish Executive lead on Disposal aspects. A useful [overview of the nuclear supply chain](#), with commentary, is produced by the Nuclear Industry Association (NIA).

International Atomic Energy Agency (IAEA)



The international aspect of the nuclear industry was to some extent a consequence of the history of the industry and concerns about weapons proliferation. These expanded with recognition that there was scope for civil nuclear power, the knowledge for which the original nuclear powers (USA, UK, Canada, USSR,) held and restricted control. Consequently various bodies developed, acting in parallel but also often in concert, to both promote nuclear matters and also determine how that can be done safely and securely.

In November 1945, President Truman and Prime Ministers Attlee of the United Kingdom and Mackenzie King of Canada, meeting in Washington, issued a "Three Nation Agreed Declaration on Atomic Energy" in which they said that they would be willing "to proceed with the exchange of fundamental scientific literature for peaceful ends with any nation that will fully reciprocate" but only when "it is possible to devise effective reciprocal and enforceable safeguards acceptable to all nations" against its use for destructive purposes. They suggested that the new-born United Nations should promptly tackle the nuclear issue. Soon afterwards, in December 1945, at a meeting in Moscow of the Council of Foreign Ministers, the USA and the United Kingdom proposed, and the USSR agreed, that a United Nations Atomic Energy Commission (UNAEC) should be created "to consider problems arising from the discovery of atomic energy and related matters." From 1945 until 1949, when the UNAEC concluded that its work had ceased to be meaningful, the proclaimed aim of the USA and the USSR and their allies was not to prevent the spread of nuclear weapons but to do away with them altogether.

On 8 December 1953 US President Eisenhower made his "Atoms for Peace" speech to the General Assembly; which a year later unanimously endorsed the creation of the new agency - the [International Atomic Energy Agency \(IAEA\)](#).

In August 1955 "The First Geneva Conference" was held with some 1500 scientist and engineer delegates and more than 1000 scientific papers being presented. Soon the only nuclear technology remaining a closely guarded secret, other than construction of the bomb itself, was that of enriching uranium; in 1956 the IAEA Statute was approved, which empowered it. The IAEA was given seven

⁴ IAEA Power Reactor Information System / Table A-1 of IAEA Nuclear technology Review 2011

functions: (1) Research into atomic energy for peaceful purposes; (2) provision of materials etc to enable research, (3) considering the under-developed areas of the world;, (4) fostering information exchange; (5) encouraging training; (6) establishing and administering safeguards; (7) establishing standards of safety; where necessary acquiring facilities etc to undertake the first six functions. The first IAEA General Conference was held in Vienna in October 1957, with by the end of it a membership of 59 Member States; by 2011 the membership had risen to 151 States.

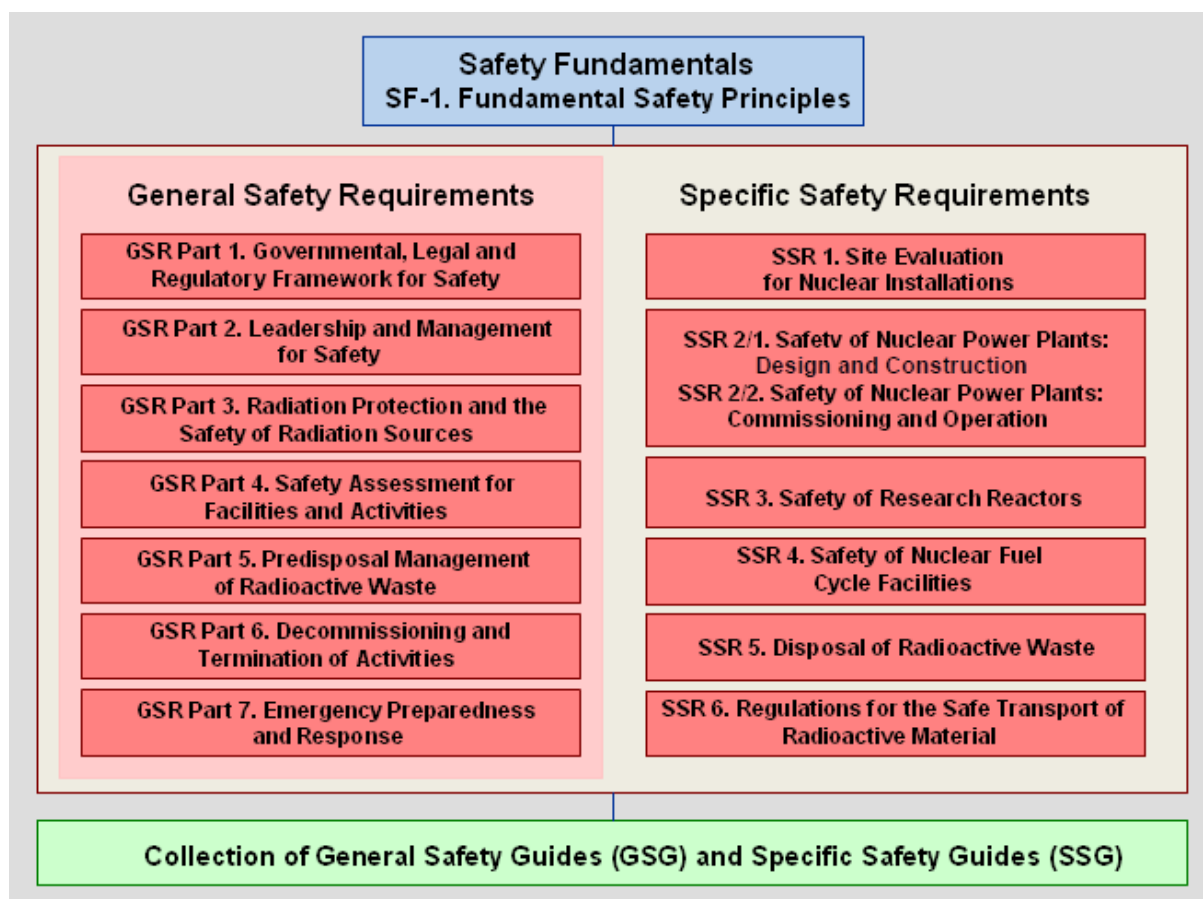
Safety (incl Transport)

In 1974, the IAEA launched the Nuclear Safety Standards (NUSS) programme. This was a comprehensive series of Codes and Safety Guides intended to ensure the safe design, siting and operation of the current generation of nuclear power reactors, and enhance their reliability. The IAEA agreed that a series of five NUSS Codes and 47 Safety Guides should be prepared between 1975 and 1980. In 1974, the Board decided NUSS documents would be recommendations.

