IAEA-NS-IRRS-2019/06 - Rev. 1
ORIGINAL: English

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

Bootle, UK

14 to 25 October 2019

DEPARTMENT OF NUCLEAR SAFETY AND SECURITY

INTEGRATED REGULATORY REVIEW SERVICE (IRRS)

TO

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

Integrated Regulatory Review Service

IAEA IRRS

REPORT OF THE

INTEGRATED REGULATORY REVIEW SERVICE (IRRS) MISSION

TO

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

Rev. 1 (April 2020)

Mission dates:	*14 to 25 October 2019*
Organizations involved:	*Department for Business, Energy and Industrial Strategy (BEIS); Department of Agriculture, Environment and Rural Affairs (DAERA); Department for Environment, Food and Rural Affairs (Defra); Department for Transport (DfT); Department of Health and Social Care (DHSC); Department of Work and Pensions (DWP); Care Quality Commission (CQC); Civil Aviation Authority (CAA); 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); Maritime and Coastguard Agency (MCA); Natural Resources Wales (NRW); Northern Ireland Environment Agency (NIEA); Northern Ireland Health Department; Office for Nuclear Regulation (ONR); Public Health England (PHE); Regulation and Quality Improvement Authority (RQIA); Scottish Environment Protection Agency (SEPA); Scottish Environment Department; Scottish Health Department; Welsh Environment Department; Welsh Health Department.*
Location:	*Bootle, THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND*
Regulated facilities, activities and exposure situations in the scope of the IRRS mission:	*Regulated facilities, activities and exposure situations in the scope of the IRRS mission: Nuclear Power Plants, Fuel Cycle Facilities, Waste Management Facilities, Decommissioning Activities, Radiation Sources Applications, Transport of Radioactive Material, Planned and Existing Occupational, Medical and Public Exposure Situations.*
Organized by:	*International Atomic Energy Agency (IAEA)*

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The number of recommendations, suggestions and good practices is in no way a measure of the status of the national infrastructure for nuclear and radiation safety. Comparisons of such numbers between IRRS reports from different countries should not be attempted.

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EXECUTIVE SUMMARY

At the request of the Government of the United Kingdom of Great Britain and Northern Ireland (UK), from 14 to 25 October 2019, an international team of senior safety experts conducted an Integrated Regulatory Review Service (IRRS) peer review mission. The purpose of this mission was to evaluate the UK's regulatory framework for nuclear and radiation safety against the IAEA safety standards. The IRRS mission was requested by the Government of the UK in March 2018. This was the fourth IRRS mission that the UK has hosted since IRRS programme began in 2006 and the first full scope mission which addressed both nuclear and radiation safety.

The IRRS mission included interviews and interactions with the Department for Business, Energy and Industrial Strategy (BEIS); Care Quality Commission (CQC); Civil Aviation Authority (CAA); Environment Agency (EA); Food Standards Agency (FSA); Food Standards Scotland (FSS); Health and Safety Executive (HSE); Health and Safety Executive for Northern Ireland (HSENI); Healthcare Improvement Scotland (HIS); Healthcare Inspectorate Wales (HIW); Maritime and Coastguard Agency (MCA); Natural Resources Wales (NRW); Northern Ireland Environment Agency (NIEA); Office for Nuclear Regulation (ONR); Public Health England (PHE); The Regulation and Quality Improvement Authority (RQIA); and Scottish Environment Protection Agency (SEPA). In addition, the following organizations participated in the preparations for the mission and supported the UK during the mission: Department of Health and Social Care (DHSC); Department for Transport (DfT); Department for Environment, Food and Rural Affairs (Defra); Scottish Environment Department; Scottish Health Department; Welsh Environment Department; Welsh Health Department; Northern Ireland Health Department; Department of Agriculture, Environment and Rural Affairs (DAERA);

The IRRS team commends the UK for hosting this very comprehensive peer review which included 16 regulatory bodies and governmental departments. Prior to the mission, the IRRS team conducted a desktop review of all the information submitted in support of the mission. The results of the review were used as an input towards the scheduling of interviews, site visits and other interactions with UK officials. As indicated in the introduction section of the IRRS report, the IRRS team acquired field evidence to supplement its desktop review. As such, the schedule was a sample representation of the regulatory bodies of the UK. The IRRS team encourages the UK Government to implement actions to address the mission's findings by the respective agencies as lessons learned in order to align with IAEA safety standards. The UK Government should consider the findings of the mission team to conduct a self-assessment and apply it to areas that have not been reviewed.

The Good Practices identified by the IRRS team are:

- ONR has developed a matrix management structure that effectively allocates resources and improves hiring, training and strategic planning practices of the organization;
- Security officers (i.e., Counter Terrorist Security Adviser), who specialize in radiological matters, advise the environment regulators on security measures for category 1 to 4 radioactive sources.

The IRRS team concluded that the preparation for the mission has re-energized cooperation between regulatory bodies in the UK and allowed a better understanding of the IAEA safety standards. The team encourages the UK to continue with this level of cooperation.

Strengths identified during the IRRS mission include:

- All regulatory authorities have dedicated and competent staff
- All regulatory authorities publish extensive regulatory guidance for authorized parties
- ONR has an effective regulatory framework for nuclear safety with clear strategies for the regulatory oversight of nuclear licensed sites

The IRRS team also identified areas for further improvement:

- The UK Government should publish a single, formalized statement of its national policy and strategy for safety
- HSE, HSENI and ONR should improve their regulatory oversight of occupational exposures, especially their processes for granting consent for high-risk activities

- CQC, HIS, HIW and RQIA should improve their oversight of medical exposures not related to the administration of radioactive substances
- HSE and other relevant regulatory authorities should develop long term inspection programs
- Several regulatory authorities should improve their respective human resource plans to align with their oversight functions for radiation safety
- All regulatory authorities should further develop their management systems
- All regulatory authorities should systematically take into account IAEA safety standards in the development of regulatory guidance

The IRRS team consisted of 18 senior regulatory experts from 14 IAEA Member States, 2 IAEA staff members and 1 IAEA administrative assistant, and 3 observers. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities and processes of the regulatory body including authorization, review and assessment, inspection, enforcement and the development and content of regulations and guides; and emergency preparedness and response. The review also included the optional review area on interface with nuclear security. Facilities, activities and exposure situations covered included nuclear power plants, radiation source applications, fuel cycle facilities, waste management facilities, decommissioning, transport of radioactive material, occupational exposure, medical exposure, and public exposure. In addition, three policy issues were discussed: (1) Public engagement around risk, (2) Regulatory Innovation and Regulating Advanced Nuclear Technologies, and (3) Management of Nuclear and Radioactive Material and Waste.

The UK authorities conducted a self-assessment in preparation for the mission and presented a preliminary action plan. The results of the self-assessment, including a summary report, and supporting documentation were provided to the IRRS team as advance reference material for the mission.

During the mission, the IRRS team performed a systematic review of all topics within the agreed scope of the review, through review of the advance reference material, conducting interviews with management and staff from the participating UK authorities. While the IRRS mission was a full scope mission and included all regulatory bodies and governmental departments, 16 regulatory authorities participated in the submission of the documentation in support of the mission. The authorities interviewed by the IRRS team were representative of the regulatory bodies in the UK. Therefore, this report does not discuss all relevant regulatory authorities in each chapter.

The IRRS team had also opportunities to observe regulatory inspections at various facilities including a nuclear power plant; a industrial radiography facility; a hospital and a radioactive waste management facility.

A meeting was also held with senior executives of BEIS, ONR, HSE and DWP.

Throughout the mission, the IRRS team received excellent support and cooperation from all of the UK's counterparts.

I. INTRODUCTION

At the request of the Government of the UK of Great Britain and Northern Ireland (UK), an international team of senior safety experts met representatives of the Department for Business, Energy and Industrial Strategy (BEIS); Care Quality Commission (CQC); Civil Aviation Authority (CAA); Environment Agency (EA); Food Standards Agency (FSA); Food Standards Scotland (FSS); Health and Safety Executive (HSE); Health and Safety Executive for Northern Ireland (HSENI); Healthcare Improvement Scotland (HIS); Healthcare Inspectorate Wales (HIW); Maritime and Coastguard Agency (MCA); Natural Resources Wales (NRW); Northern Ireland Environment Agency (NIEA); Office for Nuclear Regulation (ONR); Public Health England (PHE); The Regulation and Quality Improvement Authority (RQIA); and Scottish Environment Protection Agency (SEPA) during the period from 14 to 25 October 2019 to conduct an Integrated Regulatory Review Service (IRRS) mission.

The purpose of this IRRS peer review mission was to review the UK's regulatory framework for nuclear and radiation safety. The review mission was formally requested by the Government of the UK in March 2018. A preparatory meeting was conducted from 15 to 17 April 2019 in Liverpool to discuss the purpose, objectives and detailed preparations for the review in connection with the regulated facilities and activities in the UK and their related safety aspects and to agree the scope of the IRRS mission.

The IRRS team consisted of 18 senior regulatory experts from 14 IAEA Member States, 2 IAEA staff members and 1 IAEA administrative assistant, and 3 observers. The IRRS team carried out the review in the following areas: responsibilities and functions of the government; the global nuclear safety regime; responsibilities and functions of the regulatory body; the management system of the regulatory body; the activities and processes of the regulatory body including authorization, review and assessment, inspection, enforcement and the development and content of regulations and guides; and emergency preparedness and response. The review also included the optional review area on interface with nuclear security. Facilities, activities and exposure situations covered included nuclear power plants, radiation source applications, fuel cycle facilities, waste management facilities, decommissioning, transport of radioactive material, occupational exposure, medical exposure, and public exposure. In addition, three policy issues were discussed: (1) Public engagement around risk, (2) Regulatory Innovation and Regulating Advanced Nuclear Technologies, and (3) Management of Nuclear and Radioactive Material and Waste.

The UK authorities conducted a self-assessment in preparation for the mission and presented a preliminary action plan. The results of the self-assessment, including a summary report, and supporting documentation were provided to the IRRS team as advance reference material for the mission.

Although there have been previous IRRS and Expert Missions to the UK, these focused predominantly on nuclear safety. The current mission initiates a new review cycle of the UK regulatory framework and infrastructure against the IAEA safety standards. The outstanding findings from the previous missions are considered as well.

During the mission, the IRRS team performed a systematic review of all topics within the agreed scope of the review, through review of the advance reference material, conducting interviews with management and staff from the participating UK authorities. While tthe IRRS mission was a full scope mission and included all regulatory bodies and governmental departments, 16 regulatory authorities participated in the submission of the documentation in support of the mission. The authorities interviewed by the IRRS team were the representation of the regulatory bodies in the UK Therefore, this report does not discuss all relevant regulatory authorities in each chapter.

The IRRS team had also opportunities to observe regulatory inspections at various facilities: a nuclear power plant, NDT facility, a hospital and radioactive waste management facility.

A meeting was also held with senior executives of BEIS, ONR, HSE and the DWP.

Throughout the mission, the IRRS team received excellent support and cooperation from all the UK's counterparts.

II. OBJECTIVE AND SCOPE

The purpose of this IRRS mission was to review the nuclear and radiation safety regulatory framework in the UK against the relevant IAEA Safety Standards, to report on regulatory effectiveness and to exchange information and experience in the areas covered by the IRRS. The agreed scope of this IRRS peer review included all facilities and activities and exposure situations regulated in the UK and the optional module on interfaces of safety with nuclear security. It is expected that this IRRS mission will facilitate regulatory improvements in the UK and other Member States, utilising the knowledge gained and experiences shared between the UK and the IRRS reviewers, and the evaluation of the UK regulatory framework for nuclear and radiation safety, including areas of good practices and good performance.

The key objectives of this mission were to enhance the national legal, governmental and regulatory framework for nuclear and radiation safety, and national arrangements for emergency preparedness and response through:

a) providing an opportunity for continuous improvement of the national regulatory body through an integrated process of self-assessment and review;

b) providing the host country (Government and Regulatory authorities) with a review of regulatory technical and policy issues;

c) providing the host country (Government and Regulatory authorities) with an objective evaluation of its regulatory infrastructure with respect to IAEA Safety Standards;

d) promoting the sharing of experience and exchange of lessons learned among senior regulators;

e) providing key staff in the host country with an opportunity to discuss regulatory practices with IRRS team members who have experience of other regulatory practices in the same field;

f) providing the host country with recommendations and suggestions for improvement;

g) providing other states with information regarding good practices identified in the course of the review;

h) providing reviewers from Member States and IAEA staff with opportunities to observe different approaches to regulatory oversight and to broaden knowledge in their own field (mutual learning process);

i) contributing to the harmonization of regulatory approaches among states;

j) promoting the application of IAEA Safety Requirements; and

k) providing feedback on the use and application IAEA Safety Standards.

III. BASIS FOR THE REVIEW

I. PREPARATORY WORK AND IAEA REVIEW TEAM

At the request of the Government of the UK, a preparatory meeting for the Integrated Regulatory Review Service (IRRS) was conducted from 15 to 17 April 2019. The preparatory meeting was carried out by the appointed Team Leader, Mr Ramzi Jammal, Deputy Team Leader, Mr Fabien Feron, and the IRRS IAEA Team representatives, Mr Tim Kobetz, Team Coordinator, Ms Olga Makarovska, Deputy Team Coordinator, and the UK Counterparts.

The IRRS mission preparatory team had discussions regarding regulatory programmes and policy issues with the senior management of ONR represented by Mr Mark Foy, Chief Nuclear Inspector of the ONR, Ms Adrienne Kelbie, Chief Executive of the ONR and senior management of other regulatory authorities. It was agreed that the regulatory framework with respect to the following facilities and activities would be reviewed during the IRRS mission in terms of compliance with the applicable IAEA safety requirements and compatibility with the respective safety guides:

- Nuclear power plants
- Radiation sources applications
- Fuel cycle facilities
- Radioactive waste management
- Decommissioning
- Emergency preparedness and response
- Transport of radioactive material
- Occupational exposure
- Medical exposure
- Public exposure

Presentations were made by the UK regulatory bodies on the national context, the current status of regulatory infrastructure in the UK and the self-assessment results.

IAEA staff presented the IRRS principles, process and methodology. This was followed by a discussion on the work plan for the implementation of the IRRS mission to the UK in October 2019.

The proposed composition of the IRRS team was discussed and tentatively confirmed. Logistics including meeting and workplaces, identification of the Liaison Officer, proposed site visits, lodging and transportation arrangements were also addressed.

The UK Liaison Officers for the IRRS mission were confirmed as Mr Ian Davies-Kerwin, Mr Liam Halse and Ms Alexandra Edey, ONR.

The UK provided IAEA with the advance reference material (ARM) for the review in August 2019. In preparation for the IRRS mission, the IAEA team members reviewed the advance reference material and provided their initial impressions to the IAEA Team Coordinator prior to the commencement of the IRRS mission.

II. REFERENCES FOR THE REVIEW

The relevant IAEA Safety Standards and the Code of Conduct on the Safety and Security of Radioactive Sources were used as the basis for the review. The complete list of IAEA publications used as the references for this mission is provided in Appendix VI.

III. CONDUCT OF THE REVIEW

The initial IRRS team meeting took place on Sunday 13 October 2019 in Liverpool, directed by the IRRS Team Leader and the IRRS IAEA Team Coordinator. Discussions encompassed the general overview, the scope and specific issues of the mission, clarified the basis for the review and the background, context and objectives of the IRRS programme. The understanding of the methodology for review was reinforced. The agenda for the mission was presented to the team. As required by the IRRS Guidelines, the reviewers presented their initial impressions of the ARM and highlighted potentially significant issues to be addressed during the mission.

The host Liaison Officers were present at the initial IRRS team meeting, in accordance with the IRRS Guidelines, and presented logistical arrangements planned for the mission.

The IRRS entrance meeting was held on Monday 14 October 2019, with the participation of Ms Helen Shirley-Quirk, Director Nuclear, Department for Business, Energy and Industrial Strategy (BEIS) and Mr Mark Foy, Chief Nuclear Inspector, ONR, and senior management and staff from CQC, CAA, EA, FSA, FSS, HSE, HSENI, HIS, HIW, MCA, NRW, NIEA, ONR, RQIA and SEPA as well as representatives from Welsh Government, Scottish Government and DAERA. Opening remarks were made by Ms Helen Shirley-Quirk, Mr Mark Foy, and Mr Ramzi Jammal, IRRS Team Leader. Mr Ian Davies-Kerwin, the Liaison Officer, gave an overview of the UK's regulatory framework, the results of UK self-assessment, and the action plan prepared as a result of the pre-mission self-assessment.

During the IRRS mission, a review was conducted for review areas within the agreed scope with the objective of providing the UK with recommendations and suggestions for improvement and where appropriate, identifying good practices. The review was conducted, in addition to review of the self-assessment made by the UK, through meetings, interviews and discussions, visits to facilities and direct observations regarding the national legal, governmental and regulatory framework for safety.

The IRRS team performed its review according to the mission programme given in Appendix II.

The IRRS exit meeting was held on Friday, 25 October 2019. The opening remarks at the exit meeting were presented by Ms Helen Shirley-Quirk and were followed by the presentation of the results of the mission by the IRRS Team Leader Mr Ramzi Jammal. Closing remarks were made by Mr Greg Rzentkowski, Director, Division of Nuclear Installation Safety, Department of Nuclear Safety and Security, IAEA.

An IAEA press release was issued.

1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT

1.1 NATIONAL POLICY AND STRATEGY FOR SAFETY

The UK's constitutional arrangements assign responsibilities for environmental and health policy to the Governments of England, Scotland, Wales and Northern Ireland. Under the devolved arrangements, the legal and governmental framework for radiation safety and protection is set out across multiple legislation such as occupational, environmental, energy, transport and food safety.

The UK's regulatory framework has incorporated IAEA fundamental safety principles through the transposition of EURATOM Directives into various pieces of national legislation.

The legislative framework in the UK clearly commits to safety. The action plan developed by the UK identified the need for UK Government Departments to produce a document that sets out the regulatory bodies responsible for regulating radiological safety. To address this issue, the UK government has prepared a draft Framework for Radiation Protection and Nuclear Safety. The purpose of the draft document is to provide the public and those working with ionizing radiations a clear overview of the UK's regulatory framework.

While the draft document describes adherence to and integration of the IAEA fundamental safety objective and fundamental safety principles in the UK's regulatory framework, the UK would benefit from developing a single policy statement that clearly reinforces the government's intent and commitment to safety and to ensuring that the radiation risks associated with facilities and activities are managed in accordance with the graded approach and which demonstrates this commitment across the four UK nations. The policy statement should clearly address all of the elements specified in paragraph 2.3 in GSR Part 1 (Rev. 1).

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *While the UK government has implemented the objectives of a national policy and strategy for safety within its framework for safety, the strategy is yet to be formalized in a single policy document. This has been identified in the UK action plan.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 1 states that** "*The government shall establish a national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals".*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 1 para. 2.3 states that** "*National policy and strategy for safety shall express a long term commitment to safety. The national policy shall be promulgated as a statement of the government's intent. The strategy shall set out the mechanisms for implementing the national policy. In the national policy and strategy, account shall be taken of the following…".*
R1	**Recommendation: The UK Government should publish a single, formalized statement of its national policy and strategy for safety to include all relevant elements of GSR Part 1, Rev 1.**

1.2 ESTABLISHMENT OF A FRAMEWORK FOR SAFETY

The UK is a constitutional monarchy comprised of the UK Parliament, Scottish Parliament, National Assembly for Wales and Northern Ireland Assembly.

The UK framework for radiation safety is comprised of several pieces of legislation (Acts of Parliament and Regulations) which are part of a broader safety framework for controlling risks from a range of hazards to workers, patients, public and the environment. All four countries in the UK have laws which are aligned with the international standards.

The European Council Directive 2013/59/Euratom, the Basic Safety Standards Directive (BSSD), establishes uniform basic safety standards for the protection of people subject to occupational, medical and public exposures from ionizing radiation. Implementation of the BSSD in the UK is achieved through a number of laws and regulations. The BSSD standards are included in environmental, occupational health and safety and in radiation protection legislation. The majority of the BSSD standards are incorporated in Ionising Radiations Regulations 2017 (IRR17) and Ionising Radiations Regulations (Northern Ireland) 2017 (IRRNI17). The laws and regulations are applicable in England, Scotland and Wales and Northern Ireland.

The UK Government has made provisions in law for funding and competence of regulatory bodies.

Nuclear and radiation safety in the UK is overseen by many regulatory bodies. For example, in England a medical facility carrying out radiological and therapeutic procedures involving radiopharmaceuticals is required to be authorised under a number of laws, i.e., Ionising Radiation Regulations 2017 (IRR17), Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17), the Environment Act 1995 (EA95), Environmental Permitting (England and Wales) Regulations 2016 (EPR16), the Energy Act 2013 (TEA13) and the UK Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG). The IRRS team was assured that there is clarity about the roles and responsibilities between the regulatory bodies. However, it is noted that such an arrangement presents a challenge for coordination and communication. See chapter 5 for more details.

IRR17 and IRR(NI)17 approach for authorizations of facilities and activities requires applicants to: notify, register, or obtain consent. This requires applicants to declare that they meet the requirements of these regulations, as well as providing some details on the activities undertaken with the source of ionizing radiation. This process is followed regardless of the radiological risk of the facility or activity. The authorisation of medical radiological procedures involving radioactive substances (for example nuclear medicine) under the IR(ME)R17 incorporates prior review of the proposed activities by the Administration of Radioactive Substances Advisory Committee (ARSAC). The authorisation involving radioactive substances is undertaken by the relevant environment agency under Environmental Permitting (England and Wales) Regulations 2016 (EPR16), Radioactive Substances Act 1993 (RSA93) and Environmental Authorisations (Scotland) Regulations 2018 (EASR18).

The IRRS team concluded that the authorization process undertaken under the IRR17 and IRR(NI)17 is not consistent with the graded approach as stated in GSR Part 1, Rev 1 which requires that a review and assessment of a facility or an activity to be commensurate with the radiation risks associated with the facility or activity. A recommendation in this regard has been made in Chapter 5.