IAEA Safety Standards Series

In 2008 a new, long-term structure (see figure below) for the safety standards was adopted such that users may easily identify those safety standards that are applicable to the specific facility or activity they are dealing with.

The Safety Fundamentals (SF-1), the General Safety Requirements (GSR) in seven parts and the General Safety Guides (GSG) are applicable to all facilities and activities. These are complemented by Specific Safety Requirements (SSR) and Specific Safety Guides (SSG), which are applicable to specified facilities and activities.



Fundamental Safety Principles establishes the fundamental safety objective and principles of protection and safety. The Fundamental Safety Principles (See Section 2.1) are drafted in language to be understandable to the non-specialist reader, and convey the basis and rationale for the safety standards for those persons at senior levels in government and regulatory bodies.

Safety Requirements publications establish the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. The format and style of the requirements facilitate their use by Member States for the establishment, in a harmonized manner, of their national regulatory framework and safety guides.

Safety Guides provide recommendations and guidance on how to comply with the safety requirements, indicating an international consensus on the measures recommended. The Safety Guides present international good practices, and increasingly they reflect best practices, to help users striving to achieve high levels of safety. They reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation.

Safety standards are applicable throughout the entire lifetime of facilities and activities – existing and new – utilized for peaceful purposes, and to protective actions to reduce existing radiation risks. They are developed by means of an open and transparent process for gathering, synthesizing and integrating the knowledge and experience gained from the actual use of nuclear energy technologies and from the application of the safety standards, including knowledge of emerging trends and issues of regulatory importance.

The [IAEA Safety Glossary](#) defines and explains technical terms used in the IAEA safety standards and other safety related IAEA publications, and provides information on their usage.

The whole range of [safety standards can be accessed via the web](#), along with safety standards under development and draft standards available for comment. (*Note the formal route for UK comments is via the Office for Nuclear Regulation (ONR)*). A frequently updated status listing of all standards is maintained and published by IAEA.

Transport

In 1961, the IAEA published its first regulations for the safe transport of radioactive material. These regulations have been reviewed and updated regularly over the last 50 years, and form the basis of international modal regulations established by other United Nations bodies, such as the International Maritime Organization and the International Civil Aviation Organization. The IAEA requirements are in turn adopted by national regulatory authorities creating a strong global regulatory framework.

Regulations for the Safe Transport of Radioactive Materials are revised frequently ([latest version 2018, SSR-6 Rev 1](#)) and supported by additional guidance such as:

- [TS-G-1.1 "Advisory Material for the Regulations for the Safe Transport of Radioactive Material"](#)
- [TS-G-1.4 "The Management System for the Safe Transport of Radioactive Material"](#)
- [TS-G-1.5 "Compliance Assurance for the Safe Transport of Radioactive Material"](#).

The Regulations address all categories of radioactive material ranging from very low activity, including such materials as ores and concentrates of ores, to very high activity such as spent fuel and high-level waste. The material to be transported must be categorized on the basis of its activity concentration, total activity, fissile characteristics (if any) and other relevant subsidiary characteristics. Packaging and package requirements are then specified on the basis of the hazard of the contents and range from normal commercial packaging (for low hazard contents) to strict design and performance requirements (for higher hazard contents). Specific requirements are also established for marking, labelling, placarding of conveyances, documentation, external radiation limits, operational controls, quality assurance and notification and approval of certain shipments and package types.

Security

Nuclear security issues relate to the prevention and detection of, and response to, theft, sabotage, unauthorized access and illegal transfer or other malicious acts involving nuclear material and other radioactive substances and their associated facilities. These are addressed by international nuclear

security instruments such as the Convention on the Physical Protection of Nuclear Material and its Amendment, the Code of Conduct on the Safety and Security of Radioactive Sources, the Supplementary Guidance on the Import and Export of Radioactive Sources, the United Nations Security Council resolutions 1373 and 1540 and the International Convention for the Suppression of Acts of Nuclear Terrorism.

Convention on the Physical Protection of Nuclear Material: 1979 (as amended)

The Convention establishes measures related to the prevention, detection and punishment of offenses relating to nuclear material. The 2005 amended Convention makes it legally binding for States Parties to protect nuclear facilities and material in peaceful domestic use, storage as well as transport. It also provides for expanded cooperation between and among States regarding rapid measures to locate and recover stolen or smuggled nuclear material, mitigate any radiological consequences of sabotage, and prevent and combat related offences.

Publications in the [IAEA Nuclear Security Guidelines series](#) are issued in the following categories:

- *Nuclear Security Fundamentals* contain objectives, concepts and principles of nuclear security and provide the basis for security recommendations.
- *Recommendations* present best practices that should be adopted by Member States in the application of the Nuclear Security Fundamentals.
- *Implementing Guides* provide further elaboration of the Recommendations in broad areas and suggest measures for their implementation.
- *Technical Guidance* publications comprise: *Reference Manuals*, with detailed measures and/or guidance on how to apply the Implementing Guides in specific fields or activities.