In order to ensure an optimal framework for protection of the workers, patients, public and environment, the requirements of the general safety standards should be applied in a consistent manner across all UK nations. This includes consistent application of regulatory processes, for example authorization and review and assessment by Health and Safety Executive and ARSAC, which is overseen by the Department of Health and Social Care.

1.3 ESTABLISHMENT OF A REGULATORY BODY AND ITS INDEPENDENCE

The ‘regulatory body’ for the UK is not one single entity or a single national entity in each of the four countries of the UK. It is comprised of a number of statutory and government bodies and local authorities to fulfil the safety and protection framework.

Office for Nuclear Regulation (ONR) is sponsored by the Department for Work and Pensions (DWP) and works closely with the Department for Business, Energy and Industrial Strategy (BEIS). BEIS is responsible for setting Nuclear Policy and Nuclear Safety Policy whereas the DWP is responsible for the governance and efficiency of the ONR. DWP has no role in promoting nuclear technology or responsibilities for nuclear facilities or activities. ONR’s main function, as an independent nuclear regulatory authority, is to regulate nuclear safety, civil nuclear security, safeguard and conventional health and safety at licensed nuclear sites in Great Britain. ONR also regulates the transport of civil radioactive material in Great Britain by road, rail and inland waterway.

There are four independent regulatory bodies each for medical and environmental protection and two for occupational protections for Great Britain and Northern Ireland. There are also separate regulatory bodies for food and transport safety. These include:

- Health and Safety Executive (HSE)
- Health and Safety Executive Northern Ireland (HSENI)
- Care Quality Commission (CQC)
- Healthcare Inspectorate Wales (HIW)
- Healthcare Improvement Scotland (HIS) on behalf of the Scottish Ministers
- Regulation and Quality Improvement Authority (Northern Ireland) (RQIA)
- Environment Agency (EA)
- Scottish Environment Protection Agency (SEPA)
- Natural Resources Wales (NRW)
- Northern Ireland Environment Agency (NIEA)
- Maritime and Coastguard Agency (MCA)
- Civil Aviation Authority (CAA)
- Food Standards Agency (FSA)
- Food Standards Scotland (FSS)

Local authorities have also been assigned specific responsibilities for enforcing the workplace, health and environmental laws in premises for which they are the enforcing authority. Work undertaken by local authorities is outside the scope of this review.

Most of the regulatory bodies have broader regulatory functions in addition to radiation protection and safety. For example, both of the health and safety entities are responsible for all workplace health and safety matters. CQC has regulatory responsibilities for health and social care including inspectorate functions under the IR(ME)R17. HIS and HIW have regulatory responsibilities for health care including inspectorate functions under IR(ME)R17. RQIA has regulatory responsibilities for health and social care including inspectorate functions under the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 (IR(ME)R18). EA, NRW, NIEA and SEPA are environmental regulators which also includes regulation of activities with radioactive substances.

The regulatory bodies' activities are funded by the relevant UK government departments and include grants-in-aid and cost recovery schemes.

1.4 RESPONSIBILITY FOR SAFETY AND COMPLIANCE WITH REGULATIONS

The UK largely adopts a goal-setting regime whereby authorised parties are responsible for determining and justifying how best to achieve safety and compliance. This mitigates the risk of the responsible person or organisation considering themselves to be relieved of responsibility for safety simply by following prescriptive requirements. Furthermore, this goal setting philosophy allows the person or organisation responsible for safety to use innovative and flexible solutions based on their authorized operations.

For nuclear installations, the prime responsibility for safety rests with the licensee, as defined in the Nuclear Installations Act 1965 (NI65). Once the safety case is approved by ONR it becomes part of the licensing basis and holds the authorised party responsible to implement the regulatory requirements. The ONR carries out its regulatory oversight through authorization and inspection.

IRR17 and (IRR(NI)17 place prime responsibility for safety on authorized parties for all facilities and activities. IR(ME)R17 and IR(ME)R18 assign responsibility for safety to all employers including radiological medical practitioners for optimisation and justification of medical exposures. Such a responsibility also extends to authorised parties under EPR16, RSA93 and EASR18 including for management of radioactive waste.

Responsibility for safety in the transport of radioactive material is also assigned to authorised parties under the various transport regulations (e.g. CDG).

The responsibility for safety and compliance is not transferrable to another person except under an authorisation to another person.

1.5 COORDINATION OF AUTHORITIES WITH RESPONSIBILITIES FOR SAFETY WITHIN THE REGULATORY FRAMEWORK

The UK regulatory framework is made up of several regulatory bodies. There are legal requirements that set out the responsibility for regulators to consult other regulators on matters relating to nuclear or radiological safety. For example, under the Energy Act 2013 (TEA13) Section 96 requires the ONR and HSE to cooperate in relation to their respective functions. The UK Government's Regulators' Code also provides a framework for how UK regulators should engage with those they regulate, to ensure that their regulatory approachis transparent, consistent and proportionate.

There are arrangements in place to ensure co-ordination in the delivery of regulatory functions. In this regard there are a number of Memoranda of Understanding (MoUs) and Agency Agreements (AA) in place to ensure appropriate coordination of and liaison between the regulatory bodies with responsibilities for safety including periodic reviews of the MoUs.

The IRRS team's review has found that the MoUs and AAs are high level documents that set out general principles of working together in relation to information sharing, incident investigation and strategic collaboration. Some gaps in coordination arrangements were identified. For example, there is no MoU between EA and CQC or between HSENI and RQIA. The UK action plan has also identified the need to improve the coordination of regulatory functions on the transport of radioactive materials, and to ensure clarity around the roles and responsibilities of each respective government body or agency.

The IRRS team notes that the working arrangements between the regulatory bodies could be improved through greater emphasis on joint coordination amongst the various regulatory bodies for achieving consistency in regulatory practice and to avoid conflicting or duplication of requirements being imposed on authorized parties.

This is particularly important where a number of regulatory bodies are involved in authorisation of a facility. As an example, the IRRS team noted that medical facilities in England are regulated by HSE, CQC, EA and ONR (for transport only). Such a distribution of regulatory responsibilities could lead to complex situations, where the interfaces and communication between regulatory authorities could become a challenge.

To improve coordination between the regulatory bodies, BEIS has proposed an action under the UK action plan to establish and keep under review a co-ordination channel between senior officials in the regulatory bodies and Government Departments.

While this is a positive step, harmonisation and effective coordination of regulatory practice could be enhanced through ongoing formal and informal joint collaborations between the regulatory bodies. Regular communications to share regulatory strategies and experiences is likely to increase consistency in regulatory processes and decision making at the level of each of the countries and also a whole UK level.

Therefore, in the view of the IRRS team, to ensure effective coordination of all authorities with responsibilities for safety within the UK regulatory framework, a review including a gap analysis of the existing coordination arrangements should be undertaken by the UK government. This will enable effective regulatory partnerships between all of the relevant regulatory bodies responsible for protection and safety of facilities and activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The Government could make improvements to its approach to coordinate the collaboration of all regulatory functions between the regulatory bodies and with Government departments. This is recognized in the UK action plan.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 7 states that** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the government shall make provision for the effective coordination of their regulatory functions, to avoid any omissions or undue duplication and to avoid conflicting requirements being placed on authorized parties".*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 7 para. 2.18 states that** *"… This coordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such coordination assists in achieving consistency and in enabling authorities to benefit from each other's experience".*
S1	**Suggestion: The UK Government should consider improving the coordination among the regulatory bodies and with Government departments to ensure effective delivery of their regulatory functions including by addressing gaps in existing coordination arrangements.**

1.6 SYSTEM FOR PROTECTIVE ACTIONS TO REDUCE EXISTING OR UNREGULATED RADIATION RISKS

The UK Government has established the framework for protective actions to reduce existing or unregulated radiation risks. The environmental laws provide for protective actions to reduce radiation risks associated with unregulated sources. The laws require the consideration of principles of justification and optimisation in the application of protective actions.

The Environmental Protection Act 1990 (EP90) and the relevant regulation in each of the four countries provide a system for the identification of land contaminated with radioactivity from historic practices or the after-effects of emergencies. It also assigns responsibility and arrangements for remediation of contaminated land if it presents unacceptable radiation risk to the members of the public. The relevant regulatory bodies are EA in England, NRW in Wales, SEPA in Scotland and NIEA in Northern Ireland.

Under EASR18 and EPR16 and the High Activity Sealed Sources and Orphan Sources Regulations 2005 (which gives this responsibility to NIEA in Northern Ireland), the respective regulatory bodies are required to have plans and measures including the assignment of responsibilities, to recover orphan sources. There are also arrangements for management of exposure to radon in workplaces under the Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018 and IRR17 and IRRNI17 respectively. Local authorities, HSE and HSENI are the responsible agencies.

Disused orphan sources and other forms of radioactive waste that may occasionally be found among scrap metal are the responsibility of the environment agencies in the UK. For example, SEPA has implemented measures prohibiting the transfer or disposal of metallic sources except to landfill. SEPA Information is also provided to businesses and any other organisations to prevent the inappropriate disposal of used sealed sources and radiation generators. The monitoring checkpoints are installed at metal recycling facilities only. However, the IRRS team noted that the self-assessment report has identified that comprehensive measures have not been implemented for all scenarios where orphan sources are found.

The UK also has arrangements in place to manage the decommissioning of nuclear and non-nuclear sites and de-license those when the radiation hazards no longer exists. The Radiation (Emergency Preparedness and Public Information) Regulations in Great Britain and Northern Ireland establish the framework for the protection of the public through emergency preparedness for radiation emergencies.

The Civil Contingencies Act 2004 establishes roles and responsibilities for those involved in emergency preparation and response. For further details see sub-chapter 10.2.

1.7 PROVISIONS FOR THE DECOMMISSIONING OF FACILITIES AND THE MANAGEMENT OF RADIOACTIVE WASTE AND OF SPENT FUEL

The UK government has established a regulatory framework for safe management and disposal of radioactive waste over the lifetime of facilities and the duration of activities. This includes strategies for diversity between types of radioactive waste and the radiological characteristics of radioactive waste. The UK regulatory framework for radioactive waste management is established under EA95, RSA93, EPR16, EASR18, and Radioactive Substances Act 1993 (Amendment) Regulations (Northern Ireland) 2011 (RSR(NI)11). The framework applies to disposal of radioactive waste and is underpinned by the polluter pays principle. The conditions imposed at the time of authorisations establishes the regulatory requirements for the types and quantities of radioactive waste that may be disposed of, the disposal routes that may be used as well as the need to minimise radioactive waste creation. Additionally, the framework also requires operators to make appropriate financial provisions for reuse, recycling or disposal of high activity sealed radioactive sources.

The *UK Strategy for the Management of Solid Low-Level Waste (LLW) from the Nuclear Industry* has been developed by the Nuclear Decommissioning Authority (NDA) on behalf of UK Government in 2016 and is published jointly by the UK Government and the Devolved Administrations. It updates the 2007 LLW policy with respect of the nuclear sector to ensure it remains fit for purpose and is subject to periodic review. It provides a high-level framework for waste management solutions and applies to environmental regulators, waste producers, local planning authorities, facility operators and suppliers of waste treatment services. Under the Policy, there are three implementing strategies covering nuclear LLW, non-nuclear anthropogenic LLW and NORM waste including solid nuclear and non-nuclear LLW. The strategies aim to embed the 'waste hierarchy' principle into LLW management to minimise its environmental impact and ensure that infrastructure is used appropriately and efficiently.

There is no disposal route for higher activity waste which is currently stored in interim facilities. Following consultation with communities, a process has been defined to identify a suitable site for a Geological Disposal Facility (GDF) in England and Wales. In October 2019, BEIS designated the National Policy Statement for Geological Disposal Infrastructure which provides guidance for development consent for geological disposal infrastructure in England. The Government of Scotland published in December 2016 an Implementation strategy as part of Scotland's policy on higher activity radioactive waste. This strategy takes a phased approach as follows:

- Phase 1 (2016-2030) to include a review of the higher activity waste that is expected to arise in Scotland;
- Phase 2 (2030-2070) the Scottish Government to work with the NDA, radioactive waste producers and regulators to help develop a near-surface disposal concept for waste suitable for this management route under current technologies; and
- In Phase 3 (2070 onwards) the Scottish Government anticipates that replacement near-surface storage facilities will be constructed. Disposal technologies will be further developed, and new near-surface disposal facilities will be constructed.

Licensees are required to estimate the future costs of radioactive waste management and decommissioning and provide assurances to demonstrate that the necessary resources will be made available when necessary. The UK government through the independent segregated funds, the Nuclear Liabilities Fund has established these financial provisions so the costs for decommissioning of operating NPPs are determined for all stages of the operations.

In the case of new nuclear reactors, the UK government requires prospective licensees to develop a funded decommissioning plan to determine how the costs of implementing the decommissioning and radioactive waste management policy have been estimated and how the appropriate funds will be provisioned.

The majority of R&D work associated with LLW management is undertaken by waste producers driven by a particular need at that site. Section 88 of TEA13 enables ONR to carry out or commission research in connection with its purposes and to publish the results if it considers it appropriate to do so. Research in regard to a GDF is limited at this stage, due to the requirement for further clarity from the UK Government on siting and from

Radioactive Waste Management (RWM) Ltd on technologies. ONR recognises the need for research in this area once the position becomes clear.

In 2017, the developer RWM Ltd published a set of safety case reports for a future GDF based on its understanding of the scientific and engineering principles supporting geological disposal. ONR and the Environment Agency have assessed the 2016 generic Disposal System Safety Case at the request of RWM Ltd, to provide scrutiny and advice on parts of its work ahead of any permit or licence application.

The IRRS team was informed that a site for a GDF is yet to be identified. A siting process was launched in England in December 2018 and in Wales in January 2019 to identify possible locations. Once a location is selected, the relevant regulators in England or Wales are expected to authorise and regulate the development, operation and closure of the GDF. It is Government policy to enact necessary legislative amendments to add GDF to the list of prescribed installations requiring a nuclear site licence from ONR.

Further, the IRRS team noted that the NI65 requires that there is 'no danger' from ionising radiation on a site once it is decommissioned. The concept of 'no danger' means that the licensee is required to demonstrate that the consequences from any residual radioactivity will not exceed one-in-a-million per year risk of fatalities for the general public. BEIS, ONR and the environmental regulators are proposing a more sustainable approach to the regulation of nuclear sites in the final stages of decommissioning on the grounds of nuclear safety and environmental protection rather than demonstrating that there was no danger from ionising radiation. In support of this revised approach, the UK government has undertaken a public consultation to support proposed changes to the legislation.

The IRRS team encourages the UK Government to amend the NI65 to reflect the requirements on release of the nuclear site from regulatory control with restrictions on the future use.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The planned geological disposal facility (GDF) is outside the scope of the regulated activities of ONR as the Nuclear Installation Regulation, 1971 does not define GDF as a nuclear installation. However, governmental expectation is that a GDF will be a nuclear licensed site. In Nuclear Installation Act 1965 there is no mechanism for release of the nuclear site from regulatory control with restrictions on the future use.*	
(1)	**BASIS: GSR Part 1, Requirement 2 states that** "*The government shall establish and maintain an appropriate governmental, legal and regulatory framework for safety within which responsibilities are clearly allocated.*"
(2)	**BASIS: GSR Part 1, Requirement 2, para 2.5 states that** "*The government shall promulgate laws and statutes to make provision for an effective governmental, legal and regulatory framework for safety. This framework for safety shall set out the following:* *(2) The types of facilities and activities that are included within the scope of the framework for safety; (3) The type of authorization that is required for the operation of facilities and for the conduct of activities, in accordance with a graded approach; (4) The rationale for the authorization of new facilities and activities, as well as the applicable decision making process;.*"
(3)	**BASIS: GSR Part 6 Requirement 15 states that** *"On the completion of decommissioning actions, the licensee shall demonstrate that the end state criteria as specified in the final decommissioning plan and any additional regulatory requirements have been met. The regulatory body shall verify compliance with the end state criteria and shall decide on termination of the authorization for decommissioning."*
(4)	**BASIS: GSR Part 6 Requirement 15 para 9.3 states that** *"If the approved decommissioning end state is release from regulatory control with restrictions on the future use of the remaining structures, appropriate controls and programmes for monitoring and surveillance shall be*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	established and maintained for the optimization of protection and safety, and protection of the environment. These controls shall be subject to approval by the regulatory body".
R2	**Recommendation: The UK Government should revise:** • **the Nuclear Installation Regulations 1971 such that GDF is defined as a nuclear licensed site and is subject to ONR authorization; and** • **the Nuclear Installation Act 1965 to include requirements on release of nuclear licensed sites from regulatory control with restrictions on the future use.**

1.8 COMPETENCE FOR SAFETY

The UK Government has imposed competence requirements, under laws for workplace health and safety, nuclear facilities, environmental and medical protection, and for persons or organisations providing technical services. Regulatory bodies are also required to recruit staff with relevant professional qualifications and provide the required training and experience in areas such as legal and enforcement, safety technology, etc., as defined in the radiation specialist competency framework.

The laws also place obligations on authorised parties to have adequate numbers of qualified and experienced staff. IRR17, (IRR(NI)17 and REPPIR 2019 require workers who work with ionising radiation are given appropriate training in the field of radiation protection and safety, including emergency preparedness and response for those personnel undertaking this function. The obligations of authorised parties extend to protection of health and safety of their employees.

The IRR17/IRRNI17 makes provision for Radiation Protection Advisers (RPA) to advise on compliance with the regulations. The competence of the RPA is assessed by a body recognised by HSE. The IR(ME)R17 and IR(ME)R18 makes provision for Medical Physics Experts (MPEs) to advise on compliance with the regulations and also require employers to ensure that practitioners and operators are trained to perform the tasks in their defined scope of practice. Similarly, the environmental, food and transport safety laws require the use of appropriately trained and competent persons.

The legislations also require that authorised parties seek advice from qualified experts (radiation protection/waste advisors). The organisations that employ the qualified experts are required to be recognized. Worker's training records are required to be maintained and inspected by the regulatory bodies.

The regulatory framework requires the provision for technical services such as personal dosimetry, for classified workers (Category A workers) and the calibration of equipment to support ssauthorised parties. Individuals or organisations are able to secure approval for providing services subject to meeting criteria for competence set by HSE. Before undertaking an inspection of radiological facilities, all HIS, HIW and RQIA inspectors are required to attend a training course facilitated by Public Health England.

All inspectors joining ONR are required to have good academic qualifications and have work experience in a relevant industry. Inspectors receive the mandatory core regulatory training and the training to expand their technical expertise to gain working knowledge of other technical disciplines. Every five years, inspectors are to complete a formal legal refresher training course.

Each regulatory body is responsible for ensuring that it has the sufficient number of competent staff to carry out its regulatory functions. However, the IRRS team has noted that the number of staff employed by some regulatory bodies may be inadequate considering the breadth of radiation practices and the number of regulated entities across the UK. For example, for the 16,500 authorized parties working with ionizing radiation, HSE has 8.6 FTE general and specialist inspectors. There is some variation in competence requirements within the different regulatory bodies performing similar functions. However, these variations are addressed by providing the additional training to build and maintain the appropriate competency required to perform the regulatory functions.

Under the UK Action plan Department of Agriculture, Environment and Rural Affairs (DAERA) has identified the need to enhance the professional and technical training of staff which includes the development of a competency and evaluation framework for radioactive substances. DAERA plans to engage with other environment agencies to explore the potential to share training opportunities.

1.9 PROVISION OF TECHNICAL SERVICES

The UK Government requires that technical services are provided for nuclear safety. Technical services include dosimetry services, radiation protection advice and equipment calibration. Technical services are required to be approved by HSE under IRR17 or IRRNI17.

IRR17 enables HSE to approve suitable dosimetry services to assess doses received by category A workers, including the measurement and assessment of whole-body or part-body doses arising from external radiation (X-rays, gamma rays, beta particles or neutrons) and internal radiation. HSE also approves dosimetry services for emergency exposures from intervention during radiation emergencies, which include doses received from external and internal radiation.

There are 32 approved dosimetry services in the UK which are published on the HSE website. Such services include provision to Northern Ireland.

Similarly, there are requirements for the approval of persons or organisations as RPAs. The criteria and list of approved RPAs are published on the HSE website. Under IRR17 and IRRNI17, RPAs must be consulted to advise on compliance with IRR17. This includes the implementation of requirements as to controlled and supervised areas, prior examination of plans for installations, and the acceptance into service of new or modified sources of ionising radiation in relation to any engineering controls, design features, safety features and warning devices used to restrict exposure to ionising radiation, etc. Likewise, the requirements under EPR16, EASR18 and equivalent legislation, require authorised parties to seek advice from Radioactive Waste Advisers (RWAs) to ensure compliance with the environmental legislation covering the disposal of radioactive waste.

1.10. Policy Issue Discussion: Management of Nuclear Material and Radioactive Waste

Most of the radioactive waste that arises in the UK originates from the nuclear power industry and the defence program. The presence of NORM waste also presents its own challenges. Small amounts of waste are also generated from many medical, industrial and research activities. The UK is reviewing its policy position in relation to the management of radioactive substances and nuclear decommissioning and sought to understand experience of other countries in relation to the benefits of a risk informed approach to the management of radioactive waste; optimization of site end states for nuclear sites undergoing decommissioning; management of liquid waste containing low levels of radioactive material; and management of waste in emergencies.

Different approaches by several regulatory bodies in the respective countries of the IRRS review team were presented in the discussions and the outcome of the discussions are summarized below:

- The national plans for waste management are built on the principle that the GDF is planned long term until 2130. There is a policy that short lived material can be stored for two years and is then disposed of and the possibility of reuse by mixing waste material with other material is also considered. Early engagement and consultations with the public and interested parties is very crucial.
- NORM is treated in local municipal places and is licensed. In one country, there is a Nuclear Geological Repository only for spent fuel. The government has allocated money for cleaning up legacy sites. Considering any safeguards issues when developing a policy for management of the radioactive waste is important. There are descriptive clearance levels for disposing liquid waste. Establishing collaboration with other countries for best practices and learning from experiences of other regulators is very important. There is no definition of waste generated from emergency. Any waste generated during emergency will be the responsibility of the licensee.