Safeguards

The [safeguards system](#) comprises measures by which the IAEA independently verifies the declarations made by States about their nuclear material and activities. These measures are implemented under various types of agreements and protocols. A significant basis of safeguards has traditionally been material accountancy, containment and surveillance. Inventory information is maintained by facility operators / licensees and reported via national authorities to IAEA. IAEA Inspectors undertake independent verification.

IAEA Reports

Each year IAEA publishes [summary reports](#) including an Annual Report, a Nuclear Safety Review, a Safeguards Implementation Report, a Nuclear Technology Review, and a Technical Cooperation Report.

IAEA Treaties, Conventions and Agreements

A [full list of Treaties etc](#) is available on the IAEA web site; the following are some of the most commonly referred to:

Treaty on the Non-Proliferation of Nuclear Weapons (NPT): 1968 + additional protocols

The NPT objective is to prevent the spread of nuclear weapons and weapons technology, to promote cooperation in the peaceful uses of nuclear energy and to further the goal of achieving nuclear disarmament and general and complete disarmament. Conferences to review the operation of the Treaty have been held at five-year intervals since the Treaty went into effect in 1970. Each conference has sought to find agreement on a final declaration that would assess the implementation of the Treaty's provisions and make recommendations on measures to further strengthen it.

Convention on Early Notification of a Nuclear Accident: 1986

Adopted following the Chernobyl nuclear plant accident, this Convention establishes a notification system for nuclear accidents which have the potential for international trans-boundary release that could be of radiological safety significance for another State. It requires States to report the accident's time, location, radiation releases, and other data essential for assessing the situation. The five nuclear-weapon States (China, France, Russia, the United Kingdom, and United States) have all declared their intent also to report accidents involving nuclear weapons and nuclear weapons tests.

Convention on Nuclear Safety: 1994

The aim is to commit participating States operating land-based nuclear power plants to maintain a high level of safety by setting international benchmarks to which States would subscribe.

The obligations of the Parties are based to a large extent on the principles contained in the IAEA Safety Fundamentals document "The Safety of Nuclear Installations". These obligations cover for instance, siting, design, construction, operation, the availability of adequate financial and human resources, the assessment and verification of safety, quality assurance and emergency preparedness.

Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management: 1997

The Joint Convention applies to spent fuel and radioactive waste resulting from civilian nuclear reactors and applications and to spent fuel and radioactive waste from military or defence programmes if and when such materials are transferred permanently to and managed within exclusively civilian programmes, or when declared as spent fuel or radioactive waste for the purpose of the Convention by the Contracting Party. The Convention also applies to planned and controlled releases into the environment of liquid or gaseous radioactive materials from regulated nuclear facilities.

Vienna Convention on Civil Liability for Nuclear Damage: 1963 amended 1997

In 1963 IAEA members agreed the "Vienna Convention on Civil Liability for Nuclear Damage". Following the Chernobyl accident, the IAEA initiated work on all aspects of nuclear liability with a view to improving the basic Conventions and establishing a comprehensive liability regime. In 1988, as a result of joint efforts by the IAEA and OECD NEA, the Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention (see NEA below) was adopted. The Joint Protocol established a link between the Conventions combining them into one expanded liability regime. Parties to the Joint Protocol are treated as though they were Parties to both Conventions and a choice of law rule is provided to determine which of the two Conventions should apply to the exclusion of the other in respect of the same incident.

Code of Conduct on safety of Research Reactors: 2006**Relationship Agreements with Specialized Agencies and Intergovernmental organisations**

These relate to interactions with UNESCO, ILO, WHO, WMO, ICAO, FAO, EEC(ENEA), I-ANEA

Organisation for Economic Co-operation and Development Nuclear Energy Agency (OECD NEA)**Background**

In 1948 the Organization for European Economic Cooperation (OEEC) was established to channel US aid to 16 Western European nations; in February 1958 the OEEC set up the European Nuclear Energy Agency (ENEA). OEEC became the OECD and the Agency's name was changed in 1972, to the Nuclear Energy Agency (NEA), reflecting growing membership beyond Europe's boundaries. The first phase of the NEA's programme mainly consisted of laying the foundations for nuclear co-operation, and focused on launching several joint R&D undertakings such as the Halden and Dragon reactor projects, and the prototype Eurochemic plant for the reprocessing of spent nuclear fuels. This period came to a natural end during the late 1960s.

By the early 1970s the Agency's role had changed to one where major emphasis was placed on providing a forum for co-ordinating the national nuclear programmes of member countries, particularly in the health, safety and regulatory areas. As nuclear energy gathered momentum in the 1970s, governments came under increasing pressure from their constituents to give greater priority to the environmental aspects of nuclear energy and to the safety and regulation of nuclear power plants.

In the early 1990s, in the wake of the dissolution of the Soviet Bloc, the Agency followed the lead of the OECD and initiated a limited programme of outreach, focusing primarily on the countries of Central and Eastern Europe and the former Soviet Europe. Some of the activities in the outreach programme have increasingly become an integral part of the core programme of the Agency as additional countries with reactors of Soviet design have become members.

Mission

The [OECD NEA's](#) mission is:

"To assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally sound and economical use of nuclear energy for peaceful purposes. It strives to provide authoritative assessments and to forge common understandings on key issues as input to government decisions on nuclear energy policy and to broader OECD analyses in areas such as energy and the sustainable development of low-carbon economies."

Organisation and Activities

The NEA is a semi-autonomous body of the OECD, comprising (Nov 2018) 33 nations. It is governed by the Steering Committee for Nuclear Energy, made up of senior officials from national atomic energy authorities and associated ministries, with the work mandated to the seven standing technical committees: Committee on the Safety of Nuclear Installations (CSNI); Committee on Nuclear Regulatory Activities (CNRA); Radioactive Waste Management Committee (RWMC); Committee on Radiation Protection and Public Health (CRPPH); Nuclear Science Committee (NSC); Committee for Technical and Economic Studies on Nuclear Energy Developments; and the Fuel Cycle (NDC) and Nuclear Law Committee (NLC).