- Communication and consultation with the public and interested parties is being undertaken on building a disposal facility, and it was challenging. Liquid waste is addressed by establishing clearance levels.
- Site selection is based on land use law which also involves a high campaign. Central government defines all the process which makes it easier for public engagement with local authorities and communities.
- There is a national agency that is responsible for all radioactive waste and a masterplan for radioactive waste is in place. While debates are initiated but it was challenging to ensure the general public is fully engaged in the debate. The option for high level waste is Geological Repository.
- It is difficult to be prepared for the waste that will be generated during emergencies, because you do not know what it will be, and to come up with a clear scenario of what kind of waste will be generated. Local authorities are encouraged to identify the issue and take measures based on information as available post emergency. There is no special class of waste and it depends on the dose that it will generate to the public.

1.11. SUMMARY

Overall, the IRRS team found that UK legal and governmental framework for radiation safety and protection is in good alignment with IAEA safety standards. The framework, however, is set out across multiple pieces of legislation. The following areas of improvement have been identified:

- a single formalized statement of UK's national policy and strategy for safety which is consistent with all relevant elements of GSR Part 1, Rev 1.
- improved coordination between the regulatory and government bodies to enhance uniform and consistent application of the IAEA safety standards across and within the four countries of the UK.

2. THE GLOBAL SAFETY REGIME

2.1 INTERNATIONAL OBLIGATIONS AND ARRANGEMENTS FOR INTERNATIONAL COOPERATION

The UK participates actively in the global nuclear and radiation safety regime. It has taken a leadership role in contributing to international cooperation arrangements by working with the IAEA and other regulatory bodies in the development of codes, standards, and guidance, including participating in IAEA activities, European Nuclear Safety Regulators Group (ENSREG) committees, and NEA/OECD committees. The UK has engaged in a number of bilateral and multilateral projects to enhance safety. The IRRS team acknowledged that the UK has made strong efforts to engage with the IAEA, its associated conventions and standards, the peer review services both in terms of hosting IRRS and IPPAS missions and supporting peer review missions of national regulatory frameworks in member states.

In addition to being a signatory to the IAEA conventions, the UK has made a political commitment with regard to the Code of Conduct on the Safety and Security of Radioactive Sources. This Code aims at helping national authorities to ensure that radioactive sources are used within an appropriate framework of radiation safety and security. The Code is a well-accepted, non-legally binding international instrument and has received political support from more than 130 Member States.

The IRRS team also noted that the UK has already notified the IAEA of its intension to act in accordance with the Guidance on Import and Export of Radioactive Sources. However, the UK has not yet notified IAEA of its intention to act in accordance with the Guidance on the Management of Disused Radioactive Sources. The IRRS team has been informed that the Guidance is being implemented in practice.

The UK government has made adequate arrangements to fulfil and benefit from international cooperation and assistance to enhance safety globally. The IRRS team has noted that the Government recognises the need to continue improving these arrangements, including consequential implementation of changes to relevant regulatory requirements and guidance.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The UK Government has not yet notified IAEA of its commitment to implement the Guidance on the Management of Disused Radioactive Sources.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 14 states that** *"The government shall fulfil its respective international obligations, participate in the relevant international arrangements, including international peer reviews, and promote international cooperation and assistance to enhance safety globally".*
S2	**Suggestion: The UK Government should consider notifying the IAEA of its commitment to the Supplementary Guidance on the Management of Disused Radioactive Sources.**

2.2 SHARING OF OPERATING EXPERIENCE AND REGULATORY EXPERIENCE

UK has implemented processes to share operating and regulatory experience in relation to nuclear and radiation safety among the various regulatory bodies. The IRRS team was informed that UK regulators have also established internal mechanisms for sharing information and lessons learnt. A number of regular meetings are also held during which relevant information is shared including, for example:

- The Lessons Learned Working Group, chaired by BEIS;
- The Medical Radiation Liaison Group and IR(ME)R Inspectors summit meetings; and
- Meetings between HSE and CQC to share operational intelligence.

ONR has a Regulatory Intelligence Process, which examines international events from the nuclear and other industries, as well as from significant events in the UK outside of the nuclear sector. These are collated on a monthly basis and form part of the information used to undertake annual intelligence reviews. Through ONR, the UK has published guidance on the reporting of events which cover nuclear, radiological, transport and security events. The guidance outlines the expectations for the follow-up and identification of root causes.

The IRRS team was informed that in relation to non-nuclear obligations, BEIS has taken responsibility for coordinating feedback, including the sharing of information with the regulatory bodies. However, the IRRS team noted that the impact of UK contributions to the global safety regime could be enhanced if feedback from all regulatory bodies was more effectively coordinated in the non-nuclear areas.

As part of continuous improvement, the UK is seeking to review the means by which international learning and experience is identified and shared within the UK, and with international partners. Further, the UK action plan has identified a number of actions for continuous improvement to strengthen its current approach to the sharing of operating and regulatory experience. In this regard, BEIS with support from all relevant government departments and regulatory bodies is proposing to:

- Review and agree expectations in respect of learning from national and international experience;
- Review and agree responsibilities (including how national generic lessons are identified and promulgated); and
- Confirm that all relevant regulatory bodies have a clear process for identifying Learning from Experience and Regulatory Good Practice and taking appropriate response action.

The IRRS team acknowledges UK's efforts for seeking to improve existing arrangements to share operating and regulatory experience between all relevant stakeholders. In this regard, the UK Government, in consultation with Regulatory Bodies, should include in its planned improvements a review of the existing processes and MoUs to ensure all relevant parties are able to participate in, and contribute to, the sharing and analysis of operating and regulatory experience. Such processes should incorporate a systematic analysis of operating and regulatory experience (national and international) in all of the regulated areas. This will facilitate a more structured approach to the identification and dissemination of the lessons learnt, and their use by authorized parties, the regulatory body and other relevant authorities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing processes to share operating and regulatory experience in relation to radiation safety among the various regulatory bodies may not ensure adequate participation by all relevant regulatory bodies and systematic analysis and dissemination of operating and regulatory experience (national and international) to all relevant parties. This has been identified in the UK action plan and a number of measures have been proposed to strengthen the existing system.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 15 states that** *"The regulatory body shall make arrangements for analysis to be carried out to identify lessons to be learned from operating experience and regulatory experience, including experience in other States, and for the dissemination of the lessons learned and for their use by authorized parties, the regulatory body and other relevant authorities".*
R3	**Recommendation: The UK government, in consultation with regulatory bodies should formalise and improve existing processes and arrangements for sharing of operating and regulatory experience to ensure systematic analysis and feedback on measures taken in response to information received.**

2.3. SUMMARY

The UK is a very active participant in the international community to promote global safety. As part of continuous improvement, the UK is seeking to involve a wider range of stakeholders, regulatory bodies and authorised parties with the intention of maximising the opportunities to both share information and experience and make available global learning to all those who have an interest in improving nuclear and radiological safety.

Observations have been made with regards to fulfilling a gap in its international obligations and strengthen its existing process for sharing of operating and regulatory experience.

The following areas of improvement have been identified:

- notify the IAEA of UK's commitment to implement the Guidance on the Management of Disused Radioactive Sources
- improve existing processes and arrangements for sharing of operating and regulatory experience feedback.

3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY

As described in Chapter 1, multiple regulatory bodies have responsibilities in the regulation of nuclear and radiation safety and several bilateral MOUs have been established to ease cooperation. Although the situation looks complex for an outsider, the IRRS team concluded that, at the working level, each regulatory body understands its mandate and interfaces with other regulatory bodies. The IRRS team interviewed ONR, HSE, EA, CQC and SEPA during the Mission so the description and findings generally refer to these regulatory bodies; the others being covered at a high level based on information provided in the Advance Reference Material.

A specific interest of the IRRS team was to understand how consistency of application was achieved among the various regulatory bodies across the four countries of the UK, both within each country and between them.

As a result of the number of regulatory bodies having increased as a result of devolution, interfaces have sometimes been simplified by modifying the mandates of some. For example, ONR licenses the nuclear sites in Great Britain and interfaces primarily with HSE and the agencies responsible for environmental protection. Although in general, HSE is responsible for worker health and safety (both conventional and radiological), this is not true for nuclear construction sites such as Hinkley Point C and other nuclear licensed sites, where ONR enforces the HSWA and associated regulations as a result of the 2013 Energy Act.

ONR prepares an annual plan of its inspections on the licensed sites; which may also involve requesting HSE to carry out inspections on its behalf. Alternatively, should investigations be performed of a prospective site, HSE will have the lead for health and safety and will make ONR aware of its findings as necessary.

ONR works constructively with the regulatory agencies responsible for public exposures and protection of the environment, which authorize discharges of wastes to the environment from nuclear licensed sites or disposal of radioactive waste, to coordinate their respective regulatory activities. These agencies are also responsible for regulating the possession of radioactive sources and discharge of radioactive material in other facilities, such as hospitals, industry and universities.

Finally, the Care Quality Commission regulates medical and non- medical exposures involving radioactive substances and ionising radiation in hospitals and health establishments in England. It also regulates other non-medical exposures to ionizing radiation. Other regulatory bodies fulfil a similar function in the other countries of the UK.

The table below summarizes the responsibilities of each regulatory body (see also the draft document ‘UK Framework for Radiation Protection and Nuclear Safety’):

	ENGLAND	WALES	SCOTLAND	NORTHERN IRELAND
OCCUPATIONAL HEALTH & SAFETY	• Health and Safety Executive • Office for Nuclear Regulation (for nuclear licensed sites)			• Health and Safety Executive, Northern Ireland
NUCLEAR SAFETY (on licensed sites)	• Office for Nuclear Regulation			• No nuclear licensed sites
PUBLIC EXPOSURES & PROTECTION OF ENVIRONMENT	• Environment Agency • Food Standards Agency	• Natural Resources Wales • Food Standards Agency	• Scottish Environment Protection Agency • Food Standards Scotland	• Northern Ireland Environment Agency • Food Standards Agency
MEDICAL EXPOSURE	• Care Quality Commission	• Healthcare Inspectorate Wales on belalf of Welsh Ministers	• Healthcare Improvement Scotland on behalf of Scottish Ministers	• Regulation and Quality Improvement Authority
TRANSPORT	• Office for Nuclear Regulation			• Northern Ireland Environment Agency
	• Civil Aviation Authority and		• Maritime and Coastguard Agency	
EMERGENCY PLANNING & RESPONSE	• Office for Nuclear Regulation • Health and Safety Executive • Environment Agency • Food Standards Agency	• Office for Nuclear Regulation • Health and Safety Executive • Natural Resources Wales • Food Standards Agency	• Office for Nuclear Regulation • Health and Safety Executive • Scottish Environment Protection Agency • Food Standards Scotland	• Dept. of Agriculture, Environment and Rural Affairs • Health and Safety Executive, Northern Ireland • Food Standards Agency

3.1. ORGANIZATIONAL STRUCTURE OF THE REGULATORY BODY AND ALLOCATION OF RESOURCES

The IRRS team noted that, although the primary focus of ONR is nuclear and radiation safety, the other regulatory bodies have a far broader mandate. As a result, within those regulatory bodies, the staff dedicated to these topics is often a small unit within the organization.

ONR

The ONR Board is made up of non-executive and executive members, of which non-executive members are always in the majority. The Board provides leadership, sets strategy, agrees the overarching policy framework within which ONR operates, agrees and monitors resources and performance and ensures good governance. It has delegated all regulatory decisions to its Chief Nuclear Inspector (CNI). The ONR regulatory directorate is headed by the CNI and comprises five Divisions being:

- Operating Facilities
- New Reactors
- Sellafield, Decommissioning, Fuel and Waste
- Civil Nuclear Security and Safeguards
- Technical Division

In addition to the above regulatory Divisions, ONR has Divisions for Policy & Communications, Finance, and Human Resources.

ONR has established:

- a Senior Leadership Team: it is headed by the Chief Executive and comprises the CNI, the Directors of the five divisions and the Directors of HR, Finance and Policy & Communications;
- a Strategic Workforce Planning Group that looks ahead 20-25 years by performing environmental scans to consider their impact on resources which allow scenarios to be prepared to be used by the professional leads in proactively planning their resources. A business case is being put together to automate the process.

The five regulatory Divisions operate in a matrix management arrangement, whereby the first four divisions, known as ‘delivery areas’ form the columns, each with a delivery lead. The rows comprise specialist resources, all of which are functionally located in the Technical Division. There are approximately fifty technical areas, grouped into fifteen technical specialisms, each with a professional lead.

Resourcing discussions between the delivery leads and professional leads are held on a regular basis to ensure that appropriate resources are applied to meet the needs of each delivery area. The discussions are structured so that the delivery leads and professional leads challenge each other regarding needs and skills, in order to arrive at a shared view of what resources to apply to which needs. Each professional lead also looks at the resilience and capacity of the staff in their technical areas for forward planning purposes.

Any specialist resources which are not needed at a particular time to support the delivery leads can be applied to other purposes, such as updating TIGs or TAGs, with no impact on front-line inspections. Such work, though important, is not necessarily urgent, so can wait for resources to become available. In this manner, the Technical Division acts as a ‘safety valve’ for the organization to match workload with resource.

One strength of the matrix management discussions is that the specialist resources do not ‘self-identify’ work but apply their skills and knowledge to the priorities of the organization, adjusted with time as needs change. In the original matrix model, the delivery leads were also responsible for heading a number of specialisms. However, this did not work well since the urgent work tended to override the important (though less urgent) work. Since the model was adjusted to place the technical resources under a Technical Director, the model has functioned more effectively and efficiently in allocating resources to needs.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ONR matches its resources to needs using a matrix structure that also involves a strategic look-ahead.*	
(1)	**BASIS: GSR Part 1 Requirement 16, para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach".*
GP1	**Good Practice: ONR has developed its matrix management structure that effectively allocates resources to need. It has also improved its hiring, training and strategic planning practices so as to develop new hires and to effectively anticipate and fill future needs.**

Occupational Protection

HSE and HSENI are responsible for occupational health and safety, ionizing radiations being one of the many risks they regulate.

HSE is a non-departmental public body (NDPB). The HSE Board, made up of members who are independent of the HSE and who represent both employee and employer interests, is responsible for setting the direction of HSE. Reporting to the HSE Board is the Management Board, which is comprised of the seven most senior managers, who oversee the operation of the organisation, allocating finances and resources appropriately. HSE has its own human resources department, finance department, a division who are responsible for policy development in relation to radiation and a dedicated team of specialist radiation inspectors.

HSENI's Board is composed of members reflecting the interests of social partners and stakeholders. The Board provides strategic guidance and leadership and oversees HSENI operations. The Board is supported by a Chief Executive and a Senior Management Team comprising of three Deputy Chief Executives. HSENI have human resource and finance sections which operate under the remit of Northern Ireland Civil Service parameters. HSENI broadly follows HSE policy.

Public Exposures and Environmental Protection

The Environment Agency (EA) was also established as a NDPB, governed by an independent Board that is accountable to the Secretary of State for the Department for Environment, Food and Rural Affairs (Defra). The Board delegates responsibility for the day-to-day management of the organisation to its Chief Executive.

The Scottish Environment Protection Agency (SEPA) is also a NDPB which is accountable to the Scottish Parliament through Scottish Ministers. The SEPA Board is responsible for the overall direction and performance of the Organisation, with day-to-day management and delivery being delegated to the Chief Executive Officer.

NRW is answerable to an independent Board appointed by and accountable to the Welsh Ministers. Day-to-day management of the organisation is delegated to NRW's Chief Executive. NRW includes Radioactive Substances Regulation (RSR) as part of its duties.

NIEA is an executive agency within the Department of Agriculture, Environment and Rural Affairs (DAERA). It is headed by a Chief Executive, supported by two Executive Directors of Natural Environment and Resource Efficiency. The Industrial Pollution and Radiochemical Inspectorate (IPRI) of NIEA is responsible for radioactive substances and radioactive transport regulation, headed by the Chief Radiochemical Inspector.

Healthcare Agencies

CQC is the independent regulator of health and social care in England, the CQC Board being the senior decision-making structure. The Board delegates executive responsibility to the Chief Executive. CQC organization includes five Directorates: Hospitals Inspection, Adult Social Care Inspection (including Registration), Primary Medical Services and Integrated Care Inspection, Strategy and Intelligence and Regulatory Customer and Corporate Operations.

HIS was established with broad powers to inspect and monitor the quality of healthcare in the NHS and the independent sector in Scotland. The IR(ME)R inspectors warranted by the Scottish Ministers (as the relevant enforcement authority for Scotland) are employees of HIS, and other related functions have also been assigned to HIS including receiving and responding to reports of adverse incidents.

HIW is the inspectorate and regulator of health care in Wales and ensure compliances with IR(ME)R via inspection, notification and enforcement aspects which are delegated to HIW through an MoU between Welsh Ministers and HIW's Chief Executive.

RQIA was established to provide assurance as to the safety, quality and availability of health and social care in Northern Ireland. RQIA is the designated regulatory body for inspection and enforcement of the use of ionising radiation in the medical field.

3.2. EFFECTIVE INDEPENDENCE IN THE PERFORMANCE OF REGULATORY FUNCTIONS

Each of the regulatory bodies engaged in oversight of nuclear licensed sites or use of radiation in hospitals, business or universities perform their functions independent of outside influence. For example:

- ONR remains functionally separate from Government and is independent in its regulatory functions and decisions – the office of CNI was created in statute and all regulatory decisions are delegated to the CNI who has delegated responsibility as a suitably, qualified and experienced person directly responsible for ensuring regulatory decisions are proportionate, balanced and consistent. ONR operates under a broad DWP Framework Agreement, which ensures alignment with Government policies and priorities whilst ensuring that ONR's decision making and management remain independent. ONR works closely with BEIS: ONR can provide factual information to the BEIS Minister on matters of nuclear safety regulation, but the Minister is not responsible for the ONR's regulatory decision making.
- HSE status as a non-departmental public body ensures that the independence of the organisation is not compromised. HSE inspectors make their decisions based on evidence. Although the Secretary of State may direct HSE in relation to its functions and in the interests of safety, this power cannot be used to intervene in any particular enforcement case, thereby ensuring regulatory independence.
- The Environment Agency and the Scottish Environment Protection Agency are also both independent. The EA is independent of the operators it regulates, and has no role in promoting their business activities, the independent EA Board providing the necessary separation between day-to-day regulatory decision-making and Government. SEPA is similarly independent of the radioactive substances activities it regulates and has no role in the operation or promotion of any such activities.
- CQC's independence as a regulator is assured through the Health and Social Care Act, 2008, where CQC is given direct responsibility to regulate the purposes of the Act and its relevant statutory provisions. Government cannot direct CQC with respect to regulatory functions in a particular case - ensuring that regulatory decisions are independent.

The other regulatory bodies in the UK in the fields of occupational protection, environmental protection and medical exposures (namely HSENI, NRW, NIEA, HIS, HIW, RQIA) also perform their functions independent of outside influence, as do FSA, FSS, CAA and MCA.

3.3. STAFFING AND COMPETENCE OF THE REGULATORY BODY

ONR

ONR has about 650 personnel, more than 400 of them being technical staff. ONR prepares resourcing plans to ensure that it has an appropriate number of qualified and competent staff. These plans ensure that all disciplines have the required number of staff, with the relevant knowledge, skills and abilities to perform their regulatory functions. Within ONR's matrix structure, the Technical Director has oversight of the capacity and capability of specialist regulatory resources.

The last few years has seen the retirement of a number of experienced staff, who have mostly been replaced by younger and less experienced staff. ONR has embarked on a programme to hire and train new graduates, recruit mature people from industry, recruit suitable conventional inspectors, start an apprenticeship programme and make use of Technical Support Organisations. In order to help develop the new hires, ONR has created both a regulatory training program and a specialist training program. Salaries are appropriate for the sector to help attract and retain staff. A rotation policy applies every five years, generally between project or site inspection and review and assessment, though some staff will be rotated through other areas, such as training, regulatory assurance or the Well Informed Regulatory Decisions (WIReD) project, which seeks to derive a simplified set of regulatory processes which align with IAEA Safety Guide GSG-13.

Occupational Protection

HSE seeks to maintain about 1000 inspectors and about 1000 other professional and specialist staff, covering all areas of conventional health and safety for which HSE is responsible and, in line with workforce plans, continue to recruit trainee and specialist inspectors to maintain capability for the future. However, only about 8.6 FTEs are dedicated to ionizing radiation safety:

- The specialist Radiation Team comprises one Principal Specialist Inspector (Radiation) and one Acting Principal Specialist Inspector (Radiation) with five Specialist Inspectors (Radiation). The Specialist Inspectors (Radiation) concentrate on the high-risk facilities and activities that require consent (i.e. a licence). Only these Specialist Inspectors also inspect unsealed radioactive materials;
- Ten Ionising Radiations Regulatory Inspectors (IRRIs) who are general regulatory inspectors who have had some training in radiation safety and application of the IRRs for specific practices. The IRRIs cover lower-risk facilities, being those that only require registration (but not a licence), which make up some 16% of their inspections.

HSE is responsible for inspection of about 16,500 authorized parties who work with ionising radiations that hold about 17000 registrations and 1300 consents (for the high-risk activities). The IRRS team is of the opinion that the HSE is not able to perform adequate regulatory oversight, especially of the high-risk activities and facilities, as detailed in chapters 5 to 7.

Each year, the Specialist Inspectors (Radiation) together perform some 75 inspections of high-risk facilities and each IRRI does about ten inspections on lower-risk facilities which use ionising radiation. The results of these inspections are that 70-80% of the facilities are given a notification of contravention or an improvement or prohibition notice, which if not complied with can lead to prosecution. The combination of a low inspection frequency and a high rate of non-compliance lead the IRRS team to the conclusion that resources need to be increased, taking into account the many other areas of work which HSE regulates.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *HSE is not able to inspect both its high-risk and lower-risk activities on an appropriate frequency.*	
(1)	**BASIS: GSR Part 1 Requirement 16, para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach".*
(2)	**BASIS: GSR Part 1 Requirement 18, para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
R4	**Recommendation: The HSE should increase the number of both Specialist Inspectors (Radiation) and Ionising Radiations Regulatory Inspectors.**

HSENI employs approximately 115 staff. Among them, one Principal Inspector, two qualified inspectors and two inspectors with specialized training work with ionizing radiation. They regulate fewer than a hundred facilities.

Public exposures and Environmental Protection

Within EA, Radioactive Substances Regulation is delivered by about 100 staff (~1% of the total headcount of the organisation), separated in two groups: one for nuclear sites, the other for non-nuclear sites (i.e. hospitals, universities and small-users of radioactive materials). EA operates a capability-based recruitment system under which prospective staff are tested for their capability in key technical specialist and core skills areas against defined competence standards, which is overseen by HR to ensure that recruitment decisions are made appropriately.

SEPA employs around 1300 staff, of whom 27 are assigned to regulatory functions for ionising radiation. Currently 9.5 of the 27 posts are vacant (35%). SEPA management has agreed to temporarily reduce the activities, according to a graded approach. SEPA has now started considering external support. Since recruitment is difficult and will probably not deliver sufficiently qualified staff soon, the IRRS team considers the efforts to get external support as very important. The SEPA action plan contains further actions such as developing a Human Resources Plan and an investigation of the factors affecting the ability to recruit people. The self-assessment by SEPA-RS has also concluded that the competency framework does not cover some specific SEPA-RS competencies. It also concluded that a related training programme has to be developed. A competency matrix has already been developed as part of this activity. Further work is required such as developing the training programme. Also, the human resources plan is not yet available, because short term priority is now the recruitment of about 10 people.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *SEPA has not implemented a competence framework, training program and human resources plan for the department of Radioactive Substances. This has been identified in the self-assessment. The related management system procedures are not yet available. The department of Radioactive Substances is currently 35% understaffed and workload has been reduced accordingly.*	
(1)	**BASIS: GSR Part 1 Requirement 11, para. 2.36 (a) states that** *"The Government shall stipulate a necessary level of competence for persons with responsibilities in relation to the safety of facilities and activities".*
(2)	**BASIS: GSR Part 1 Requirement 11, para. 2.36 (b) states that** *"The Government shall make provision for adequate arrangements for the regulatory body and its support organizations to build and maintain expertise in the disciplines necessary for discharge of the regulatory body's responsibilities in relation to safety".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(3)	**BASIS: GSR Part 1 Requirement 18, para. 4.11 states that** *"…A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
(4)	**BASIS: GSR Part 1 Requirement 18, para. 4.12 states that** *"The human resources plan for the regulatory body shall cover recruitment and, where relevant, rotation of staff in order to obtain staff with appropriate competence and skills, and shall include a strategy to compensate for the departure of qualified staff."*
(5)	**BASIS: GSR Part 1 Requirement 18, para. 4.13 states that** *"A process shall be established to develop and maintain the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. This process shall include the development of a specific training programme on the basis of an analysis of the necessary competence and skills."*
(6)	**BASIS: GSG-12 para. 6.86 (use of external support) states that:** *"If the regulatory body is not entirely self-sufficient in all the technical or functional areas necessary to discharge its responsibilities, it should seek advice or assistance, as appropriate, from external experts as described in Appendix I. In this case, the regulatory body should have the necessary competence to evaluate the work of the external expert."*
(7)	**BASIS: GSG-13, paragraph 3.312 states that** *"The regulatory body should adopt clear administrative procedures governing the taking of enforcement actions, which should be documented in internal guidance. All inspectors and other staff of the regulatory body should be trained in, and knowledgeable about, the procedures".*
R5	**Recommendation: SEPA should continue to develop and implement a competence framework and develop a human resources and training plan in its department of radioactive substances, including related procedures.**

Within NIEA, 5 technical staff deliver regulatory ionising radiation functions.

At NRW, a total of 11 technical staff deliver regulatory ionising radiation functions. They benefit from specialist support from the EA for nuclear site regulation.

Healthcare Agencies

CQC employs one Inspection Manager and five Clinical specialist inspectors to regulate relevant IR(ME)R services. Because of vacancy the CQC at the moment only have four inspectors. The IRRS team learned that CQC has tried to recruit a new inspector for eight months but not been able to attract suitably qualified or experienced applicants. All inspectors and the inspection manager employed by CQC are either registered radiographers or clinical scientists with at least 5 years post qualification experience. These inspectors undertake regular CPD to maintain their professional registration and ensure that their knowledge of clinical practice is up to date. The IRRS team learned that CQC has faced challenges to implement an inspection programme that ensures that every facility and activity is regularly inspected.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *The IRRS team learned that CQC has faced challenges to implement an inspection programme that ensures that every facility, and activity is regularly inspected.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 16, para. 4.5 states that** *"The regulatory body has the responsibility for structuring its organization and managing its available resources so as to fulfil its statutory obligations effectively. The regulatory body shall allocate resources commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach".*
(2)	**BASIS: GSR Part 1 (Rev 1) Requirement 18 states that** *"The regulatory body shall employ a sufficient number of qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities."*
(3)	**BASIS: GSR Part 1 (Rev 1) Requirement 18, para. 4.11 states that** *"The regulatory body has to have appropriately qualified and competent staff. A human resources plan shall be developed that states the number of staff necessary and the essential knowledge, skills and abilities for them to perform all the necessary regulatory functions."*
R6	**Recommendation: CQC should allocate resources to regulate relevant IR(ME)R activities, commensurate with the radiation risks associated and in accordance with a graded approach. CQC should also seek to increase its number of inspectors so as to be able to increase the frequency with which facilities are inspected.**

HIS currently employs one full-time inspector with part-time support from three other inspectors, making a total of 1.7 full time equivalents (FTEs) to regulate relevant IR(ME)R services. All inspectors come from a regulation background and have undergone training with Public Health England. The IRRS team learned that HIS, which took over as the enforcing authority for IR(ME)R17 in 2018, is still reviewing the resources required to fulfil their statutory duties.

HIW has a team of 5 experienced inspectors who have undertaken training to enable them to fulfil HIW's inspection, notification and enforcement functions. HIW also has a service level agreement in place with Public Health England (medical exposures group) to provide technical advice as necessary.

RQIA has a team of 5 technical staff. All inspectors are experienced nurses with a good knowledge of acute hospitals and radiation departments. All IR(ME)R18 inspectors receive specialised training from PHE and receive regular update training to maintain their competence. RQIA also has a contract in place with Public Health England (medical exposures group) to provide technical advice as necessary.

3.4. LIAISON WITH ADVISORY BODIES AND SUPPORT ORGANIZATIONS

ONR has arrangements for obtaining external technical or professional advice from contractors if needed in support of its regulatory functions. Although ONR ensures that it is appropriately resourced to effectively regulate the UK nuclear industry, its portfolio is technically complex so from time to time it needs to access outside technical support.

In order for the CNI to be able to access experienced specialists, a panel of experts has been established. The CNI's Independent Advisory Panel provides advice on relevant topics such as regulatory policies and strategies to future developments in nuclear technologies and the regulation of such innovations. At the beginning of 2019, two members of the NGO community were appointed to the panel to provide a more diverse perspective and challenge.

HSE has a team of radiation specialists who are able to give technical and expert advice on radiation issues. In the rare event that they do not have the necessary expertise, HSE can procure research and advice from external organisations that is considered by HSE regulatory specialists who will then come to an independent decision. In addition to procuring research and advice from external organisations, Public Health England is able to advise HSE on radiological protection matters.

The EA occasionally contracts out work including radiological assessments and R&D to support regulatory objectives. It also works closely with other organisations to influence and advise on research into areas such as impact assessment and radioactive waste management.

SEPA has arrangements in place whereby it can procure external technical support or advice.

CQC can also utilise independent experts for its inspections, if required.

The other regulatory bodies in the UK in the fields of occupational protection, environmental protection and medical exposures (namely HSENI, NRW, NIEA, HIS, HIW, RQIA) also are able to liaise with advisory bodies or support organizations should they need to, as can FSA, FSS, CAA and MCA.

3.5. LIAISON BETWEEN THE REGULATORY BODY AND AUTHORIZED PARTIES

Overall, the IRRS team found that many arrangements are in place to get feedback from authorized parties, either on an individual basis or with industry groups or professional societies. This includes but is more often than not limited to the development of regulations and regulatory guidance (see chapter 9). In addition to informal communication, formal communication methods include compliance assessment reports, notices and formal letters. For non-nuclear sites, whenever a site inspector has been designated, he or she is often the principal communication point for the permit holder in relation to radioactive substances regulation.

Strategic industry and policy groups such as the Radioactive Substances Policy Group, the Nuclear Decommissioning Strategic Policy Group, the Safety Directors' Forum, the Nuclear Industry Liaison Group and Small Users Liaison Group are also fora where stakeholders' viewpoints can be expressed to inform future decisions.

ONR

ONR engages at all levels of management at its licensed sites and at corporate level to ensure regulatory clarity. For example, ONR and nuclear site licence holders adopt a formal hierarchy for meetings to address and resolve issues arising from regulatory processes. The ONR goal setting approach allows a collective view of risk and potential solutions to be derived in order to achieve safe and secure operations which will identify good practices to be shared with others to encourage continuous improvement. Nothing in this approach alters the obligation on industry to comply with the law and does not prevent ONR from holding the industry to account on behalf of the public.

ONR has a lot of contact with NDA which is responsible under the Energy Act 2004 for the decommissioning of the UK's legacy sites and also holds the budget. ONR continues to regulate the safety of those sites and can hold NDA to account via the Energy Act 2013. Looking forward, BEIS is leading a policy project on decommissioning, looking to reduce the timeline to when the site becomes safe enough to be able to be handed over to the relevant regulatory authority (without actually being decommissioned).

A recent development has been the need for ONR to prepare for the UK exiting the European Union, which includes establishing a UK State System of Accountancy for and Control of Nuclear Materials to replace the existing Euratom system. A project to do this recently completed Phase 1 which determined what must be done to meet the UK's obligations on reporting, nuclear materials accountancy and control. An IT system has been put in place for use by the licensees and authorized parties, with the goal to minimize impact on how they report to the IAEA and has been trialled in parallel with the existing Euratom reporting system for Capenhurst, Springfield and parts of Sellafield. The project has been rated as successful following four reviews by the Infrastructure Projects Authority. Phase 2 to replace the Euratom reporting with another for all facilities covered by the voluntary offer agreement is now underway and due to complete in January 2021. This will be analogous to the current approach for nuclear safety and security in that it will be goal-setting regime. Staffing has been increased from six to thirty, of which twenty-one are inspectors, located in the re-titled Civil Nuclear Security and Safeguards Division.

Occupational Protection, Environment Agencies and Healthcare Agencies

Stakeholder engagement is an integral part of the way that HSE operates. HSE works together with stakeholders, which allows HSE to understand their concerns and enables HSE to ensure that its policies and operational processes are practical and proportionate. The IRRS team was made aware of the outreach done while developing IRR17. Also, more than 530 HSE stakeholders are members of an online Radiation Community of Interest

HSENI provides information on its website and links to the HSE website where further information can be found and updates are provided via the HSE Radiation Community of Interest.

Both EA and SEPA develop effective relationships with their authorised parties and have clear two-way formal and informal mechanisms of communication in place. For nuclear permit holders, the EA has adopted a formal hierarchy for meetings to address and resolve issues arising from regulatory processes.

CQC also has both formal and informal communications channels with its providers of regulated activity. CQC has regular communication with many professional bodies, such as the Royal College of Radiologists, Institute of Physics and Engineering in Medicine and Society and College of Radiographers.

The other regulatory bodies in the UK in the fields of environmental protection and medical exposures (namely NRW, NIEA, HIS, HIW, RQIA) also liaise with their authorized parties by various means, as do the FSA, FSS, CAA and MCA.

3.6. STABILITY AND CONSISTENCY OF REGULATORY CONTROL

ONR has established clearly defined policies, principles, criteria and safety objectives for implementation of its core processes in its Strategic Plan 2016 – 2020 and Corporate Plan 2019/20 which summarises its regulatory focus and describes some of the challenges, risks and opportunities for the year ahead. ONR's regulatory control focuses on a range of interventions, with regulatory attention being given to the safety, security and safeguards performance of licensees, influencing improvements where necessary. Extensive regulatory guidance is developed to support a consistent regulatory approach. For example, ONR's Safety Assessment Principles (SAPs), together with supporting Technical Assessment Guides (TAGs), guide ONR staff in their regulatory judgements and recommendations when assessing nuclear site licensees' safety submissions.

About a year ago ONR has introduced an additional layer of assurance in terms of consistency, confidence and continuous improvement of the delivery of safety and security outcomes, creating the 3-tier Integrated Assurance Framework. Through this framework the existing elements and the additional Regulatory Assurance Function work together. It drives the internal regulatory feedback. All tiers form a set of independent defence-in-depth layers. About 1% of ONR staff is executing this function. The IRRS team noted that recently a Regulatory Assurance audit has been conducted, resulting in three recommendations related to permitting guidance, assessment reports and assessment work that ONR normally contracts to HSE. It was also noted by the team that ONR will inform the international community of regulatory bodies about this approach in an upcoming IAEA conference.

ONR inspectors receive extensive and ongoing training to enable them to make knowledgeable judgements and avoid subjectivity in decision making.

HSE's strategy, along with its business plan, sets out the priorities for 2019/2020. All local authority and HSE staff who make enforcement decisions are required to follow HSE's Enforcement Policy Statement. HSE has developed an Enforcement Management Model to help inspectors be consistent in making enforcement decisions, by giving guidance on whether or not to take action and if so what enforcement action to take (such as issue an improvement notice, a prohibition notice or refer for prosecution).

EA operates in accordance with a Quality Management System accredited to ISO 9001, which includes requirements related to decision-making and staff training and competency. These ensure that EA operates in accordance with the Regulators' Code and that its regulatory control is stable and consistent.

SEPA helps achieve regulatory consistency by peer reviewing all significant decisions related to applications and enforcement. SEPA also undertakes an annual review of inspection findings to assist in identifying any inconsistencies.

CQC minimises the subjectivity of inspection and enforcement by means of a peer review by senior staff who compare against judgements made of similar services locally and nationally and by discussing inspector enforcement decisions at a management review meeting.

The other regulatory bodies in the UK in the fields of environmental protection and medical exposures (namely NRW, NIEA, HIS, HIW, RQIA) also have mechanisms to support stability and consistency of regulatory control, as do FSA, FSS, CAA and MCA. PHE medical exposures group provides technical advice as necessary to HIW and RQIA.

3.7. SAFETY RELATED RECORDS

Although all of the regulatory bodies maintain their own safety-related records that are necessary in order to discharge their regulatory functions, the main responsibility rests with the the authorised parties.

ONR makes provision for establishing, maintaining and retrieving adequate records relating to the safety of facilities and activities. It requires licensees to take account of relevant legislative and statutory requirements when identifying the records to be retained and their retention periods. Licence Conditions require the licensees to establish arrangements to identify which operational records are to be kept.

HSE hosts the Central Index of Dose Information, which is the UK's national database of occupational exposure to ionising radiation. CIDI is a national dose registry and maintains data if an employer ceases operation but is not used for further purposes. If CIDI was to receive information from approved dosimetry services more frequently than the current annual basis, it could be used for other purposes (e.g. for the planning of inspections, periodic assessment of personal dosimetry data per sector, professions etc.). HSE also keeps records of all accidents, events and occurrences that are reported to it by employers under the relevant statutory provisions.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *A national dose register (CIDI) receives data on an annual basis. Besides maintaining data relevant to occupational exposures it may be valuable for other purposes.*	
(1)	**GSG-7, para. 7.265 states that** *"Consideration should be given to the establishment of a national dose registry as a central point for the collection and maintenance of dose records. The storage of information at the national dose registry should be such as to allow workers, during and after their working life, to retrieve information on the doses they received while occupationally exposed. Long term storage of such information in a national dose registry also serves the following purposes: …* *(b) It allows periodic analysis of all data on exposures collected in order to characterize the situation at the national level with regard to occupational exposure".*
S3	**Suggestion: The HSE should consider reviewing the operational aspects of CIDI to receive data more frequently and enhance its capabilities to facilitate its own and other regulatory bodies' activities.**

Permits issued by EA and NRW require that all records required to be made by the permit be retained until notified in writing by the EA that they no longer need to be retained. Similarly, all authorisations issued by SEPA require appropriate records to be made and kept to ensure and demonstrate compliance with the authorisation.

A challenge across licensees and regulators is records management where more than one organization is involved, such as transition from the Generic Design Assessment (GDA) process to becoming a licenced site. which will involve transfer of records from vendors/designers to operators.

A challenge for the future is records-keeping related to waste management, which will involve many facilities and organizations as waste moves from storage to pre-disposal management to disposal. A framework document issued in December 2018 sets the path. Radioactive Waste Management Ltd. (a wholly owned subsidiary of the NDA) is

responsible for implementing plans for the geological disposal of higher activity radioactive wastes in England and Wales. A future GDF will be subject to authorisation by both the relevant environment agency and the ONR.

HSE, HSENI and ONR, in accordance with IRR17, maintain oversight of occupational exposure protection from radiation sources. However, HSE, HSENI and ONR do not maintain a register of radioactive sources or radiation generators, which may make it difficult to plan their regulatory activities. The IRRS team was informed that there are no clear arrangements whereby bodies such as CQC, HIS, HIW and RQIA are able to obtain such information on the distributions of radioactive source and generators as might be helpful in planning their regulatory oversight activities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The register of radiation sources and radiation generators maintained by HSE, HSENI and ONR does not contain information about their exact numbers, characteristics and location, to enable adequate regulatory oversight by the relevant regulatory authorities.*	
(1)	**BASIS: GSR Part 1 Requirement 35, para. 4.63 states that** *"The regulatory body shall make provision for establishing and maintaining the following registers and inventories* *- Registers of sealed radioactive sources and radiation generators".*
R7	**Recommendation: The HSE, HSENI and ONR should establish and maintain a single register of radiation sources and radiation generators which contain information about their exact numbers, characteristics and location to enable adequate regulatory oversight by the relevant regulatory authorities.**

3.8. COMMUNICATION AND CONSULTATION WITH INTERESTED PARTIES

The IRRS team found that stakeholder engagement is performed by each regulatory body with a variety of outreach efforts. This variation is due to the applicable legislative or regulatory requirements. For example, the environment agencies undertake more public consultations.

In all cases, each regulatory body website is the main tool used to make information available to interested parties. Other initiatives, such as stakeholder forums, may be used on a case by case basis or as standing groups.

Communication with interested parties by ONR has improved in the past years: A Policy and Communications Director was appointed about 1.5 years ago and a Head of Communications is now being sought.

Engagement with the local communities around the sites is led by the site operators in the form of site stakeholder groups or local liaison committees, often chaired by local authority officials or elected representatives, in which the site inspectors from the different RBs participate and report back. However, there is no coordination between the sites and no central stakeholder engagement on the part of ONR, though a plan is being developed. ONR is currently undertaking its third annual stakeholder survey (duty holders, licensees, NGOs and other stakeholders), seeking feedback to inform future stakeholder engagement to regulated parties.

HSE has long had a central communications and policy group, and also has in place a five-year strategy. To launch the strategy HSE holds roadshows and workshops targeting stakeholders from many different sectors including hospitals, business and academia. A concerns and advice team has been established to respond to questions or to offer advice; more complex enquiries are passed to teams with the relevant specialist knowledge. Recent regulations that were developed to implement the Basic Safety Standards Directive identified stakeholder groups and HSE engaged with as many of them as possible. The Information Commissioner (in effect the UK Ombudsman) can be contacted to resolve disagreements if line management is unable to resolve a query or complaint. A similar path exists for ONR.

While the public is consulted during the permitting process for radioactive substances activities implemented by EA, SEPA, NRW and NIEA, no similar provisions are in place regarding the nuclear site licensing process performed by ONR.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ONR is not required by the Nuclear Installations Act to consult on its regulatory decisions and regulatory guidance.*	
(1)	**BASIS: GSR Part 1 Requirement 36 para. 4.67 states that** *"Interested parties including the public shall have an opportunity to be consulted in the process for making significant regulatory decisions, subject to national legislation and international obligations".*
(2)	**BASIS: GSR Part 1 Requirement 36 states that** *"The regulatory body shall promote the establishment of appropriate means of informing and consulting interested parties and the public about the possible radiation risks associated with facilities and activities, and about the processes and decisions of the regulatory body".*
(3)	**BASIS: GSR Part 1 Requirement 34 para. 4.61 states that** *"The government or the regulatory body shall establish, within the legal framework, processes for establishing or adopting, promoting and amending regulations and guides. These processes shall involve consultation with interested parties in the development of the regulations and guides …".*
R8	**Recommendation: ONR should establish provisions for interested parties and the public to be appropriately consulted in its process for making significant regulatory decisions, establishing regulatory guidance or when updating licence conditions.**

3.9. Policy Issue Discussion: Public engagement around risk

Given the importance of the civil nuclear industry in the UK, and the continued benefits of radiation in industrial and medical contexts, engagement and support from the public continues to be essential. It is UK practice to engage the public in several different contexts, some driven by legal consultation requirements, but equally importantly because being open and transparent is critical to public safety and in gaining public trust of the regulatory framework for nuclear and radiation safety.

The purpose of this policy discussion was to exchange experiences between the IRRS team members and the regulatory bodies in the UK on engaging with the public to increase their understanding associated with the safety and risks in the use of nuclear energy and ionising radiation.

The IRRS team provided the following insights to the UK:

- It is important to demonstrate the independence of the regulatory body
- Communication professionals and specialists are beneficial in providing assistance to the regulatory body to facilitate public consultation for significant regulatory decisions
- Web casting of hearings and other regulatory meetings is very beneficial in reaching a broad range of stakeholders
- Summary reports of significant regulatory decisions should be published in plain language to assist public understanding of the outcomes
- The use of independent technical experts (e.g., engineering specialists, academic staff, etc.) may assist regulatory bodies in gaining public confidence
- Preannounced, routine (annual, semi-annual) public outreach meetings are useful for explaining the safety and risk issues associated with local nuclear facilities and maintaining the public's confidence in the regulatory body

- It is important to keep public meetings focused on the use of available scientific information in regulatory decision making
- In response to nuclear and radiological events, the media is normally more focused on engaging with the regulatory body than the operator
- In presenting the risks associated with the use of nuclear facilities and radiological activities it is useful to compare the risks to other familiar risks (e.g., airplane travel, dental x-rays, etc.)
- Regulatory bodies should monitor public reaction to all emergencies, not just radiological, and learn from those reactions

3.10. Policy Issue Discussion: Regulatory innovation and regulating advanced nuclear technologies

The UK Government is committed to addressing climate-change and meeting its domestic net-zero carbon targets. Nuclear, potentially including advanced nuclear technologies (ANTs) and other technical innovations, will have an important role to play.