In 2010 CNRA held a workshop on 'Experience from Inspecting Safety Culture, Inspection of Licensee Safety Management Systems and Effectiveness of Regulator Inspection Process'. The workshop proceedings ([Report 5](#)) and national pre-question reports ([Report 6](#)) are on the web site. Pages 32 to 36 of Report 5 record the discussion groups on Licensee Safety Management Systems and provide a useful insight into international regulatory expectations and thinking. Issues raised include:

- the need for grading according to safety significance;
- certification to ISO9001 should not automatically lead to attention / inspection;
- senior management has a prominent role in implementation and continuous improvement of the management system;
- need to consider both programmes/processes and outcomes/findings;
- overly complicated processes are cumbersome for effective implantation of the management system and understanding it;
- management systems failures do lead to major events (e.g. Davis Besse vessel head corrosion);
- a focus on root causes of problems is necessary rather than fixing individual problems.

Multinational Design Evaluation Programme (MDEP)

The NEA performs the Technical Secretariat functions for [MDEP](#). MDEP is a multinational initiative taken by national safety authorities to develop innovative approaches to leverage the resources and knowledge of the national regulatory authorities who are currently or will be tasked with the review of new reactor power plant designs. Activities include a working group on Codes and Standards and the [Vendor Inspection Co-operation Working Group \(VICWG\)](#).

[VICWG-02 Technical report](#) "Survey on Quality Assurance Program Requirements" provides responses by Canada, China, Finland, France, Japan, Russian Federation, South Korea, South Africa, UK and USA on their national requirements match against US 10-CFR-50 Appx B.

[VICWG Programme Plan 2018-19](#) outlines the objective of the group which is essentially to bring about the international harmonisation of QA/QC standards for reactor and reactor equipment suppliers.

Conventions on Civil Liability for Nuclear Damage

There are two basic international regimes for nuclear third party liability in force: the Convention on Third Party Liability in the Field of Nuclear Energy ("the Paris Convention") was established in 1960 under the auspices of the NEA and covers most West European countries, while the Convention on Civil Liability for Nuclear Damage ("the Vienna Convention") was established in 1963 under the auspices of the International Atomic Energy Agency (IAEA) and is worldwide in character. UK is a signatory to the Paris convention.

Coverage under the Paris Convention is extended by the Supplementary Convention on Third Party Liability in the Field of Nuclear Energy of 1963 ("the Brussels Supplementary Convention").

The Paris Convention and the Brussels Supplementary Convention have both been amended three times: by Additional Protocols adopted in 1964, 1982 & 2004. Furthermore, the Paris and Vienna Conventions have been linked by the Joint Protocol Relating to the Application of the Vienna Convention and the Paris Convention of 1988 ("the Joint Protocol") which entered into force in 1992. The Paris and the Vienna Conventions are supplemented, in relation to maritime transport, by the Convention Relating to Civil Liability in the Field of Maritime Carriage of Nuclear Material of 1971 ("the 1971 Brussels Convention").

EU/EURATOM

European activities in nuclear matters have been undertaken since 1957 through the EURATOM treaty that established the European Atomic Energy Community, with an aim of assisting the development of a civil nuclear industry in Europe. Article 2 of the treaty requires the community to:

- Promote research and ensure the dissemination of technical information
- Establish uniform safety standards to protect the health of workers and the general public and ensure they are applied
- Facilitate investment particularly by ventures to establish basic development installations
- Ensure all users in the Community obtain an equitable supply of ores and nuclear fuels
- Make certain, by supervision, that nuclear materials are not diverted to non-intended purposes
- Exercise the right of ownership in respect of special fissile materials
- Create a common market in specialised materials and equipment
- Establish relations to foster progress in the peaceful use of nuclear energy

Other sections of the treaty expand on these requirements. Falling out from the EURATOM treaty requirements are the following directives:

- Council directive 96/29/EURATOM: 13 May 1996: Basic Safety Standards for the Protection of the Health of Workers and the General Public against the Dangers Arising from Ionising Radiation: OJ L 159, 29.6.1996, p.1.

Note: A Revision Draft EURATOM Basic Safety Standards Directive' was produced and adopted by the European Council in September 2011 - COM(2011)593 adopted 29 Sept 2011.

Note: In the UK the BSS are largely, but not completely, met by the Ionising Radiations Regulations. The Environmental Permitting (England and Wales) Regulations also directly apply.

- Council directive 87/600/EURATOM of 14 December 1987: Community Arrangements for the Early Exchange of Information in the Event of a Radiological Emergency: OJ L 371, 30.12.1987, p.31.
- Council directive 89/618/EURATOM of 27 November 1989: Informing the General Public about Health Protection Measures to be Applied and Steps to be Taken in the Event of a Radiological Emergency: OJ L 357, 7.12.1989, p.31.

- Note In the UK the directive is implemented by the Radiation (Emergency Preparedness and Public Information) Regulations (REPPiR).
- Council directive 2003/122/EURATOM on the Control of High-activity Sealed Radioactive Sources and Orphan Sources; OJ No L 346, 31.12.2003, p57.
- Council Directive 2009/71/EURATOM on Establishing a Community Framework for the Nuclear Safety of Nuclear Installations: OJ L 172, 2.7.2009, p18.

The United Kingdom announced its intention to withdraw from Euratom on 26 January 2017, as part of Brexit. Withdrawal will only become effective following negotiations on Brexit terms, as of January 2019 this is scheduled for 29th March 2019.

The [Nuclear Safeguards Act 2018](#), makes provision for safeguards after withdrawal from Euratom.