An important area for innovation is demonstrating safety, security and environmental compliance. Given the nature of the nuclear hazard, high standards of safety, security and environmental compliance must be required. It is important for the development of innovation that these standards are suitable for new technologies and continue to be applied within an enabling framework of dialogue between regulators and industry.

The IRRS team provided the following insights to the UK regarding this use of ANTs and innovative technologies:

- It is important for regulators to collaborate on ANTs and SMRs
    - Continue to collaborate through bi-lateral and multi-national agreements and working groups (e.g., Multinational Design Evaluation Programme (MDEP))
    - Regulators should work collectively to identify potential technical and licensing issues in advance that could lead to delays in the implementation of SMRs
    - Publish information on website regarding licensing impediments in the design
    - Regulatory bodies will need to work toward balancing the use of harmonized standards with maintaining the appropriate national sovereignty of their legal systems.
- Regulatory bodies must prepare for the use of innovative technologies
    - The use of innovative technologies is driven by cost savings and the reduction in replacement parts for aging equipment
    - Use of standardized components
        - Regulatory bodies should develop guidance on the use of standardized components
        - New technologies (e.g., 3D-printing) will be used for the manufacture of replacement parts
        - Research programmes should address the manufacture of components using innovative technologies
    - Vendors are entering the nuclear marketplace (especially ones that use innovative technologies) that have not previously been required to meet the stringent quality assurance requirements for nuclear components (including services such as welders and welding techniques)

3.11. SUMMARY

The UK framework for nuclear and radiation safety involves many regulatory bodies, each enforcing specific regulations. A unique aspect is that for most of the regulatory bodies, radiation safety is only one of the many areas they regulate.

The clear message the IRRS team received was that where several regulatory bodies deal with a particular authorized party, each arranges its inspections separately; joint or synchronised inspections being the exception.

The IRRS team found that ONR's matrix management approach is working well, resourcing discussions take place on a regular basis between the delivery leads and professional leads to ensure that resources are being applied to needs.

The following areas of improvement have been identified:

- The inspection resources of HSE, SEPA and CQC and their means of application;
- The database of radiation sources and radiation generators maintained by HSE;
- The capabilities of CIDI;
- Consultation of ONR with the public and interested parties.

4. MANAGEMENT SYSTEM OF THE REGULATORY BODY

As indicated in the introduction section of the IRRS report, the IRRS team acquired field evidence to supplement its desktop review. As such, the schedule was a sample representation of four regulatory bodies of the UK (CQC, EA, HSE and ONR).

4.1. RESPONSIBILITY AND LEADERSHIP FOR SAFETY

ONR RESPONSIBILITY AND LEADERSHIP FOR SAFETY

ONR is governed by a Board consisting of executive and non-executive directors. The Board's role is to, in furtherance of ONR's Mission: provide leadership; set strategy; agree the overarching policy framework within which ONR operates as a regulator, agree and monitor resources and performance and ensure good governance.

The Chief Executive is responsible for establishing, applying, sustaining and continually improving the ONR Management System in accordance with the Management System Policy.

A corporate strategy is established by ONR every five years. The strategy informs development of ONR annual Corporate Plans. ONR's Mission, Vision and Strategic Themes are provided in ONRs' Management System Manual and further detailed in the ONR Corporate Plan.

The Senior Leadership Team (SLT) is responsible for leading the ONR team to deliver ONR's Mission and Vision. It is the strategic executive decision-making body, supporting the Board to carry out legislative, policy, operational and administrative functions and requirements. As role models, SLT members are accountable for providing exemplary leadership and delegating work to engage and develop sustainable improvements, staff development, and a positive safety and security culture.

The Regulatory Leadership Team (RLT) is the primary regulatory decision-making body that provides leadership to ensure ONR's regulatory strategy is delivered and that ONR is effectively and efficiently regulating all authorized parties across its various purposes.

Individual expectations are communicated to the ONR's staff by various means including a Behaviour Framework aligned to the Strategic Themes that have been developed for all personnel and rolled out through training and performance management. ONR personnel's performance is measured against the Behaviour Framework as well as delivery objectives. This helps to foster and sustain beliefs and attitudes within ONR that support safety and security culture.

EA RESPONSIBILITY AND LEADERSHIP FOR SAFETY

EA's leadership for, and commitment to, safety, security and achieving environmental outcomes by the senior management are expressed through corporate plans and strategies. Individual expectation and objectives are derived from strategic objective and communicated annually to the EA staff.

The EA's Strategic Business Plan for Regulated Industry 2018-2023 provides a longer-term strategic view of its priority activities and how the EA will manage its people and funding to deliver them.

EA is investing in its people to ensure everyone is supported, developed and resilient in delivering the key outcomes. Questioning and learning attitude is maintained through open and honest two-way feedback between EA's managers and employees.

CQC RESPONSIBILITY AND LEADERSHIP FOR SAFETY

Safety is one of the core principles on which CQC activity is based. In discharging regulatory responsibilities, operational staff have a commitment to safety, not only within the services regulated, but also to the safety of CQC staff, whether those in operational roles or those working in other areas of CQC's business.

The CQC Board provides leadership and ensures CQC is successful and sustainable, sets CQC strategy, purpose and values, is the head of the management structure and is supported by the executive team. The CQC Executive

team is responsible for CQC's day-to-day running, oversees the delivery of its business plan objectives, ensures resources are used properly and manages its performance well.

Individual expectations are provided in CQC's strategy and annual business plan. In accordance with CQC key governance principles everyone involved in CQC will be clear about their roles and responsibilities and how these contribute to delivering CQC's strategy.

HSE RESPONSIBILITY AND LEADERSHIP FOR SAFETY

HSE is the regulatory body for occupational health and safety in GB. There is a general expectation that HSE's own policies and procedures for managing health and safety risks are the same as those it regulates.

The HSE Business Plans outlines its key areas of work for and reinforces its existing commitment to:

- Lead and engage with others to improve workplace health and safety;
- Provide an effective regulatory framework;
- Secure effective management and control of risk;
- Reduce the likelihood of low-frequency, high-impact catastrophic incidents; and
- Enable improvement through efficient and effective delivery.

This annual Business Plan is supplemented by published sector and divisional work plans to provide transparency to stakeholders.

The HSE is led by a Board, made up of members who are independent of the HSE who represent both employer and employee and others. The Board are responsible for setting the direction of HSE and oversees the operation of the organisation and provides leadership in relation to all hazards and associated risks HSE regulates, both within the organisation and outside among those regulated.

All HSE staff are encouraged to see themselves as regulators whether or not they are operational inspectors. Staff are expected to be enquiring and questioning consistent with a regulatory body charged with ensuring good standards of compliance. Training and development, internal and external decision-making processes, health and safety policy and management structures and the inspection, auditing and reporting on performance rely on this enquiry, challenge and questioning.

4.2. RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

ONR RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The Chief Executive is responsible for establishing, applying, sustaining and continually improving the ONR Management System in accordance with the Management System Policy through the Governance and Executive Office. Process Owners are tasked by the Senior Leadership Team and Directors to establish, deploy, monitor and improve the necessary process and supporting arrangements which deliver ONR's outputs in support of goals and deliverables.

The ONR Corporate Plan and annual Business Plan for each directorate detail the corporate, directorate and divisional milestones (goals) which align to ONR's Strategic Themes; risks to be mitigated, opportunities to be realised and the necessary Key Performance Indicators.

Corporate milestones are agreed upon by the Board and the Senior Leadership Team. Directors are accountable for achieving their Directorate milestones. Project Teams may be constituted by Directors to deliver the work required in the achievement of milestones. Variations to milestones and goals are addressed via a robust change control process.

EA RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

The EA operates a management system in-line with EA Quality Policy and Environmental Statement. All EA staff are responsible for proper implementation of the EA management system. The Radioactive Substances Regulation

function is one of many functions in the EA and its management system covers a vast array of processes that are not directly based on IAEA GSR Part 2, however, many of the arrangements are consistent with its requirements. The EA management system promotes and supports quality standards and ensures its processes and procedures are standardised, managed, and continually improved. All EA staff are responsible for contributing to the management system and its commitment to quality. EA's goals are described in corporate and strategic plans and periodically reviewed.

CQC RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

As a regulator, CQC holds other organisations to account for the quality of their governance.

CQC is held to account by the DHSC in terms of delivering its responsibilities properly through formal processes. The Corporate Governance Framework exists to support and challenge CQC in its accountability. The CQC Chief Executive is accountable as CQC's Accounting Officer for the operation of the Framework, which has been mandated by the CQC Board. All CQC line managers are responsible for understanding and operating within the Framework themselves and ensuring that their staff do likewise.

A set of values and goals were established to show the way CQC act, to be consistent, and to provide a solid foundation upon which a positive culture and a high performing organisation will be built. Achievement of goals are annually assessed by the CQC Board.

The key governance principles to which CQC subscribes are:

- CQC will demonstrate effective leadership and will set clear direction;
- CQC will be open, transparent and accessible in the way it conducts its business;
- CQC will be accountable and will ensure that decisions are well made and effectively implemented;
- CQC will manage risk and performance effectively; and
- Everyone in CQC will demonstrate their commitment to CQC's values and will behave with integrity.

HSE RESPONSIBILITY FOR INTEGRATION OF SAFETY INTO THE MANAGEMENT SYSTEM

In accordance with HSE's health and safety policy statement, the Chief Executive (CE) expressed commitment to ensure that together with the Management Board (MB), they provide the necessary leadership and resources to:

- Seek continuous improvement in its safety management system, health and safety performance and safety culture - benefiting from the contributions of safety representatives and workforce engagement, including HSE's health and safety committees;
- Define individual health and safety responsibilities and competencies across HSE, while encouraging people to take personal responsibility for their own safety and health and those colleagues and teams around them;
- Comply with relevant health and safety legislation; statutory guidance such as Approved Codes of Practice; relevant product and practice standards; guidance and other recognised good practice, and other requirements;
- Operate a safety management system which puts in place effective control measures which are proportionate to the level of risk and document, implement and maintain this system around HSE's key areas of risk.

HSE's health and safety policy is reviewed every 3 years, or sooner if required.

4.3. THE MANAGEMENT SYSTEM

ONR MANAGEMENT SYSTEM

In January 2019, ONR initiated its Management System Improvement Project (MSIP). MSIP is designed to give ONR the management system that it needs, mindful of findings raised by the IAEA 2014 Expert mission and the

outputs of ONR's self-assessment work performed in advance of this Mission. ONR's Management System Policy requires ONR to develop, deploy, resource, and continually improve a management system which meets the requirements of the IAEA GSR Part 2. The Management System covers the identification and achievement of its safety and security goals as described in the Corporate and Directorate Business Plans.

The ONR Management System is an integrated, processed based system and is intended to cover the core regulatory processes associated with ONR's statutory purposes as well as its support processes. The ONR Management System Manual and the computer system "How2" describe ONR's organisational structure, internal and external interfaces, processes, responsibilities and accountabilities. The Manual refers to ONR's Organisational Change Process, a transparent and proportionate process for the management of organisational change and applied in a manner proportionate to the complexity and novelty of the change.

The ONR management systemintegrates safety, health, security, quality, human and organisational factors, societal and economic elements.

The IRRS team was informed that the formal integration of environmental elements with all other management system elements, as well as the complete description of the interactions between processes is still under consideration.

ONR's arrangements for resolution of possible conflicts in the decision-making process are set out in instruction "Resolving Differences of Professional Opinion in ONR".

The documentation of the ONR Management System is described in the Management System Manual and on the How2 computer system. Documentation is controlled in accordance with "Control of Management System Documented Information".

ONR interaction with interested parties, internally and externally, is undertaken in accordance with the annual Regulatory Directorate and Policy and Communications Directorate Business Plans.

Application of the graded approach in ONR Management System is achieved through ONR's fundamental principle of proportionality based on the level of risk associated with each of the facilities and activities they regulate and deployed throughout the regulatory processes. This approach is properly reflected in licensing and inspection activities and in some of the review and assessment activities (PSR for NPPs).

The IRRS team was informed that the implementation of graded approach is, in some cases, implicit rather than explicit due to, for example, ONR's reliance on Professional Leads' (PLs) decisions. In order to have a systematic graded approach, this requires a better formalisation to ensure consistency with respect to the implementation of the graded approach.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing management systems of ONR does not fully comply with the IAEA Safety Standards with respect to the formalization and implementation of the integration of environmental elements with all other management system elements, regulatory core/management and support process, promotion of safety culture, processes for measurement, assessment and improvement of management system, leadership for safety and of safety culture, as well as formalization of the use of a graded approach for all facilities and activities. Most of these findings were also identified by ONR in their Action Plan.*	
(1)	**BASIS: GSR Part 2 Requirement 6 states that** *"The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised".*
(2)	**BASIS: GSR Part 2, Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organization's goals without compromising safety".*
(3)	**BASIS: GSR Part 2, para 4.29 states that "***The sequencing of a process and the interactions between processes shall be specified so that safety is not compromised. Effective interaction between*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	interfacing processes shall be ensured".
(4)	***BASIS: GSG 12 para. 2.27 states that "****The regulatory body should establish policies to promote the use of a graded approach, transparency and consistency, and the broad sharing of information and ideas, to help ensure the highest standards of protection and safety, while giving due account to the protection of sensitive information".*
(5)	**BASIS: GSG 3.1 para. 2.40 states that** *"For all products and activities within a process, all the requirements of and demands on the relevant process should first be considered. By using the grading methodology, it may be possible to identify products and activities of lesser significance within a process. For products and activities of lesser significance, it is then possible to determine whether all the controls and checks of the process are necessary. Controls and checks that could be graded include, for example, aspects such as qualification and training for individuals, type and format of procedures, and requirements on verification, inspection, testing, material, records and the performance of suppliers".*
(6)	**BASIS: GSG 3.1 para. 2.43 states that** "*It is common sense to apply tighter controls to more important products and activities. A methodology for grading should be developed that ensures that all individuals in the organization apply this common sense approach in a uniform manner".*
(7)	**BASIS: GSR Part 2, Requirement 12 states that** *"The management system and leadership for safety shall be such as to foster and sustain a strong safety culture".*
(8)	**BASIS: GSR Part 2, Requirement 13 state that** *"The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety".*
(9)	**BASIS: GSR Part 2, para 6.4 states that** *"Independent assessments and self-assessments of the management system shall be regularly conducted to evaluate its effectiveness and to identify opportunities for its improvement".*
(10)	**BASIS: GSR Part 2, Requirement 14 states that** *"Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization".*
R9	**Recommendation: ONR should further develop and implement its Integrated Management System to fully comply with the IAEA safety standards.**

EA MANAGEMENT SYSTEM

The EA management system integrates safety, health, environmental, security, quality, human and organisational factors, societal and economic elements. These aspects of work are brought together by managers when setting and reviewing objectives, approving documents under the Non-Financial Scheme of Delegation (NFSoD) and financial matters under the Financial Scheme of Delegation (FSOD).

Organizational structure, interfaces (internal and external), processes, responsibilities, accountabilities in the regulatory body are described and made available, in electronic format, to the EA staff. Management of organisational changes are implemented with the aid of a set of guides and tools before any change is put in practice.

The IRRS team was informed that the use of independent review before decisions significant for safety are made, are not formalized in the EA's management system but implemented on a case by case basis. Application of the

graded approach to the management system is more implicit than explicit not being formalized to ensure transparency and consistency in its implementation.

EA interaction with interested parties, internally and externally is done in accordance with provisions set in "Environmental permitting: handling and determining applications for radioactive substances activities on nuclear sites".

Documentation of the EA management system is web-based documentation, its content being controlled, revised and retained in accordance with "Controlled content - how to plan, produce, review and withdraw content "and "Document classification".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing management systems of EA does not fully comply with the IAEA Safety Standards with respect to the formalization and implementation of the independent review to be made before decisions significant for safety are made, formalization of the use of a graded approach, regulatory process interfaces and its associated performance indicators, as well as processes for measurement, assessment and improvement of management system, including the establishment of process for non-conformances reporting and corrective action plan. These findings were also identified by EA in their Action Plan.*	
(1)	***BASIS: GSG Part 2, Requirements 6 para. 4.14 states that "****Arrangements shall be established in the management system for an independent review to be made before decisions significant for safety are made".*
(2)	**BASIS: GSR Part 2, Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organization's goals without compromising safety".*
(3)	**BASIS: GSR Part 2, para 4.29 states that "***The sequencing of a process and the interactions between processes shall be specified so that safety is not compromised. Effective interaction between interfacing processes shall be ensured".*
(4)	***BASIS: GSG 12 – Table 2A, Process Management states that*** *"Develop individual process:* *…. (4) Specify control points and performance indicators".*
(5)	***BASIS: GSG 12 para. 2.27 states that "****The regulatory body should establish policies to promote the use of a graded approach, transparency and consistency, and the broad sharing of information and ideas, to help ensure the highest standards of protection and safety, while giving due account to the protection of sensitive information".*
(6)	**BASIS: GSG 3.1 para. 2.40 states that** *"For all products and activities within a process, all the requirements of and demands on the relevant process should first be considered. By using the grading methodology, it may be possible to identify products and activities of lesser significance within a process. For products and activities of lesser significance, it is then possible to determine whether all the controls and checks of the process are necessary. Controls and checks that could be graded include, for example, aspects such as qualification and training for individuals, type and format of procedures, and requirements on verification, inspection, testing, material, records and the performance of suppliers".*
(7)	**BASIS: GSR Part 2, Requirement 13 state that** *"The effectiveness of the management system shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety".*
(8)	**BASIS: GSG -12, para. 5.48 states that** *"The integrated management system review should cover all significant sources of information on performance, including the following: … Non-conformances*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	and the progress and effectiveness of corrective and preventive actions".
R10	**Recommendation: EA should further develop and implement its Integrated Management System to fully comply with the IAEA safety standards.**

CQC MANAGEMENT SYSTEM

CQC management system integrates safety, health, environmental, security, quality, human and organisational factors, societal and economic elements. Organizational structure, interfaces (internal and external), processes, responsibilities, accountabilities in the regulatory body are described and made available in electronic format to the CQC staff.

The process of management of organisational changes is not yet completely formalized. CQC has an action to formalize a Management of organisational changes process with the aim of a set of guides and tools before any change is put in practice, in its next strategic plan.

The management system is applied using a graded approach. CQC use intelligence monitoring and data gathered to prioritise inspecting locations and providers that are high risk, in a targeted, risk-based approach. The CQC provides arrangements for the resolution of conflicts arising in the decision-making process. CQC also consult with the public and providers, and other stakeholders, with regards to regulatory decision making where required or appropriate. CQC interaction with interested parties, internally and externally is done by an engagement team under the Engagement Directorate.

Documentation of the CQC management system is web-based, its content being controlled, revised, and retained in accordance with CQC specific rules and procedures, developed in accordance with national legislation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The existing management systems of CQC does not fully comply with the IAEA Safety Standards with respect to the formalization process for identification, planning, control and management of organizational change, content and format of the inspections and enforcement processes with regards to the establishment of associated performance indicators and process owners, arrangements for measurement, assessment and improvement of leadership for safety and of safety culture. Some of these findings were also identified by the CQC and will be considered in its next strategy.*	
(1)	**BASIS: GSR Part 2, Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organization's goals without compromising safety".*
(2)	**BASIS: GSR Part 2, para 4.29 states that** "*The sequencing of a process and the interactions between processes shall be specified so that safety is not compromised. Effective interaction between interfacing processes shall be ensured".*
(3)	***BASIS: GSG 12, para 5.13 states that*** *"The roles and responsibilities of individuals involved in each process should be identified in the development phase of the integrated management system, which includes the identification and definition of the processes. For each process a process owner should be assigned".*
(4)	**BASIS: GSR Part 2, para 4.13 states that** *"Provision shall be made in the management system to identify any changes (including organizational changes and the cumulative effects of minor changes) that could have significant implications for safety and to ensure that they are appropriately analysed".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(5)	**BASIS: GSR Part 2, Requirement 14 states that** *"Senior management shall regularly commission assessments of leadership for safety and of safety culture in its own organization".*
S4	**Suggestion: Within its Integrated Management System, CQC should consider enhancing its processes for oversight of radiation safety.**

HSE MANAGEMENT SYSTEM

HSE management system integrates safety, health, environmental, security, quality, human and organisational factors, societal and economic elements. HSE's internal management systems are consistent with the goals, mission and objectives established in its Strategic and Annual Business Plans.

Organizational structure, interfaces (internal and external), processes, responsibilities, accountabilities in the regulatory body are described and made available in electronic format to the HSE staff. Management of organisational changes is ensured through a dedicated HSE Change Framework Process. Strategic Communications, Campaigns and Strategic Engagement are established by HSE to ensure effective interfaces with internal and external stakeholders.

Application of graded approach principle in inspection and enforcement activities is implemented in accordance with HSE Enforcement Policy. Independent review, before decisions significant for safety are made, is done in accordance with HSE operational guidance investigation procedure.

Documentation is controlled, reviewed and retained in accordance with "Control of Management System Documented Information".

4.4. MANAGEMENT OF RESOURCES

ONR MANAGEMENT OF RESOURCES

ONR's policy on the training and development of staff is to provide continuous professional development in organisational, regulatory, technical and behavioural capabilities as necessary for regulatory efficiency and effectiveness, maximise the potential of staff, considering business needs and ONR's aim to provide a worthwhile, challenging and varied career. It is expected that, for all staff, career development will be achieved through a combination of experience within a job function as well as experience across a variety of job functions.

ONR Management has overall responsibility for the maintenance and operation of ONR's training and development arrangements, and their future development. Directors are responsible for ensuring that time is made available to those who must follow and play a part in implementing the arrangements set out in this document. ONR's Professional Leads are responsible for determination of the competences and resources necessary to carry out the regulatory activities.

An ONR Academy has been established to provide a centre for training and development. The academy has produced ONR's Regulatory Competency Framework which sets out the competencies relating to regulatory processes and to ONR's legal, regulatory and organisational basis. ONR has developed a model of competence which reflects the knowledge, skills and behaviours required for a regulatory body, encompassing all its staff.

EA MANAGEMENT OF RESOURCES

EA's Team Leaders and team members are responsible for identifying and agreeing the capabilities that need to be developed to meet the needs of that team and succession plans. The skills and competences for particular roles in the EA are established in accordance with EA's Technical Development Frameworks (TDF) and are achieved by

qualifications, training, mentoring, experience, workshops, secondments, etc. Leadership training is delivered as part of the TDF.

CQC MANAGEMENT OF RESOURCES

CQC inspectors receive guidance, training and leadership courses. CQC is undertaking change and improvement programmes. There is a suite of learning that is provided in house by CQC's Academy, including health and safety training, which helps to meet all CQC's health and safety requirements and do all that is necessary to ensure inspectors remain healthy and free from harm in the workplace.

The People Directorate is responsible for setting the policies and practices that impact CQC colleagues and drives the cultural change that will further embed its values and behaviours, creates an organisation that has improvement and learning attitude. In developing this business plan, CQC's People Directorate business plan has been developed with the involvement of the Executive Team, Senior Leadership Team, commercial, and finance colleagues as part of regular engagement.

HSE MANAGEMENT OF RESOURCES

HSE Line Managers are responsible for ensuring that team members are equipped with the necessary skills and experience to undertake their role safely. HSE's Performance Management System requires formal discussion between line managers and staff to take place every 8-weeks.

Training and development to support achieving competence is available to HSE staff through several routes:

- Formally through the wider UK Government's central Civil Service Learning;
- Apprenticeships;
- Specialist training providers;
- Universities and colleges; and
- Informally through mentoring, job shadowing, on-the-job training, supervision, procedures, secondment to other government departments etc.

In addition, delivery of training programmes and assessment of an individual's competence to perform their roles safely, are made through a combination of formal training facilitated through HSE's Learning and Development Team (LDT), and personal development discussions within the line management chain. HSE's LDT facilitate access to Regulatory Training programme as well as to the Leadership Programmes.

4.5. MANAGEMENT OF PROCESSES AND ACTIVITIES

ONR MANAGEMENT OF PROCESSES AND ACTIVITIES

The ONR Management System is process based. Processes have been established and deployed to consistently deliver the outputs associated with ONR's statutory purposes and other non-statutory outputs. These processes are made available through the web based How2 system. The processes are illustrated on interactive process maps. Each process step is identified along with the responsibilities and associated documentation.

The ONR Management System Improvement Project (MSIP) was initiated in 2019 and is under implementation. The IRRS team was informed that formalization of some management and support processes, as well as some of the interfaces and specific performance indicators, are not fully developed yet.

Processes are identified, developed, and modified in accordance with ONR's Control of Documented Management System Information procedure. The procedure requires that processes and supporting documents are prepared and reviewed by appropriate persons, approved for issue by the Process Owners, and issued and made available to personnel via the How2 system. Records of documented information are maintained in a Records database, in accordance with national legal requirements.

Process Owners are assigned for all processes and are responsible for developing, deploying and maintaining the process and supporting documentation, and for monitoring improving the effectiveness of the processes. Professional Leads perform the role of Process Owner for regulatory processes. Support Function Heads perform this role for support processes.

ONR's roles and responsibilities for procurement and contracts are set out in the process maps and associated documentation. Professional Leads perform the role of 'ONR Intelligent Customer' having a clear understanding and knowledge of the product or service being supplied. The PL retains the right level of competence to specify the scope and standard of a required product or service, and subsequently to assess whether the product or service supplied meets the applicable safety requirements, liaising with ONR technical specialists as necessary.

The issue concerning the completeness of the management system processes is addressed in Recommendation R9 in sub-chapter 4.3.

EA MANAGEMENT OF PROCESSES AND ACTIVITIES

Identification, development and modification of processes, including interfaces and interactions, documentation of processes, process maps, procedures, instructions, etc, are done in accordance with ISO standards and improved to ensure reasonable compliance with GSR Part 2.

Each process has assigned a process owner responsible for developing, deploying and maintaining the process and supporting documentation. However, the IRRS team was informed that interfaces between processes as well as its performance indicators are not fully formalized.

This issue on comprehensiveness of the management system processes is addressed in Recommendation R10 in sub-chapter 4.3.

CQC MANAGEMENT OF PROCESSES AND ACTIVITIES

All CQC management system documents, starting with inspection methodology, inspection guidance for inspectors and providers, as well as handbooks, guides, templates, written scheme of delegation and policies for different sectors and areas of inspection are made available to their staff on the CQC intranet and dedicated internet pages.

Processes are identified, developed and modified in accordance with CQC control of documented information procedure. CQC has not formally assigned a process owner responsible for developing, deploying and maintaining the process and supporting documentation. Performance indicators are not fully formalized for each process.

This issue on comprehensiveness of the management system processes is addressed in Suggestion S4 in sub-chapter 4.3.

HSE MANAGEMENT OF PROCESSES AND ACTIVITIES

The HSE Management System is integrated and process based. Processes have been established and deployed to consistently deliver the outputs associated with HSE's statutory purposes.

These processes are made available through the web-based Management System. The processes are illustrated on interactive process maps. Each process step is identified along with the responsibilities and associated documentation and its indicators. Processes are identified, developed and modified in accordance with HSE control of documented information procedure.

Assignation of a process owner responsible for developing, deploying and maintaining the process and supporting documentation is not clearly visible in the current HSE management system documentation.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *The existing management systems of HSE does not fully comply with the IAEA Safety Standards with*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
respect to the clear visibility of the process owners.	
(1)	**BASIS: GSR Part 2, Requirement 10 states that** *"Processes and activities shall be developed and shall be effectively managed to achieve the organization's goals without compromising safety".*
(2)	***BASIS: GSG 12, para 5.13 states that*** *"The roles and responsibilities of individuals involved in each process should be identified in the development phase of the integrated management system, which includes the identification and definition of the processes. For each process a process owner should be assigned".*
(3)	***BASIS: GSG 12, para 5.14 states that*** *"The process owner is responsible for the management of the assigned process and should be made accountable for ensuring that the process is clearly identified, documented, reviewed, maintained and improved. Usually, this is a manager with a direct interest in the outcome of the process or who has the most resources involved".*
S5	**Suggestion: HSE should consider improvement of its Integrated Management System with respect to the clear visibility of the process owners.**

4.6. CULTURE FOR SAFETY

ONR CULTURE FOR SAFETY

ONR has recognised the need **to further strengthen** its organisational culture, focusing on organisational values and behaviours and is one of the top ten priorities in its Corporate Plan for 2019-2020. This includes delivery of enhanced leadership development, talent management and succession planning to improve leadership capability and resilience. ONR is committed to deliver strategic leadership and to implement skill enhancement programmes to improve the management and leadership capability of the organisation and signal the importance of these roles.

A questioning and learning attitude is a key attribute required and tested in the recruitment of ONR inspectors and is part of the safety and security culture of the organisation. However, ONR recognises that this is not yet explicit and fully systemised within the management system and work is ongoing to address this.

The issue on culture for safety is addressed in Recommendation R9 in sub-chapter 4.3.

EA CULTURE FOR SAFETY

EA sets out the general roles and responsibilities which support and promote the EA's Health, Safety and Wellbeing Values and Commitments and manage health, safety and wellbeing risks. This document is supported by Operational Instructions, which detail specific tasks and roles relevant to that Operational Instruction. The document sets out responsibilities at all levels of the organization.

The EA's core values and commitments show how its employees will work together to keep each other safe and well. The "How we do things" culture statement focuses on the importance of creating a working environment that supports the wellbeing of its employees highlighted as 'Stay safe and grow'. Ensuring employees keep safe and well at work will help the EA be a better organisation that is fit for the future.

CQC CULTURE FOR SAFETY

CQC fosters a strong safety culture through its Health and Safety Policy and Strategy. CQC's management system are responsible for fostering a strong safety culture, and this is detailed within the documents that are available to all staff on the intranet. CQC has a duty to ensure all employees are safe while at work and that the working environment does not negatively affect wellbeing.

CQC staff are encouraged to report incidents and learn from any incidents that occur at work. There is an incident reporting policy for this. This policy has been developed to detail the procedure to be followed in the event of an accident or incident at work or involving a member of staff working away from the CQC on official business.

The purpose of accident/incident investigation is to identify the cause of all work-related accidents, injuries, near misses, ill health conditions and violence at work incidents in order to prevent or reduce the likelihood of recurrences.

HSE CULTURE FOR SAFETY

Health and safety culture within HSE is facilitated through specific structures, arrangements, processes and levels of authority. There are several management system documents available in support of fostering strong safety culture in HSE, such as: Policy Statements, HSE's values and expectations, Organisational aims in relation to safety, roles, responsibilities and accountabilities from CE to individual colleagues, communication and consultation arrangements with colleagues and divisions, Self-regulation in HSE, Tiers of risk assessment (corporate to individual), and audit and review. These materials are available to all staff on the internal intranet, with staff expected and encouraged to read and understand the material and intent.

These arrangements are further embedded within the organization through line managers and leaders of work activities who via roles and responsibilities carry out regular team meetings or face to face meetings where health, safety, and welfare is a priority discussion focus.

HSE's approach is to ensure events and information about its risks are effectively captured, analysed, and where needed, escalated for management action.

4.7. MEASUREMENT, ASSESSMENT AND IMPROVEMENT

ONR MEASUREMENT, ASSESSMENT AND IMPROVEMENT

Several arrangements for measuring and assessing the ongoing effectiveness of its management system were put in place by ONR such as:

- The ONR Governance Arrangements which set out the corporate governance structure for ONR, reflecting the principles of the Cabinet Office Code of Good Practice on Corporate Governance, while taking account of particular requirements for independent nuclear regulation
- ONR's Integrated Audit and Assurance Framework (IAAF), which is based on the Three Lines of Defence Approach. The framework is delivered on behalf of the organisation from within the Finance Directorate. The Audit and Risk Assurance Committee (ARAC) is responsible for ensuring the maintenance of appropriate and adequate audit processes, including audit of the management system. The ARAC is a standing committee of the ONR Board and chaired by a non-executive member of the Board. The IAAF findings are reported directly into the ONR Board via the Chief Executive and Chief Nuclear Inspector Board reports for every ONR Board meeting. Audits and reviews identify recommendations for improvement and these are tracked through to completion by the SLT and the ARAC. ONR has openly shared this approach with other international regulators as a good practice and it is summarised in the IAEA TECDOC on Regulatory Experience that will be launched in November 2019.

However, the IRRS team was informed that not all management system tools required to support continuous improvement of the management system, as required by GSR Part 2, are properly integrated into ONR's management system, such as management reviews, self-assessments, management of non-conformities. A process for independent assessment of leadership for safety and of safety culture was not yet implemented. These issues were identified in, and are being addressed through, the ONR's action plan.

The issue on measurement, assessment and improvement process is addressed in Recommendation R9 in sub-chapter 4.3.

EA MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The EA has several arrangements in place to measure performance, including business, personal and safety performance. These include:

- The Audit and Risk Assurance Committee oversees the work of internal and external audit and ensures that the EA has effective controls in place to manage operational, financial, reputational and other risks.
- The Environment & Business (E&B) Committee recommends the approach and delivery of regulated industry, non-flood water and land business responsibilities to the Environment Agency Board.
- E&B Board provides a strategic overview of all the work E&B does and a clear line of sight from funding to activity to outcome.
- The Deputy Director, Radioactive Substances & Installations Regulation (RSIR) represents Radioactive Substances Regulation (RSR) on the Regulated Industry Business Board (RIBB) which provides oversight of regulated industry. The RIBB streamline decision making and join up cross-cutting issues. The RIBB discuss high level technical, business, people and performance items.
- The Deputy Director RSIR routinely chairs the RSR Portfolio Group which provides functional leadership, including governance and assurance.

Independent assessment of leadership for safety and of safety culture is performed annually by EA. The results of which are used to maintain a strong safety culture and to foster a learning attitude within the organization.

However, the IRRS team was informed that not all management system tools required to support continuous improvement of the management system, as required by GSR Part 2, are put in practice by EA yet, such as process self-assessments, management of non-conformities.

This issue on measurement, assessment and improvement process is addressed in Recommendation R10 in sub-chapter 4.3.

CQC MEASUREMENT, ASSESSMENT AND IMPROVEMENT

The management system is reviewed in several ways. There are quarterly performance reports which go to the Board and feed into an Annual Report and Accounts across the financial year. Assessment of operational delivery and activity reporting is performed weekly. CQC Senior Leadership Team hold monthly Operational Performance and Quality Improvement Deep Dives and provide a monthly performance report on operational performance. The Audit and Corporate Governance Committee (ACGC) hold management assurance processes reviews.

The IRRS team noted that assessments of leadership for safety and the safety culture in its own organization is not performed regularly as it pertains to radiation safety oversight.

This issue on measurement, assessment and improvement process is addressed in Suggestion S4 in sub-chapter 4.3.

HSE MEASUREMENT, ASSESSMENT AND IMPROVEMENT

HSE has several programs in place for measurement, assessment and improvement of its management systems, such as audits of performance against the health and safety management system procedures, internal audit of the management system, process self-assessment reports, etc.

The review process for the health and safety management system is a documented process set out within the management system.

The corporate health and safety advisers(s) coordinate(s) the health and safety management system management reviews as part of the quarterly health and safety committee(s) meetings(s).

The HSE has also implemented several assessments to assess leadership for safety and safety culture and more specifically safety leadership. An annual staff survey draws out key information to explore the overall leadership approach and how that impacts on all colleagues.

HSE has developed and implemented a “Corporate Intelligence” application that enables the monitoring and analysis of HSE key performance indicators including the time utilization, cost recovery and operational metrics. This allows managers at all levels to access routine operational performance information in a consistent and consolidated format, eliminating the original methods of running, downloading, extraction and subsequent reporting repetitively that was time/resource intensive. In addition, this application is meant to reduce inconsistency caused by the fact that in most of the cases, the summary reports need to be re-constructed and presented in ad-hoc management reports, the ability to produce consistency across divisions being potentially compromised.

The IRRS team considers the use of a Corporate Intelligence application that consolidates organisational key performance indicators across Divisions by HSE a good performance.

4.8. SUMMARY

CQC, EA, HSE and ONR that are involved in the regulation of nuclear and radiological safety across the UK have well developed management systems which reflect a mature approach to leadership and management for safety and safety culture. However, there are elements and requirements from IAEA Safety Standards and Guides that are not yet fully implemented in UK regulatory bodies’ management system documents.

Observations have been made for fully satisfying the requirements set out in the IAEA safety standards.

The following areas of improvement have been identified for UK regulatory bodies, on a case by case basis:

- integration of safety, health, environmental and other aspects into management system;
- formalisation for the use of graded approach principle;
- promotion and maintenance of safety culture;
- regulatory core/management and support process;
- processes for measurement, assessment and improvement of the management system.

5. AUTHORIZATION

5.1. GENERIC ISSUES

The UK legal framework for the authorization of nuclear and radation facilities and activities is established under the provisions of the NIA65, EPR16, RSA93, EASR18, and the IRR17 and IRRNI17. The HSE and the HSENI have the authorization responsibilities related to occupational and public exposures from facilities and activities, with the exception of those facilities that fall under the authorization responsibilities of the ONR and the relevant environment agency. The authorization of medical exposures for the administration of radioactive substances is carried out by PHE on behalf of the relevant licensing authorities. Other regulatory bodies are involved in the authorization processes related to radioactive substances, public exposures and the protection of the environment (EA, NRW, SEPA and NIEA) and transport of radioactive material (several competent authorities).

Any organization wanting to build and operate a nuclear facility needs a nuclear site licence. The activities requiring a nuclear site licence basically include all activities involving the production, storage, transport or use of enriched uranium or plutonium, nuclear reactors and the production of isotopes from irradiated material for industrial, chemical and other purposes.

The ONR grants nuclear site licences for an indefinite term under the NIA65 for the construction and operation of nuclear facilities. Licenses cover the full life-cycle of nuclear facilities, from construction to operation and to decommissioning. The NIA65 allows ONR to attach conditions to nuclear sites licenses, by means of a standard suite of 36 license conditions (LCs). LCs have a legal status under the EA 2013 and place legal duties on the licensees. LCs cover design, construction, operation and decommissioning of nuclear facilities. Licence Condition 23 (Operating Rules) requires a safety case to be produced that identify limits and conditions for all operations that may affect safety in a nuclear facility. In addition to this, ONR may implement its primary powers to specify or approve limits, conditions and controls on the licensee's activities. The NIA65 enables ONR to attach additional conditions if the need arises.

A licence may be revoked by the ONR or surrendered by the licensee. The amendment of a licence may be required in order to reduce the area of the licensed site or to add or remove license conditions (an increase in the area of the licensed site will require the issue of a new licence). Once issued, licences or licence variations are made available to the public by the ONR upon request, but are not published on the ONR's website or by other means.

Before a site licence is granted, a detailed safety assessment of any new facility is required to be submitted and is subsequently reviewed by the ONR. An independent verification of the safety assessment before it is used by the operating organization or submitted to the regulatory body is performed. ONR's expectations for safety assessments are set out in the Safety Assessments Principles (SAP). ONR has also published its internal guidance on its expectations for safety cases in a technical assessment guide (NS-TAST-GD-051). For an existing licensed site on which a new nuclear facility is to be built, a safety assessment is required as part of the licence application.

When a new activity or a plant modification is to be performed on a licensed site, a new authorization may be required, depending on the safety significance of the modification following a graded approach. Modifications or experiments are implemented under the requirements of the standard licence condition LC22 through which the licensee can choose to provide powers to ONR (called derived or secondary powers) to authorize higher risks activities. These authorizations are controlled through the ONR's flexible permissioning process, which is described in ONR's guidance NS-PER-GD-001. The adequacy of a licensee's LC22 arrangements are regularly inspected by the ONR. These arrangements include, for example, a description of the process implemented by licensees to categorize modifications according to their safety significance.

When an activity is not already addressed by a licensable activity, employers who intend to work with ionizing radiations on nuclear sites are required to either notify, register, or obtain consent via the ONR process (see also sub-chapter 5.5).

Adequate arrangements are in place to ensure that only suitably qualified and experienced persons perform any duties which may affect the safety of operations in nuclear facilities.

Permits for radioactive substances activities, that include authorizations to discharge radioactive gaseous or liquid effluents to the environment, are issued by the EA, the SEPA, NRW and NIEA. During this regulatory process,

provisions are in place to inform and consult interested parties and the public about the authorization processes implemented by the EA, the SEPA, NRW and the NIEA. In the case of new nuclear reactors (above an output power of 50 MW_e), the public is consulted at an early stage by the future applicant in the framework of the Nationally Significant Infrastructure Planning Process. Although the ONR and the environment agencies are consultees in this process, the ONR is not directly involved in this consultation mechanism, which is not focused on the ONR decision making process and occurs before applications for new nuclear sites are submitted to the ONR. Recommendation R8 in sub-chapter 3.8 addresses this topic.

The Justification of Practices Involving Ionising Radiation Regulations 2004 (*JoPIIRR* 2004) amended in 2018 ensures that each new class or type of practice utilizing ionizing radiation is 'justified' in advanced of being first adopted or approved. In this context, 'justified' means that the individual or societal benefit resulting from the class or type of practice outweighs the potential health detriment. Guidance on the application and administration of these regulations includes a list of existing classes or types of practices in the UK. 13 May 2000 was the transposition deadline for the 1996 Basic Safety Standards Directive, some elements of which were implemented by the coming into force of the JoPPIIR 2004. Activities which are the subject of these Regulations can only be considered 'existing' if they are included within a class or type of practice detailed in this guidance list or if there is evidence to show they were in existence prior to 13 May 2000. 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.

5.2. AUTHORIZATION OF NUCLEAR POWER PLANTS

Fifteen power reactors (14 advanced gas-cooled reactors, or AGR, and one pressurized water reactors), located at eight sites, are operated in the UK. Two EPR power reactors are currently under construction at the Hinkley Point site. The authorization process related to nuclear power plants is similar to other nuclear facilities and is described in sub-chapter 5.1.

The ONR and the EA have developed the Generic Design Assessment (GDA) process, for new reactors. This joint process is undertaken by both the ONR and EA and aim at involving regulators with nuclear reactor design companies at the earliest stage and where they can have the most influence. During the GDA process, environmental, safety and security aspects of reactor designs are assessed before the construction of a nuclear reactor starts. The GDA process is open and transparent. Reports are published at the end of each process step allowing anyone to view the detailed design information and have the opportunity to comment via the GDA comments process. Guidance about the GDA process for requesting parties has been issued by both ONR and EA (ONR-GDA-GD-001 and the EA Process and Information Document). At the end of the GDA process, providing that the ONR is fully satisfied with the generic safety and security aspects, a Design Acceptance Confirmation (DAC) is issued. If the EA is fully satisfied with the generic environmental and radioactive waste management aspects, a Statement of Design Acceptability (SoDA) is also issued. However, such confirmations do not guarantee that ONR or EA will automatically authorize the construction and operation of the nuclear power reactor at a specific site. NRW also participates in GDA where new designs are proposed or likely to be proposed for use in Wales.

The licence for a nuclear power plant is granted for an indefinite period and, in principle, can cover the entire life-cycle of the site from construction and commissioning through operation and decommissioning. In practice, as stated above, a licence modification (called a variation) may be required to reduce the area of the licensed site or to add or remove license conditions. Moreover, as part of the licensing processing, ONR considers the adequacy of the arrangements in place to meet the requirements of the LCs and can approve all or parts of these arrangements, ensuring that licensees cannot deviate from agreed programs without further ONR written approval. ONR may apply regulatory control by specifying hold-points (i.e., before a NPP enters a care and maintenance stage or between decommissioning stages).

Design modifications of existing nuclear power plants may require authorization from the ONR before being implemented and commissioned, depending on their safety significance and following a graded approach, as described in sub-chapter 5.1.