International Organisations

European Nuclear Safety Regulators Group (ENSREG)

[ENSREG](#) was established in 2007, by the European Commission, as a High Level Advisory Group on Nuclear Safety and Waste Management. It comprises top regulators and civil servants from all 27 EU Member states plus the Commission, working on a consensus basis.

Western European Nuclear Regulator's Association (WENRA)

[WENRA](#) formed in 1999, is a network of Chief Regulators of EU countries with nuclear power plants and Switzerland as well as of other interested European countries which have been granted observer status.

The main objectives of WENRA are to develop a common approach to nuclear safety, to provide an independent capability to examine nuclear safety in applicant countries and to be a network of chief nuclear safety regulators in Europe exchanging experience and discussing significant safety issues.

WENRA have produced "Safety Reference Levels" for Reactors, Decommissioning, Waste and Spent Fuel Storage. These are clear statements of requirements, grouped by topics including Management of Safety, cross referencing to IAEA Requirements. (Note having been developed over several years the separate topic SRLs are worded differently.) They have also undertaken benchmarking, which is reported in the SRL reports.

World Institute for Nuclear Security (WINS)

[WINS](#) was established to provide an international forum for those accountable for nuclear security to share and promote the implementation of best security practices. It has both individual and corporate members, and is based in Vienna. It is working closely with IAEA and WANO and as of December 2018 had produced some 35 'Best Practice Guides' available to members via their web site.

The Institute of Nuclear Power Operations (INPO)

[INPO](#) was established by the nuclear power industry in December 1979 as a not-for-profit organization headquartered in Atlanta USA, charged with a mission to promote the highest levels of safety and reliability – to promote excellence – in the operation of commercial nuclear power plants. INPO was established in response to The Kemeny Commission – set up by President Jimmy Carter to investigate the March 1979 accident at the Three Mile Island nuclear power plant – which had recommended that:

- The (nuclear power) industry should establish a program that specified appropriate safety standards including those for management, quality assurance, and operating procedures and practices, and that conducts independent evaluations.
- There must be a systematic gathering, review, and analysis of operating experience at all nuclear power plants coupled with an industry-wide international communications network to facilitate the speedy flow of this information to affected parties.

INPO aim to achieve their mission by:

- Establishing performance objectives, criteria and guidelines for the nuclear power industry

- Conducting regular detailed evaluations of nuclear power plants
- Providing assistance to help nuclear power plants continually improve their performance

The four cornerstones of INPO are claimed as:

- Plant evaluations
- Training and accreditation
- Events analysis and information exchange
- Assistance

World Association of Nuclear Operators (WANO)

[WANO](#)'s declared mission is to maximise the safety and reliability of nuclear power plants worldwide by working together to assess, benchmark and improve performance through mutual support, exchange of information and emulation of best practices.

Operating from London, Atlanta, Moscow, Paris and Tokyo; WANO exists to help its members accomplish the highest levels of operational safety and reliability achieved through a series of programmes which include peer reviews, technical support and access to a global library of operating experience. UK members in 2018 included EDF, Magnox, Sellafield and NDA.

WANO produce Performance Objectives and Criteria which are available on registration.

Nuclear Energy Institute (NEI)

[NEI](#) is a US based organisation which, with member participation, develops policy on key legislative and regulatory issues affecting the industry. It has over 350 members in 15 countries spanning the range of commercial nuclear technologies.

Electric Power Research Institute (EPRI)

[EPRI](#) is a US based organisation, operating beyond nuclear but having two areas of nuclear activity – Advanced Nuclear Technology and Risk and Reliability.

The European Atomic Forum (FORATOM)

[FORATOM](#) is a Brussels-based trade association for the nuclear energy industry in Europe. Its main purpose is to promote the use of nuclear energy in Europe by representing the interests of this important and multi-faceted industrial sector in energy policy discussions involving the EU institutions and provide a "bridge" between the industry and the institutions (Members of the European Parliament and key policy-makers in the European Commission). The membership is made up of 15 (Dec 2018) national nuclear associations and also represents nearly 800 firms.

2.3 UK Government, Regulatory Organisation and Nuclear Industry

UK government involvement in nuclear matters is divided between several departments, depending on the aspects covered.

Fundamentally [BEIS](#) (Department for Business, Energy & Industrial Strategy) is responsible for the safe and secure operation of the civil nuclear programme, the Ministry of Defence (MoD) for the defence programme, with the Department for Environment, Food and Rural Affairs (DEFRA) and Devolved Governments for waste discharges and disposal. The Foreign and Commonwealth Office (FCO) take the overview on non-proliferation of nuclear weapons and represents the UK in formal linkages with foreign governments and international organisations such as the IAEA.

Regulatory aspects lie around safety, security, safeguards, transport and environment. Historically these were undertaken by separate organisations, but in 2007 security (Office for Civil Nuclear Security (OCNS)) and UK Safeguards both transferred to join safety in HSE's Nuclear Directorate (which included the Nuclear Installations Inspectorate (NII)). In February 2011 the Government announced that an independent statutory body, known as the Office for Nuclear Regulation (ONR) was to be set up with the Radioactive Materials Transport Team (RMTT) transferring from the Department for Transport (DfT). Since April 2014 the Office for Nuclear Regulation (ONR), has

statutory responsibility for ensuring that there is an adequate framework for regulating nuclear sites in the UK. The ONR is accountable to the Secretary of State for BEIS.

The Environment Agency (EA) in England, Natural Resources Wales and the Scottish Environment Protection Agency (SEPA) regulate the routine discharge and disposal of nuclear waste and other radioactive material. (There are *no licensed nuclear sites in Northern Ireland, although there are non-licensable applications which are regulated by the Northern Ireland Environment Agency (NIEA)*). EA is accountable to the Secretary of State for the Environment, Food and Rural Affairs for its work in England, Natural Resources Wales to the National Assembly for Wales, and SEPA is accountable to the Scottish Government.