Pursuant to the Standard Licence Condition 15, licensees shall implement adequate arrangements for periodic and systematic review of the safety of their facilities. Periodic safety assessments are performed every 10 years and their results are assessed by the ONR. The Technical Assessment Guide NS-TAST-GD-050 provides guidance to assist the ONR Inspectors in judging the adequacy of PSR. Nuclear power plants licensees implement aging management programs that are reviewed by the ONR. Moreover, an ENSREG Topical Peer Review on aging management was performed in 2017.

5.3. AUTHORIZATION OF FUEL CYCLE FACILITIES

The following Fuel Cycle Facilities (FCFs) are located in the UK:

- The Springfields Fuel Fabrication Plant;
- The Capenhurst Enrichment Facility;
- The Dounreay Nuclear Site;
- Sellafield.

The authorization process related to FCFs, for both front-end and back-end FCFs, is similar to other nuclear facilities and is described in sub-chapter 5.1. The licensing procedures for the FCFs are carried out in accordance with the NIA65. The responsibility for subsequent licensing rests with the ONR and the relevant environment agency.

5.4. AUTHORIZATION OF RADIOACTIVE WASTE MANAGEMENT FACILITIES

The authorization process of radioactive waste (RAW) management facilities at nuclear and non-nuclear sites is no different from the generic process. It involves planning permission issued by the UK government or local government determining if the development is an appropriate use of the land; and the relevant environment agency, and the ONR for nuclear facilities, provide pre-application advice to the applicant to identify the expectations of the regulatory bodies with respect to the authorization process. Applicants are guided through the application and permitting process. Following the pre-application advice applicants submit a license application to the ONR (for nuclear licensed site only) and a permit application to the relevant environment agency (for both nuclear and non-nuclear licensed sites). Once the relevant authorizations/license are granted, the ONR and the relevant environment agency further regulate the site in accordance with the license and authorization conditions and related regulatory guidance. The licensee has to follow license conditions until the decommissioning phase, requests the ONR for respective approvals. Once the site is decommissioned the licensee requests the ONR for de-licensing and EAs for surrender of permit. ONR's license conditions do not address the closure of a disposal facility and may be considered as safety significant modifications.

For existing disposal facilities, ONR for nuclear facilities, HSE for non-nuclear facilities and the relevant environment agency are the responsible regulators until the facility is closed and de-licensed. Then, the relevant environment agency has the regulatory responsibilities for the post-closure stage. After closure of the disposal facility and any period of active institutional control (up to 300 years), the authorization holder applies to the relevant environment agency to cance lthe permit.

The IRRS team was informed that plans for construction of a geological disposal facility (GDF) are only relevant in England and Wales. No site has yet been identified and the developer is currently seeking volunteer host communities for a potential location. Once a location is selected, the relevant environment agency is expected to authorise the development, operation and closure of the GDF from an environmental legislation perspective. At the same time, a GDF will be subject to the requirements of the NIA65 and will require a licence from the ONR. The NIA65 defines the framework of regulatory activities performed by the ONR, but the Nuclear Installation

Regulation 1971 specifies this framework prescribing 8 types of nuclear installations which are regulated by the ONR. This list, however, does not consider any kind of disposal facilities.

On non-nuclear licensed sites, the relevant environment agency (England, Scotland, Wales or Northern Ireland) is responsible for the regulation of RAW management, including disposal. Operators of these facilities and organizations that generate RAW are subject to authorization by the relevant environment agency.

5.5. AUTHORIZATION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

Employers (operators) intending to work with ionizing radiation on a nuclear site must notify, register or obtain consent from ONR under the IRR17 if the work is not already addressed by a licensable activity under the NIA65. The employers must seek consent via ONR's graded process and application forms. On receipt of the application ONR will review the licensee's compliance history regarding control of contractors working on the licensee's site in conjunction with the details of the work to be undertaken. If there is an adverse trend ONR will consider performing an inspection on the licensee's arrangements and their implementation. ONR is in regular contact with the licensees to ensure that contractors who are deemed to undertake a practice defined under IRR17 on their premises have the appropriate certification. The ONR process is documented in working level guidance documents which are now currently captured in ONR's management system.

The HSE and the HSENI are responsible for the authorization provisions of the IRR17 and the IRRNI17 for radiation sources in non-nuclear facilities and activities. The requirements for authorization are identical in both sets of regulations.

The HSE and HSENI's authorization system, in accordance with a graded approach, regulates work with radiation according to radiological risk with low risk activities requiring notification to HSE or HSENI, higher risk activities requiring registration and the highest risk, consent. Thus, IRR17 and IRRNI17 require all employers who wish to commence work with ionizing radiations to notify or register with or gain consent from HSE or HSENI.

Notification is required for work with small quantities of radioactive material below thresholds specified in the IRR17/IRRNI17.

Registration is required for work with radiation generators and work with radionuclides above certain thresholds.

Consent is required for the deliberate administration of radioactive substances to persons and animals, the exploitation and closure of uranium mines, the deliberate addition of radioactive substances in the production or manufacture of consumer products or other products; the operation of accelerators, industrial radiography, industrial irradiation ; any practice involving a high-activity sealed source; the operation, decommissioning or closure of any facility for the long-term storage or disposal of radioactive waste and practices discharging significant amounts of radioactive material into the environment.

Employers seeking to notify, register or gain consent from HSE or HSENI use on-line application systems. The processes of assessment and the granting of registration or consent are identical in HSE and HSENI. HSE and HSENI have produced guidance for employers on how to notify, register or gain consent.

Applicants are required to submit information including the nature of their work with ionizing radiation, details of the number of employees engaged in this work and the number of sites at which they carry out this work. Applicants for registration and consent are asked to confirm that they comply with the requirements of the IRR17/IRRNI17, with a more detailed question set applying to consents, commensurate to the risk. Registration and consent certificates are subsequently issued automatically by the HSE and HSENI on-line system, provided the applicant has provided the required information, confirmed their compliance with the IRR17/IRRNI17 and paid a fee of £25 (but there is no fee to be paid in Northern Ireland). Both HSE and HSENI apply the same conditions to registrations and consents.

The information required from applicants and the affirmative answers to the questions they are asked to give HSE/HSENI sufficient surety that a registration or consent should be granted. HSE/HSENI considers that the information and confirmations given by the applicants is sufficient to demonstrate safety. Regardless of the regulatory process followed, applicants are never required to submit a safety assessment to the regulatory body. Thus, safety assessments are not submitted and subsequently assessed by the regulatory body prior to the granting of the authorization.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Under IRR17 and IRRNI17, employers who intend to work with ionizing radiations must either notify, register or gain consent from the competent regulatory body. When a consent from the regulatory body is required (i.e., an authorization), safety assessments are not required to be submitted to and subsequently assessed by the regulatory body prior to the granting of the authorization.*	
(1)	***BASIS: GSR Part 1 Requirement 24 states that*** *"Prior to the granting of an authorization, the applicant shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body in accordance with clearly specified procedures. The extent of the regulatory control applied shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach".*
(2)	***BASIS: GSR Part 3, Para 3.29 states that*** *"the regulatory body shall establish requirements for persons or organizations responsible for facilities and activities that give rise to radiation risks to conduct an appropriate safety assessment 28. Prior to the granting of an authorization, the responsible person or organization shall be required to submit a safety assessment, which shall be reviewed and assessed by the regulatory body".*
(3)	***BASIS: GSR Part 1 Requirement 24, para. 4.31 states that*** *"In the granting of an authorization for a facility or an activity, the regulatory body may have to impose limits, conditions and controls on the authorized party's subsequent activities".*
R11	**Recommendation: The ONR, HSE and HSENI should request the applicants seeking authorization for the safety significant activities and facilities to submit a safety assessment in accordance with IRR17, which should be reviewed before granting the authorization. When deemed necessary, the ONR, HSE and HSENI should be able to impose limits, conditions and controls on the authorized party's subsequent activities.**

Information on authorizations, including certificates granted, is kept on secure databases held by HSE (BSSD database) and HSENI (Case Management System – CMS) respectively. There are also a number of formal Memoranda of Understanding and Working Level Agreements to ensure the flow of information and cooperation between HSE/HSENI and other relevant government agencies, departments and administrations.

Registrations and consents have no expiry or end dates, and therefore employers do not need to apply for renewal of their authorizations. However, they must inform HSE/HSENI if there are any changes to the information supplied or they cease the activity for which they were granted a registration or consent.

ONR, HSE and HSENI have the power to revoke registrations or consents when they consider it appropriate. Both HSE and HSENI have an appeal procedure in case a registration or consent is revoked. However, no appeal procedures exist for those who have failed to gain a registration or consent as ONR, HSE and HSENI never reject applications. Thus, the implementation of measures to address this recommendation should include provisions to establish a process allowing authorized parties to appeal against a regulatory decision relating to an authorization for a facility or an activity.

The regulations EPR16, EASR18 and RSA93 provide legal mandates to EA, NRW, SEPA and NIEA to issue permits for radioactive substances activities for the protection of public exposure and protection of the environment as a result of the keeping and use of radioactive substances, and the disposal or discharge of radioactive substances activities.

All the relevant environment agencies use standard application forms and authorization templates which apply to different types of radioactive substances activities and whether nuclear or non-nuclear facility. The relevant environment agencies publish guidance, application forms, etc. via their respective websites.

Authorizations issued by the relevant environment agency are not normally time limited. However, the ability to use tailored conditions can be used at various stages of a facility's lifetime, such as design and construction or in the latter stages on decommissioning. Regulations also allow periodic review such that changes throughout the lifetime of the facility can be addressed as necessary. The relevant regulations also provide the mechanisms for surrendering permits, either partially or fully.

5.6. AUTHORIZATION OF DECOMMISSIONING ACTIVITIES

In the UK, the decommissioning of nuclear facilities is subject to the same legislative requirements and regulatory expectations that apply to the other phases of a nuclear facility's lifecycle (see sub-chapter 5.1). Thus, nuclear facilities under decommissioning are regulated by the ONR and the licence conditions of a nuclear site require licensees to have arrangements for the decommissioning of any plant or process that may affect safety and to have a decommissioning plan. The relevant environment agency is a consultee to the ONR on the assessment of operator's environmental impact assessment. The relevant environment agency is also a consultee during the de-licensing process. The environment agencies have developed joint guidance on requirements for release from radioactive substances regulation that set out the standards that a nuclear site must meet to enable it to be released from Radioactive Substance Regulation.

The decommissioning of non-nuclear facilities is regulated by HSE, HSENI and the relevant environment agency (see sub-chapter 5.5).

5.7. AUTHORIZATION OF TRANSPORT

The Competent Authority (CA) for civil transport of Class 7 (radioactive material) dangerous goods varies within the UK dependent on mode and region, and the following are the relevant competent authorities:

- ONR – by road, rail and inland waterways in Great Britain (although in practice inland waterway is not used);
- NIEA– by road in Northern Ireland;
- HSENI – by rail and inland waterway in Northern Ireland (although in practice this is not used);
- The Secretary of State for Transport delivered through the Maritime and Coastguard Agency (MCA) – for British registered ships and all other ships whilst in United Kingdom territorial waters;
- Civil Aviation Authority (CAA) – by air.

The regulations governing transport apply a graded approach and the aspects of radioactive materials transport involving the higher hazards are regulated by a permissioning regime in which certain designs and activities require prior CA approval. As well as being the CA for inland transport in GB, ONR also provides advice to and, for this permissioning regime (involving approval of designs and activities), acts on behalf of the other civilian UK CAs and agencies mentioned above (with the exception of HSE-NI). This arrangement is formalised through Agency Agreements (legal documents used to transfer statutory responsibilities between bodies) as set out in the Energy Act. For transport, there is no Agency Agreement between ONR and HSE-NI, the reason being that in practice, radioactive material is not transported by rail and inland waterway in Northern Ireland. Therefore, ONR issue all necessary approval or validation certificates as appropriate for civil carriage of Class 7 dangerous goods.

Compliance is required in the UK with all the approvals required by the IAEA safety standard SSR-6, which are included in the Modal Regulations in force for each mode of transport (ADR, RID, IMDG code and the ICAO Technical Instructions for road, rail, sea and air respectively).

Issuing Approvals and Validations

Organisations apply to ONR for CA approval for new designs, renewal of existing approvals, validation of overseas approvals or modifications to approved designs. Guidance for applicants is given in the 'Applicant's Guide' TRA-PER-GD-014.

All requirements from IAEA's SSR-6 are directly captured; however, the requirements for radiation protection programme for special use vessels is not included in the modal texts for road, rail and air as it only applies to sea. In

IMDG for sea, radiation protection programme for special use vessels is grouped under paragraph ‘Certain Shipments’.

For a design or shipment which requires CA approval and originates in the UK, ONR assess the application and if satisfied issue an approval and produce a proportionate justification detailing the basis for the decision to grant the approval (e.g. Project Assessment Report (PAR)). The guide also includes further details of the assessment process.

For a design or shipment which requires CA approval and originates outside the UK, ONR will assess the application and if satisfied issue an approval or validation where multilateral approval is required or unilateral approval is required but the design originates outside a country Contracting Party to ADR and RID.

The requirements for what information must be included in an approval document are captured in the modal regulations e.g. ADR, RID etc. ONR have incorporated the information mandated by SSR-6 (and the modal regulations) into the process for preparation of approvals (TRA-PER-GD-009).

Designs requiring only unilateral approval (e.g. B(U) package design) and originating outside the UK that have been approved by the CA of a country Contracting Party to ADR and RID are permitted to be transported in the UK without the need for further approval for use in the UK.

Designs requiring only unilateral approval but originating outside a country Contracting Party to ADR and RID require further endorsement or approval by the CA of an ADR/RID Contracting Party. ONR may validate these by countersigning the original certificate, following a proportionate degree of assessment.

Multilateral approval is required for certain designs and shipments (e.g., B(U)F or B(M)), especially those of higher radiological hazard and for all fissile materials. The first approval is by the CA of the country of origin and then subsequent approvals are issued by the CAs of the countries through or into which the shipment is made. For designs or shipments originating outside the UK that require multilateral approval, approvals may be granted by ONR for use in the UK either by a new certificate of approval (CoA) or by the validation of the original CoA if no additional controls or restrictions are to be applied.

There are legal requirements for the CA to be informed of serial numbers of certain prescribed transport packaging in line with SSR-6. This requirement is implemented in the UK (6.4.23.19 of ADR, RID and IMDG and Part 6 Chapter 7.23.1 of ICAO Technical Instructions). Through the previously mentioned Agency Agreements with the other CAs, ONR assumes responsibility for receiving notification of packaging serial numbers. An action had been raised to review the current register of serial numbers which have a valid package design approval and the team noted that this was now complete.

5.8. AUTHORIZATION ISSUES FOR OCCUPATIONAL EXPOSURE

The HSE and HSENI for non-nuclear activities and ONR for nuclear facilities and civil transport in GB are responsible under regulation IRR17 and IRRNI17 to authorize practices related to occupational exposure. The IRRS team was informed that data from the HSE and HSENI database of authorized practices is available to other regulatory bodies upon request.

The application procedure for any type of authorization does not require the applicant to submit any documentation or to disclose any information about the safety assessment for protection of workers. There is no review and assessment conducted prior to issuing authorization by HSE and HSENI in relation to protection of workers, Assessment is not done in relation to special arrangements and workplaces affected with radon or NORM materials. This issue has been addressed in Recommendation R11 in sub-chapter 5.5.

Only approved dosimetry services may operate and are authorized by the HSE. Their approval is valid indefinitely, while their measurement results are conforming the requirements of being in certain bands of uncertainty. Their authorization process for dosimetry services is based on a verification of compliance with the requirements as established in the relevant guidelines (see sub-chapter 9.9).

Giving proper instructions for work and the training are to be provided by the employers or external services that do not require approval from the regulatory body. The radiation protection supervisors may receive training from

service providers which are not approved by any regulatory bodies. This has a potential impact on the safety of workers, as it is up to the discretion of the service provider to decide what information it includes in its curricula.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Providing training and proper instructions for work are required to be provided by the employers or external services and does not need approval from the regulatory body. The radiation protection supervisors may receive training from service providers which are not approved by any regulatory body.*	
(1)	***BASIS: GSG-7, para. 3.156 states that*** *"It may be appropriate and convenient for the regulatory body to recognize certain training centres and courses for their quality and suitability. Such recognition can be formally conferred by the process of accreditation".*
S6	**Suggestion: The HSE should consider setting up appropriate mechanisms for either the formal recognition or accreditation of training and educational service providers.**

HSE has the responsibility to approve individual dosimetry service providers, whereas the services offering calibration of radiological instruments may be recognized by the United Kingdom Accreditation Service (UKAS) based on the appropriate standards applicable for calibration laboratories. According to IRR17 and IRRNI17, along with the approved code of practice guideline, the regulation gives the duty to employ a suitably qualified person to perform calibrations of instruments. This devolves the responsibility of judging the appropriate services for calibration to the employers, while the regulatory body should retain the right to approve and recognize such services.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *According to the approved code of practice guideline for IRR17, the regulation gives the opportunity to employ a suitably qualified person to perform calibrations of instruments. This devolves the responsibility of employing the appropriate services for calibration to the employers, while the regulatory body should retain the right to approve and recognise such services.*	
(1)	***BASIS: GSR Part 3 Requirement 20, para. 3.73 (c) states that*** "*The regulatory body shall be responsible, as appropriate, for: …* *(c) Authorization or approval of service providers for individual monitoring and calibration services …"*
(2)	***BASIS: GSG-7 8.1 states that*** "*Any technical service providers for protection and safety should be qualified by certain procedures. The services provided by technical service providers can be divided into two categories: …* *(b)Calibration and testing and assay services, including:* *(i) Monitoring services, including individual monitoring, workplace monitoring and environmental monitoring;* *(ii) Calibration and calibration verification services for monitoring devices and radiation sources."*
S7	**Suggestion: The HSE should consider providing, in addition to the UKAS, approval to certain calibration services or individuals.**

5.9. AUTHORIZATION ISSUES FOR MEDICAL EXPOSURE

Authorization for the administration of radioactive substances to individuals as part of medical exposures is addressed in IR(ME)R17 in Great Britain and in IR(ME)R18 in Northern Ireland. Both IR(ME)R17 and

IR(ME)R18 require licensing of employers and practitioners responsible for the administration of radioactive materials to individuals for diagnosis, treatment or research. The IRRS team was informed that this also includes the use of “afterloading” devices for brachytherapy treatment. Employers’ licenses are specific to the site or facility where the administration of radioactive substances will take place. The regulations IR(ME)R17 and IR(ME)R18 do not require authorization for other types of medical applications, e.g. plain radiography, computed tomography, interventional radiology or linear accelerators for external beam radiotherapy. The regulatory bodies for medical exposures rely on HSE and HSENI authorization process for information about these sources. However, the HSE and HSENI do not maintain a register of sealed radioactive sources or radiation generators. Recommendation R7 in sub-chapter 3.7 address these matters.

For practitioners in Great Britain, the licensing authority is the Secretary of State; in Northern Ireland, it is the Department of Health for Northern Ireland. Only one license is required regardless of where the practitioner is working as authorized party.

For employers, the licensing authority for England is the Secretary of State; in Scotland, it is the Scottish Ministers; in Wales, it is the Welsh Ministers; and in Northern Ireland it is the Department of Health. Employers’ licenses are specific to each medical radiological installation.

Operational aspects of licensing are carried out by Public Health England (PHE) on behalf of the licensing authorities, advised where appropriate by the Administration of Radioactive Substances Advisory Committee (ARSAC). ARSAC is an independent expert committee sponsored by the Department of Health and Social Care. ARSAC advises the licensing authorities on the granting, amendment and renewal of licenses required under IR(ME)R. ARSAC members are volunteers and are experts in nuclear medicine, medical physics and radio-pharmacy and are appointed through a formal process. Application forms for practitioner and employer licenses are available on the ARSAC website. An indicative list of information to be included with license applications is included in IR(ME)R. Specific guidance for licensee applicants is included in the ARSAC Notes for Guidance. PHE collects the scientific advice regarding the assessment of the applications from the ARSAC members and use it to make a recommendation to the licensing authority whether the license should be granted. If approved, PHE issues the license on behalf of the licensing authority. PHE maintains records of all application decisions by ARSAC. However, information about granted licenses are only shared with the enforcing authorities if they specifically request it. Licenses are issued for five years and may be subject to conditions. The Licensing Authority may vary or revoke licenses at any time if necessary.

While *JoPIIRR* 2004 covers the justification of practices involving ionizing radiation IR(ME)R17 and IR(ME)R18 cover all aspects of justification or exposures on an individual level. IR(ME)R17 and IR(ME)R18 further require that the employer establishes referral guidelines for medical exposures.

IR(ME)R17 and IR(ME)R18 include requirements that employers and medical practitioners ensure that protection and safety is optimized for each medical exposure. This includes requirements on the employer to regularly review and make available diagnostic reference levels (DRLs) and requirements on the employer to establish a framework of general procedures, protocols and quality assurance programmes. IR(ME)R17 and IR(ME)R18 also require the employer to establish dose constraints for volunteers participating in biomedical research and for carers and comforters. In the “Guidance to the Ionising Radiation (Medical Exposure) Regulations" it is stated that dose constraint of 5 mSv, for carers and comforters, can be considered appropriate for most circumstances.

IR(ME)R18 and IR(ME)R17 prohibit a practitioner or authorized party from carrying out a medical exposure without having been adequately trained and requires the employer’s procedures to include provision for clinical audit to be carried out. The regulations also set out the duties of the employer in relation to accidental or unintended medical exposures.