Public Health England (PHE) predominantly through the '[Centre for Radiation, Chemical and Environmental Hazards](#)' carries out Public Health England's work on ionising and non-ionising radiations (which until the 2005 merger was known as National Radiation Protection Board (NRPB)). PHE provide the Secretariat for two national committees:

- The Administration of Radioactive Substances Advisory Committee ([ARSAC](#)), which advises the Department of Health (DH) on matters relating to the granting of certificates to practice nuclear medicine in the UK, and other related scientific and radiological safety issues.
- The Committee on Medical Aspects of Radiation in the Environment ([COMARE](#)) is an independent expert advisory committee with members chosen for their medical and scientific expertise and recruited from Universities, Research and Medical Institutes. The Committee offers independent advice to all Government Departments and Devolved Authorities, not just the Health Departments, and is responsible for assessing and advising them on the health effects of natural and man-made radiation. It is also asked to assess the adequacy of the available data and it advises on the need for further research.

PHE provide advice across government in radiation emergencies and also co-ordinates the National Arrangements for Incidents involving Radioactivity ([NAIR](#))

The [Food Standards Agency \(FSA\)](#) has responsibility for radioactivity in food, naturally occurring, deliberate treatment and post-accident controls. It works largely in conjunction with EA/SEPA and PHE.

Fig 1 shows the main overall relationships.

UK Civil nuclear industry

The UK has many organisations involved in civil nuclear, split into the following sectors,

- Government
- Regulators
- Industry Companies
- Existing Decommissioning, Reprocessing and Waste Management Contracts and Work streams
- New Build
- Existing Generation
- Trade Unions
- Professional Bodies
- Research & Development
- Industry Supporting Bodies
- Skills Development Bodies

Other areas involving ionising radiation uses such as medical are not so easily identified.

UK Defence Nuclear

Whilst the Ministry of Defence (MoD) is responsible for defence nuclear matters, the detailed parts of the organisation are harder to identify.

- Royal Navy - Fleet Commander's purpose is to provide ships, submarines and aircraft ready for any operations that the Government requires. RN operates three fleet submarines of the

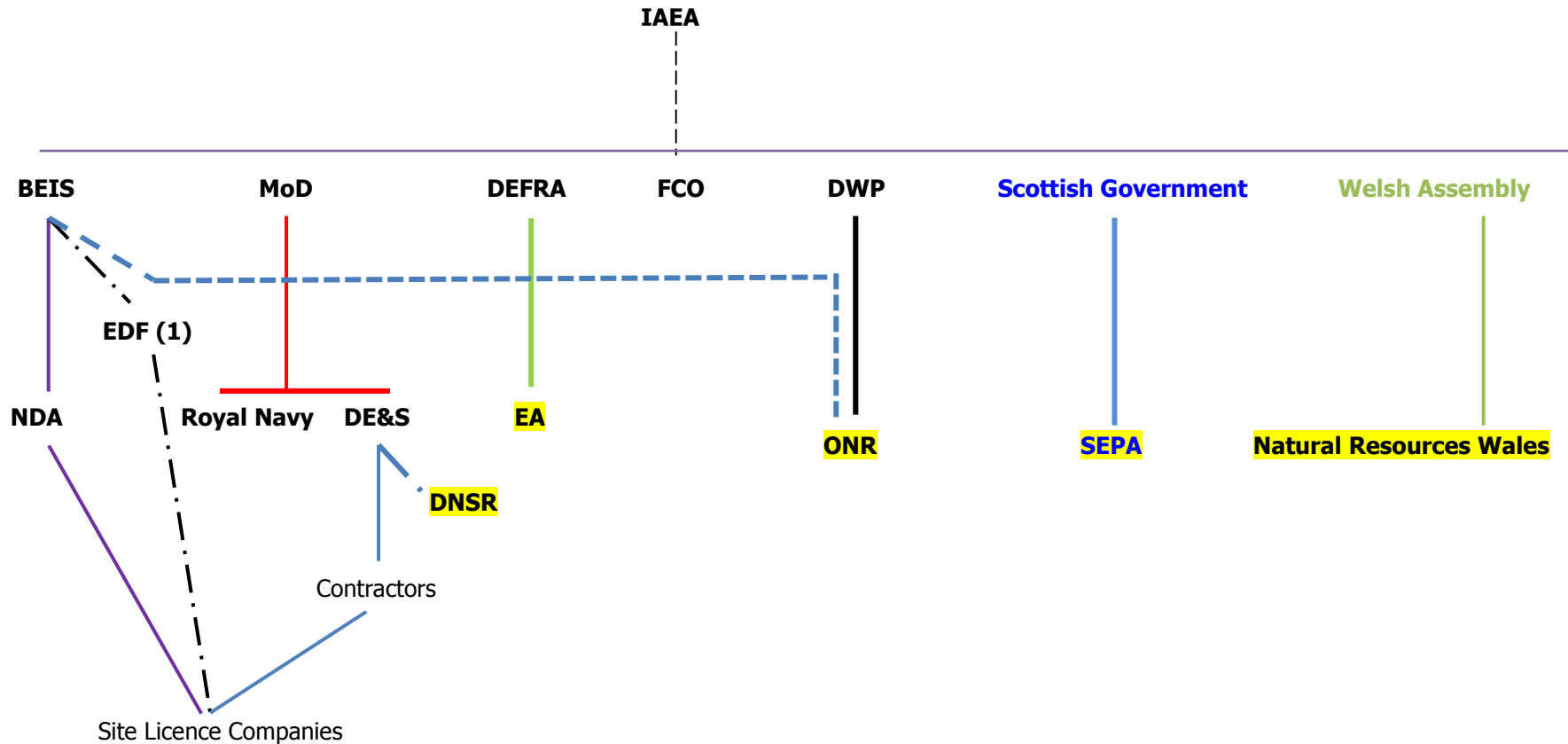
Trafalgar and seven (four commissioned and three in build) of the Astute class and four ballistic missile submarines of the Vanguard class (to be replaced by four Successor/Dreadnought which have started construction). All submarines are nuclear powered. Twenty nuclear submarines are laid up at Rosyth and Davenport awaiting decommissioning.

- [MoD Defence Equipment & Support \(DE&S\)](#) includes the Chief of Materiel (Submarines) whose organisation covers:
 - Submarine Acquisition: responsible for Submarine Programmes, Submarine Production, Future submarines, Commercial and maritime Underwater Future Capability
 - Submarines support which includes Finance, Engineering, In-Service Submarines, Nuclear Propulsion, Strategic Weapons, Naval Authority Group and Combat systems.
- [Defence Safety Authority \(DSA\)](#) and its Defence Nuclear Safety Regulator (DNSR) are the internal MoD regulatory authorities, working to
 - [JSP518](#) – Regulation of the Naval Nuclear Propulsion Programme
 - [JSP538](#) - Regulation of the Nuclear Weapons Programme

Design and manufacture of naval propulsion systems are undertaken by Rolls Royce, whilst design and construction of submarines is undertaken by BAe Systems Marine. The bases at Devonport and Rosyth are owned and operated, whilst Clyde is operated, by Babcock Marine.

Naval sites are not all licensed and the term Authorised sites may be found which is the equivalent under regulation by DNSR. Where Nuclear Powered Warships are berthed in locations outside Authorised sites, these locations are termed Operational Berths.

Figure 1: UK government organisation



Notes

(1) EDF is used here as the example of an Operator. It would relate to both EDF-E NGL, in relation to Generation, or to NNB Gen Co for Nuclear New Build.

2.4 UK Legal and Regulatory Requirements

Scope and approach

The aim of this Section is to set out how the nuclear industry in the UK is regulated and the resulting nuclear specific legislation. In doing so it should be recognised that Government policy on nuclear matters is the responsibility of the departments/devolved bodies identified in Section 2 – for civil nuclear Department for Business, Energy, and Industrial Strategy lead with New Nuclear Policy, Nuclear & Radioactive Waste Policy, and National Policy Statements for Energy Infrastructure. In the area of Decommissioning and Radioactive Waste the Nuclear Decommissioning Authority (NDA) undertake much of the detailed development on behalf of BEIS and establish the arrangements for the management of the implementation.

The nature of nuclear regulation is different from that of other high hazard industries because the potential human, environmental and economic consequences of a serious release of radioactive material could be greater by orders of magnitude than those of an accident in another sector; furthermore, the impact could extend far beyond national borders. Nuclear regulation is uniquely intrusive and intensive, and takes account of risks broader than simply those of health and safety at work, as is reflected in the security and safeguards regimes.

Application

Tier 1 and 2 contractors need to have strong understanding of the UK nuclear law application; whilst Tier 3 and 4 contractors should be aware of both normal legal duties and why requirements are likely to be placed via contractual requirements.

Undertaking of activities

General & Safety

Since 1959¹ civil nuclear activities can only be undertaken on licensed sites and the licence contains licence conditions 'necessary or desirable in the interests of safety'. Licences are issued by the Office for Nuclear Regulation (ONR). Additionally any activity involving the extraction of plutonium or uranium, or any treatment of uranium such as to increase the proportion of the isotope 235, requires a permit in writing from the Minister.

The [Nuclear Installations Act](#) also addresses issues of liability / insurance which are handled by DECC.

Activities that are licensable additional to installing / operating nuclear reactors are prescribed in the [Nuclear Installation Regulations](#) as those used for:

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

¹ Nuclear Installations Act; 1959 was consolidated into Nuclear Installations Act 1965 (1965 Chap 57), amended by the Nuclear Installations Act 1969 (1969 Chap 18).

A fuller list of applicable UK legislation can be found via National Archives index search on [nuclear radioactive](#) and [atomic](#). The following regulations in particular will be applied frequently:

- Ionising Radiations Regulations 2017 ([IRR17](#))
- Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999 ([EIADR 99](#))
- Radiation (Emergency Preparedness and Public Information) Regulations 2001 ([REPPPIR](#)) – to be revised and republished in 2019.

Conventional health and safety regulation (for example construction work, electrical safety, machinery-guarding, work at heights and storage and use of chemicals) is regulated at nuclear sites by the ONR.

Security

Security on major civil sites in future will be addressed by the [Nuclear Security Regulations 2018](#). The application goes beyond licensed sites to a few major industrial facilities. Only premises having approved security plans, and approved carriers can be used. Regulation is undertaken by ONR who in time will produce guidance. Regulation of hospitals, universities and other smaller scale facilities is undertaken by the police, whilst security of military sites is undertaken by MoD.

Transport

Three international agreements relate to the carriage of dangerous goods, to which the UK is a party). These agreements, cover road, rail and inland waterway and known in short as ADR/RID/ADN, are as follows:

- "ADR": the European Agreement concerning the International Carriage of Dangerous Goods by Road (signed at Geneva on 30 September 1957);
- "RID": the Convention concerning International Carriage by Rail (signed at Berne on 9 May 1980) (the Regulation concerning the International Carriage of Dangerous Goods by Rail).
- "ADN": the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterway (signed at Geneva on 26 May 2000);

Regulation of each is addressed in the UK by the [Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations](#) but a common thread leads back to the IAEA Transport Safety Requirements and Safety Guides. Regulation is undertaken by ONR.

Topics addressed include international radioactive packaging, labelling, handling and storage in transit and recordkeeping or supply of information. The lead source is IAEA "Regulations for the Safe Transport of Radioactive Material, now SSR-6 Rev 1 2018; section 306 and 307 specifically address Management System and Compliance Assurance, while section VII relates to test procedures.

Additional guidance can be found in the [IAEA guides](#) in particular [TS-G-1.4](#) and [TS-G-1.5](#); the latter includes model checklists for inspections; and in [ONR Transport guidance](#).

Safeguards

Nuclear safeguards are measures to verify that States comply with their international obligations not to use nuclear materials (plutonium, uranium and thorium) from their civil nuclear programmes to manufacture nuclear weapons. The need for such verification is reflected in the requirements of the Treaty on the Non-Proliferation of Nuclear Weapons (NPT) for the application of safeguards by the International Atomic Energy Agency (IAEA). Also, the Treaty Establishing the European Atomic Energy Community (the Euratom Treaty) includes requirements for the application of safeguards by the European Commission. The primary safeguards 'regulators' are at the time of writing the safeguards inspectorates of IAEA and Euratom. When the UK leaves the EU, the UK will replace the inspection function currently provided by Euratom with resources from ONR.

Within the UK, the Foreign and Commonwealth Office (FCO) provides the UK perspective on the Non Proliferation Treaty (NPT) and Nuclear Cooperation Agreements (NCAs), whilst BEIS Nuclear Non-

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Proliferation Policy Unit leads on non-proliferation aspects of BEIS's policy interest. ONR Safeguards undertake the detailed regulatory activities and interactions with IAEA.

Key UK legislation includes:

- [Nuclear Explosions \(Prohibition and Inspections\) Act 1998](#).
- [Nuclear Safeguards Act 2018](#).
- [The Uranium Enrichment Technology \(Prohibition of Disclosure\) Regulations 2004](#).
- [The Nuclear Safeguards \(Notification\) Regulations 2004](#):

Environment

Environmental regulation depends on the location of the facility and thus discharge/ disposal authorisation is required. For England and Wales, regulation is by the EA whilst for Scotland it is by SEPA. Further information on Radioactive waste (with links to Scottish Government, Welsh Assembly and Northern Ireland Department of the Environment web sites) is published on the [BEIS website](#). EA publish information via two web pages, [one for radioactive substances users](#), such as hospitals, research organisations, radiographers and process industries, and [one for civil or defence related nuclear sites](#).

In England and Wales, [The Environmental Permitting \(England and Wales\) Regulations 2016](#) apply. These regulations are not only related to 'radioactive substances activities' which are specifically addressed in Schedule 23.

EA has [published guidance on Radioactive Substances Regulation](#) including RSR 1, Environmental Principles (2010) and Management Arrangements at Nuclear Sites (2010).

On 1 September 2018, the Environmental Authorisations (Scotland) Regulations 2018 (EA(S)R) came into force for radioactive substances activities in Scotland. This replaces the Radioactive Substances Act 1993 (RSA93), associated Exemption Order and the High-Activity Sealed Sources and Orphan Sources Regulations 2005 – for guidance on the law as applied in Scotland see the [SEPA Radioactive Substances website](#).

Licensing

In relation to all civil and privately managed defence sites, the ONR's Chief Nuclear Inspector grants [nuclear site licences](#) under the NI Act. The ONR ensures compliance with licences and their conditions and takes enforcement action where appropriate. Other defence nuclear sites that are Crown sites (ie MoD-controlled) are exempt from the licensing requirements of the NI Act. Aspects of these sites are regulated by the ONR under the provisions of Health and Safety at Work Act (HSWA) and associated regulations, working in conjunction with the Defence Nuclear Safety Regulator (DNSR).

The nuclear site licence is a legal document, issued before the start of construction and remaining in place throughout the life of the facility, until it can be shown that there has ceased to be any danger from ionising radiations from anything on the site. It contains site-specific information, such as the licensee's address and the location of the site, and defines the number and type of installations permitted. Licence Conditions, covering design, construction, operation, and decommissioning, are attached to each licence. These conditions require licensees to implement adequate arrangements to ensure compliance. Since 1990 there have been standardised LCs (currently 36); of particular note in relation to 'quality' is LC17 – 'Management Systems' (until 2011 entitled Quality Assurance).

Where a new site is to be licensed, or where an existing site is to be relicensed to accommodate the introduction of an additional class of prescribed activity, ONR will scrutinise the developing design safety case to assess whether the operations at the site will be adequately safe [as undertaken in relation to [Nuclear New Build Generic Design Assessment \(GDA\) activity](#)]

NI Act also states that a licence can be granted only to a corporate body and is not transferable. It follows that the licensee must be a company which is also the principal user of the site.

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

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

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

Application of LCs

ONR's safety activities are defined in generic aspects of [permissioning which includes assessment and issue of licence instruments](#), and [compliance that includes issue of licences and intervention \(inspection\)](#). Further details on these and the regulatory expectations set out in guidance to inspectors are published on the ONR website, along with links to safety assessment principles (SAPs), technical inspection guides (TIGs) and technical assessment guides (TAGs). Guides will cross-refer to applicable IAEA safety publications. Guidance on ALARP and comparisons to WENRA Reference Levels can be found via the SAPs page.

[New reactor \(generic design\) assessment guidance](#) and [geological disposal](#) guidance can be found via links on the ONR website.

It should be noted that conventional H&S legislation, which applies regardless of nuclear regulation, in the Management of Health and Safety at Work Regulations 1999, Regulation 5 Health and Safety Arrangements, (1) requires "Every employer shall make and give effect to such arrangements as are appropriate, having regard to the nature of his activities and the size of his undertaking, for the effective planning, organisation, control, monitoring and review of the preventive and protective measures."

Environmental authorisations

Environmental authorisations are required over and above licensing. Guidance is provided by the respective national environment agencies.