IR(ME)R17 also sets out requirements for records of all relevant training to carry out any exposures, records of accidental or unintended exposures; and also requires that equipment used for interventional radiology and computed tomography that was installed on or after 6 February 2018 be able to transfer information relating to relevant parameters for assessing the dose to the record of a person’s exposure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The IR(ME)R does not require authorization for other sources than for the administration of radioactive substances to individuals as part of medical exposures. Hence, the use of medical applications, such as plain radiography; computed tomography; interventional radiology; or linear accelerators for external beam radiotherapy, for medical purposes (diagnosis and treatment) is not subject to an authorization process in relation to medical exposure.*	
(1)	***BASIS: SSG-46, para. 2.71 states that*** *"Regulatory bodies should consider which form of authorization is appropriate for a given type of medical radiation facility. Coupled with the type of authorization is the level of complexity of the documentation that should be submitted to the regulatory body prior to the authorization*".
(2)	***BASIS: SSG-46, para. 2.72 states that*** *"Medical radiation facilities are, in principle, better candidates for individualized licensing than for registration. It would be expected that licensing would be used for radiation therapy facilities, nuclear medicine facilities, facilities performing image guided interventional procedures and for most diagnostic radiology facilities. For some simple forms of diagnostic radiology, such as dental radiography (without CBCT) and DXA, authorization through registration may be acceptable".*
S8	**Suggestion: The UK Government should consider establishing a licensing regime for radiation therapy facilities, facilities performing image guided interventional procedures and diagnostic radiology facilities with regards to medical exposures.**

5.10. AUTHORIZATION ISSUES FOR PUBLIC EXPOSURE

Authorization to providers of consumer products

The HSE and the Office for Product Safety and Standards (OPSS) are involved in the regulation of "consumer products". HSE/HSENI is responsible for issuing "Consents" for deliberate addition of radioactive substances in the production or manufacture of consumer products and other products under the provisions of IRR17 and IRRNI17. Such deliberate addition of radioactive substances in the production or manufacture of consumer products requires justification under the JoPIIRR 2004.

For products to be placed on the market in the UK they must meet the safety requirements of the General Product Safety Regulations 2005 (GPSR 2005). The regulation of consumer products under the GPSR 2005 is the responsibility of the OPSS, which is a department within BEIS.

The regulation of consumer products is not reflected in the draft "Framework for Radiation Protection and Nuclear Safety".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The regulatory framework related to "Consumer Products" is not reflected in the draft document "Framework for Radiation Protection and Nuclear Safety". Also, there is no sufficient guidance available pertaining to "Consumer Products" regulation.*	
(1)	***BASIS: GSR Part 3, Requirement 29 para 3.118 states that*** *"The government or the regulatory body shall establish the responsibilities of registrants and licensees, of suppliers, and of providers of consumer products in relation to the application of requirements for public exposure in planned exposure situations".*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
S9	**Suggestion: The UK Government should consider including information on the regulation of "Consumer Products" in its draft "Framework for Radiation Protection and Nuclear Safety". In addition to that, the OPSS and the HSE should consider developing further guidance pertaining to "Consumer Products" regulations.**

Remediation of Land

Remediation of land notice is served to the "appropriate person" for remediation of land declared as Radioactive Contaminated Land (RCL). RCL is a type of special site under EPA90, to which in order to be designated as a special site, the land must have become contaminated as a result of an emergency, which has been declared ended, a past practice or a past work activity. The Radioactive Contaminated Land Statutory Guidance for England, Wales and Scotland provides a comprehensive explanation of how existing exposure situations arising from contaminated land are identified and designated as well as identifying the relevant authority responsible for designating the land as RCL and remediating the land. To date, no land has ever been designated as such in the UK, as there is usually a preference for voluntary remedial action.

Radioactive Contaminated Land (Enabling Powers) (England) Regulations 2005 and the Radioactive Contaminated Land (Modification of Enactments) (England) Regulations 2006, the Radioactive Contaminated Land (Scotland) Regulations 2007; the Radioactive Contaminated Land (Modification of Enactments) (Wales) Regulations 2006 and the Radioactive Contaminated Land Regulations (Northern Ireland) 2006, along with their amendments provide the necessary regulatory framework in the context of remediation.

Radioactive waste discharges and disposals

The Environment Agencies (England, Scotland, Wales and Northern Ireland) regulate radioactive disposals, i.e., the discharge of solid, gaseous and aqueous radioactive wastes on and from nuclear facilities and non-nuclear facilities by way of issuances of permits/authorizations. These permits/authorizations are valid until there is a possible change in the limits and conditions of the permit. The driving factors for changes in the limits and conditions of the permit are policy, environmental impact, guidance/procedure, process (e.g., site operations change), and technology (e.g., changes in Best Available Techniques (BAT) or Best Practicable Means).

5.11. SUMMARY

The UK regulatory framework for the authorization system for nuclear and non-nuclear facilities and activities is established under the provisions of the NIA65, EPR16, EASR18, RSA93, IRR17, IRRNI17, IR(ME)R and involve several regulatory bodies. This legal framework is well developed and implemented and includes consideration of a graded approach. It is, in general, in line with IAEA safety standards.

However, areas for improvement in the authorization process were identified and include:

- the public engagement in ONR regulatory decision-making process, e.g., during the licensing process for nuclear facilities (addressed in sub-chapter 3.8);
- the regulatory framework related to the authorization of the geological disposal facility (addressed in sub-chapter 1.7);
- the implementation of the authorization provisions of the IRR17 and the IRRNI17, which deal with occupational exposures and public exposures from work activities other than from authorised discharges and disposals of radioactive waste (submittals and reviews of safety assessments, limits, conditions and controls on the authorized party's subsequent activities and appeal process);
- the mechanisms for the formal recognition or accreditation of training and educational service providers;
- the approval of suitably qualified people or services to perform calibration activities;

- the licensing procedure for radiation therapy facilities, facilities performing image guided interventional procedures and diagnostic radiology facilities; and
- the regulatory provisions related to consumer products containing radioactive materials.

6. REVIEW AND ASSESSMENT

6.1. GENERIC ISSUES

This paragraph will only discuss the nuclear activities of the ONR and the three environment agencies (EA, SEPA and NRW). The generic issues related to the non-nuclear activities are dealt with in the sub-chapters of 6.2.

6.1.1. MANAGEMENT OF REVIEW AND ASSESSMENT

ONR regulates the design, construction and operation of any nuclear installation for which a nuclear site licence is required under the Nuclear Installations Act (NIA65). Review and assessment of information is an integral part of ONR's determination of whether a licensee complies with its legal requirements and regulatory expectations. Most of ONR's permissioning decisions are based on the safety-case prepared by the operator. The process is guided by ONR's Safety Assessment Principles (SAPs) and Technical Assessment Guidelines (TAGs), which are publicly available. The SAPs and TAGs reference relevant good practice, for instance IAEA standards, WENRA reference levels, licensees' own standards and criteria, engineering codes; international regulatory practice; learning from other relevant high hazard industries. ONR publishes the basis and outcome of permissioning decisions on its website.

The SAPs and TAGs are used for review and assessment activities such as, Generic Design Assessment of new reactors, site-licence, commissioning, operation, modifications, and start up after refuelling and periodic safety reviews (PSR). Licences do not have an expiry date. After each PSR, the licensee must be able to demonstrate that, with the implementation of any identified modifications, risks are reduced to a level that is as low as reasonably practicable until the next PSR.

A graded approach is incorporated in the ONR regulatory framework through several mechanisms, such as:

- Grading of operators' arrangements for modifications, safety case documentation, operating rules etc.
- The SAPs define expectations for the categorisation of safety functions and the classification of SSCs. The most significant safety functions and SSCs require higher levels of substantiation and evidence to be available, and also attract greater regulatory attention.
- Numerical targets to aid judgements on whether radiological hazards are adequately controlled, and the risk is reduced to as low as is reasonably practicable (ALARP). The nine numerical targets defined in the SAPs introduce the concept of Basic Safety Objectives (BSOs) and Basic Safety Levels (BSLs). If the level of risk is below the BSO, it is recognized that further consideration of the safety case would not be reasonable.

The consolidated recommendation to inform the management decision, taking into account the judgements from all the disciplines engaged (as well as other factors), is summarised in either a Project Assessment Report (PAR) or a Decision Record. These are informed by and reference supporting Assessment Reports. These documents justify the recommended regulatory decision and the basis for the recommendation. As part of ONR's approval process, assessment reports are also subject to a "peer review". The peer review includes consideration of whether appropriate codes and standards have been applied. The assessment report is also subject to an "acceptance review" by the relevant professional lead. For its decisions ONR, as a standard procedure, will consult other authorities, notably the environment agencies.

The IRRS team has reviewed in some detail the ONR's review and assessment approaches in the areas of PSR, site-licensing, modifications and start-up after refuelling. In addition, the team has looked at ONR's handling of ageing-related challenges. One is related to the cracking of graphite at some of the reactors of the AGR-fleet. This safety case is currently one of the most challenging ones for ONR, because of the high uncertainties in the modelling of graphite performance (cracking) relevant to the delivery of its required safety functions. For these reactors this may lead to significant reduction of the remaining lifetime. To deal with this uncertainty and lack of information, ONR has required sufficient safety margin with a high degree of certainty for the restart of the reactor. ONR is working with universities to build knowledge of graphite behaviour and performance. Another challenge with ageing for some of AGRs relates to the boilers. Given the issues with ageing ONR has concluded that a more proactive approach is needed and initiated a series of ageing management inspections to inform its assessment of the AGR

Periodic Safety Review submissions provided by the licensee. Also, it requires a more proactive approach from the licensee.

For the nuclear sites the disposal including discharge of radioactive waste are regulated by the environment agencies EA, SEPA and NRW under the EPR 16, and EASR18. The regulators use a graded approach to permitting and setting conditions through the consideration of the scale of the operation, the hazards present and the level of risks involved. There are several stages where review and assessment is required: during the application for an authorisation, during periodic audits, when proposing modifications which may lead to a variation of the authorisation, and during decommissioning. Applicants must also demonstrate that they apply proportionate controls to their radioactive substances activities through optimisation and the use of best available techniques which are verified by the environmental regulator. Consideration is also given to other relevant information such as government guidance and policies, past waste disposal data, previous inspection findings, and environmental data, before granting an authorisation. Consultations with certain organizations and the public are also carried out. Responses from these consultees are reviewed as part of the application determination. The environment agencies may also carry out pre-authorisation inspections of the facilities and activities to ensure that they are ready to comply with regulatory requirements.

The EA's permitting decisions are recorded in decision documents and technical trails as per EA permitting Operating Instructions. Discharge limits are set at the minimum necessary to permit the normal operation including any operational fluctuations that are expected to occur over the lifetime of the facility. For example, this might take account of the potential for fuel failure for a nuclear power plant. EA's guidance on the Environmental Principles provides a standard framework for underpinning the technical assessments and decisions.

All sites that dispose of radioactive waste are required to provide regular reports of discharges and disposals including an annual summary of their disposals using the EA's Pollution Inventory Electronic Data Capture system. Reviewing pollution inventory data allows the EA to identify anomalies and trends in the data submitted, using previous years' data to facilitate this.

6.1.2. ORGANIZATION AND TECHNICAL RESOURCES FOR REVIEW AND ASSESSMENT

ONR employs about 400 technical staff, of which about 300 perform review and assessment activities. ONR organises its specialist assessment staff into fifteen specialisms, e.g. Mechanical Engineering, Structural Integrity, Civil Engineering/External Hazards, Cyber Security and Safeguards. Financial security of decommissioning for instance is a matter for the NDA. Each specialism is overseen by a Professional Lead, with responsibility for setting the strategy and standards within each group.

Review and assessment to support permissioning decisions are typically undertaken by warranted inspectors. To be recruited into ONR as an inspector, the individual concerned would need to demonstrate:

- Analytical skills derived from a sound education and training in relevant science or technical subject, plus experience of application of those skills in practice
- An understanding of the application of discipline-specific technological knowledge and subject skill in the nuclear sector.
- Technical knowledge and experience of its application in a nuclear industrial context to the extent necessary to have obvious credibility when interacting with a wide range of nuclear stakeholders.
- Understanding of nuclear and radiological hazards and appreciation of the way in which safety functional requirements of structures systems and components are derived for their control.

ONR provide in-house regulatory and legal courses, plus on-the-job and discipline specific training. This is described more in Chapter 3. Key competencies include understanding of safety cases and their implementation, and sound regulatory decision-making ability.

ONR has no TSO, but a framework of technical support contractors, is used if a certain competence is not available in-house or if there is a temporary need for more capacity. External technical support is also utilised to support independence in decisions related to graphite degradation in the AGRs. To inform ONR about international practices and developments, it cooperates in various forums such as MDEP, dealing for instance with encouraging

multinational convergence of codes, standards and safety goals in the area of new reactor regulation, the SMR regulators forum and exchanges with ASN (PWR-technology). Because of their unique design, the opportunities for international exchange on technology- specific aspects of the AGRs is limited. ONR's Chief Nuclear Inspector has an advisory body but does not use it for regulatory decision making. ONR has the policy not to develop their own computer tools, but to have in house staff that have experience with those tools, that are able to specify and judge work from contractors.

The EA has around 75 staff for its nuclear activities and has an SLA with NRW to carry out specific technical work related to nuclear activities on NRW's behalf at nuclear sites in Wales.

EA has dedicated teams for nuclear waste assessment and radiological monitoring and assessment, and a number of subject matter groups that will assure maintaining the competence, for instance by participation in several international conferences, committees and fora such as NEA (CRPPH, RWMC, CDLM), IAEA (RASSC, WASSC) and WENRA. Where appropriate, information is disseminated to the NRW and SEPA. SEPA experts participate in some of the EA subject matter groups. SEPA and EA cooperate in both EdF and NDA sites regulators' groups. Cooperation with ONR is well established through MoUs and underlying guidance. EA and SEPA use some tools related to assessments like IRAT-2 (initial radiological assessment tool) and PC-CREAM (dispersion models developed by Public Health England). Some technical support is also sought from different organizations like Public Health England, Universities.

EA appoints its staff according to competence standards and requirements derived from a systematic training needs analysis and a formal staff development / refresher programme. In accordance with EA Workforce Planning guidance succession plans exist for key radioactive substances regulation staff. The EA's succession planning builds capability, ensures knowledge transfer, supports the retention of talented people and skills, provides business continuity and reduces business risk by planning for turnover / skills loss. An EA Guide describes its arrangements for developing 'fully capable' nuclear and non-nuclear regulators. It also sets out how regulators can be accredited as Radioactive Waste Compliance Advisers (RWCA). It is expected that all EA staff involved in radioactive substances regulation will complete the requirements for 'fully capable regulator' and achieve RWCA status within 3 years of appointment. All staff who have achieved RWCA status are expected to carry out continuing professional development (CPD), and retain evidence, sufficient to ensure that renewal of RWCA certification can be achieved on a rolling 5-yearly basis. EA has developed a Resource Strategy.

The SEPA Radioactive Substances unit now has 27 positions based on an analysis in 2018 to determine its future resources needs. Several recruitment campaigns have had limited results. Currently out of the 27 posts 9.5 are vacant (35%). SEPA management has agreed to temporarily reduce the activities, according to a graded approach. SEPA has now started considering external support. Since recruitment is difficult and will probably not deliver sufficiently qualified staff soon, the IRRS team considers the efforts to get external support as very important. The SEPA action plan contains further actions such as developing a Human Resources Plan and an investigation of the factors affecting the ability to recruit people. The self-assessment by SEPA-RS has also concluded that the competency framework existing at SEPA, does not cover SEPA-RS. It also concluded that a related training programme has to be developed. A SEPA-RS competency matrix has already been developed as part of this activity. Further work is required such as developing the training programme. Also, the human resources plan is not yet available, because short term priority is now the recruitment of about 10 people. In chapter 3, sub-chapter 3.3 a recommendation has been developed.

6.1.3. BASES FOR REVIEW AND ASSESSMENT

ONR's internal guidance (SAPs and TAGs) is written for inspectors but is also publicly available. As a result, the internal ONR guidance informs the licensees' safety assessment and associated information. The ONR guidance includes expectations on the scope and quality of deterministic and probabilistic safety analysis. The guidance is in alignment with IAEA standards and international good practices and are consistently applied throughout the regulatory activities in combination with the Licence Conditions and Management System procedures. ONR has sufficient powers related to the licence conditions to get access to all the information it needs for the decision. On

top of that the regulatory assurance function amongst others aims to promote consistency ONR-wide (see sub-chapter 6.1.4).

For the environment agencies, refer to sub-chapters 6.1.1 and 6.1.2.

6.1.4. PERFORMANCE OF REVIEW AND ASSESSMENT

ONR verifies the completeness and quality of submissions. Generally, the submission is not rejected, but additional information is requested if required. Independent verification by the licensee is one of the items that is checked if applicable. The scope of the safety analyses is amongst others checked against international practice, like IAEA and WENRA. There are many interactions between ONR and the licensee before submissions are sent in, and during the review through inspections and meetings at several levels. Through the regular engagement of ONR with the licensees over the years it gains trust about the quality of the work of the licensee in general, including the safety analyses. In the GDA-area also an external consultant is used to undertake independent confirmatory modelling of a selected sample of the submitted analyses. Licence Condition 24(4) requires categorization of modifications. In the ONR guidance for modifications there are more detailed expectations on categorization. The higher the category the more detailed and comprehensive the submission should be. ONR has the power to require additional work if needed. The arrangement for interface between review and assessment and inspections are in place through the TAGs and TIGs.

In general, the approaches of the environment agencies are similar, although adapted to the activities they have to regulate.

About two years ago ONR introduced an additional layer of assuring the consistency, confidence and continuous improvement of the delivery of safety and security outcomes, creating the 3-tier Integrated Assurance Framework. For more details see chapter 3, sub-chapter 3.6.

6.2. REVIEW AND ASSESSMENT FOR NUCLEAR POWER PLANTS

The below builds on information provided in sub-chapter 6.1.

The review and assessment of operating power plants also includes the regulatory control of the return to power following a periodic shutdown. ONR requires reactor licensees to obtain its consent before starting up after a periodic shutdown. Prior to a scheduled outage, ONR engages with the licensee to understand its intentions and objectives. These engagements inform ONR's multi-disciplinary inspection and assessment plan, which is used together with the information contained in the licensee's formal submission requesting a consent to restart to judge whether nuclear safety issues have been satisfactorily addressed. For new nuclear power reactors, there is a preliminary assessment phase undertaken by ONR and the EA before a site licence and environmental permit are applied for called Generic Design Assessment (GDA).

Three reactor designs have completed the GDA process, resulting in ONR issuing a Design Acceptance Confirmation (DAC) and the EA granting a Statement of Design Acceptability (SoDA). In addition, the HPR1000 design is currently under assessment.

GDA uses SAPs, TAGs, REPs (EA Regulatory Guidance), IAEA standards, design codes etc. in exactly the same way as permissioning assessments to ensure consistent regulatory judgements are made about the adequacy of the design and supplied submissions. However, the level of engineering substantiation provided can be different because of the stage of design development. The requirement to demonstrate that the risks have been reduced to ALARP and radiation exposures as low as reasonably achievable (ALARA) (through the application of BAT/BPM) has been applied remains fundamental. Relevant good practice, which forms the basis of these principles, is set by latest codes, standards and guidance, therefore ensuring that modern expectations for safety and environmental protection are met.

The DAC and SoDA represent the regulators' expert judgement at the time it is provided. As it relates to a generic design and the associated generic submissions, they do not guarantee that regulators will later give formal permission for the start of construction of a nuclear power station based on that design. However, it does represent

an agreement with the Requesting Party, that the regulators would not intend to re-assess generic matters related to the design that have already been accepted in the GDA process.

6.3. REVIEW AND ASSESSMENT FOR FUEL CYCLE FACILITIES

The review and assessment framework for FCFs (both front-end and back-end fuel cycle facilities) is the same as for NPPs. The licensing procedures for the FCFs are carried out in accordance with the Nuclear Installations Act 1965 (NIA65). The review and assessment process for fuel cycle facilities is no different from that described in Section 6.1. ONR and the relevant environment agency undertake review and assessment in a proportionate and targeted manner, in accordance with licencing and permitting arrangements, and dependent on the activities and hazard being considered by the authorized party. In addition to regulating Fuel Cycle Facilities as Radioactive Substances Activities, the EA also regulates relevant activities as Chemical Activities under EPR16.

In addition to this, ONR has primary powers available to it to enable it to specify and/or approve limits, conditions and controls on the licensee's subsequent activities. The NIA65 enables ONR to attach additional conditions if the need arises. The attachment of the licence conditions enables ONR to apply regulatory controls to arrangements, processes and/or changes to the facilities lifecycle.

As stated in chapter 5, nuclear site licences do not have an expiry date and so in principle cover the entire lifecycle of the facilities on the site. Within this framework, ONR operates a permissioning process to control the activities of the licensee. This is enabled by the standard 36 license conditions.

6.4. REVIEW AND ASSESSMENT FOR WASTE MANAGEMENT FACILITIES

On nuclear licensed sites, ONR and the relevant environment agency jointly regulate the management of RAW. The review and assessment process for the construction, commissioning, operation and decommissioning of RAW management facilities is no different from the general review and assessment approach of the regulatory bodies. That includes a requirement for licensees to perform periodic safety reviews under LC15 (Periodic Review) of the nuclear site licence.

The environment agencies for England, Wales and Scotland have responsibility for the regulation, review and assessment process of RAW disposal at nuclear licensed sites and other premises using radioactive substances. There are no RAW disposal facilities in Northern Ireland. The environment agencies' guidance on near surface disposal facilities (NSD-GRA) and geological disposal (GD-GRA) requires developers/operators to carry out environmental safety assessments and develop an Environmental Safety Case (ESC) addressing the operational and long-term environmental performance of disposal facilities. The environment agencies will only grant an authorisation for disposal if the operator has submitted an acceptable ESC. The NSD-GRA requires the ESC to be periodically reviewed throughout the lifetime of a disposal facility. A similar approach will be applied for planned GDF.

Management of RAW at non-nuclear sites is regulated by the relevant environment agency. In England and Wales the EPR 16 provides the mechanism for issuing permits for radioactive substances activities. The radioactive substances activities include, among others, also the accumulation and disposal of RAW. The EA and NRW provide standard application forms and associated guidance documents to support operators through the application process. These include guidance on the documents that should be submitted with the application for both nuclear and non-nuclear sites. At non-nuclear sites the EA and NRW undertake periodic reviews at a maximum period of 4 years which includes assessment of whether the permit contains limits and conditions that reflect current regulatory practice and the use of BAT is supported by an appropriate and recent radiological impact assessment.

In Scotland EA(S)R 2018, provides the mechanism for issuing permits for radioactive substances activities. The permit conditions require regular review of the management systems, written procedures, justification of BPM, a RAW management plan, security plans, financial provisions for management of HASS and an environmental monitoring programme.

In Northern Ireland, NIEA carries out an annual review of compliance at each facility holding a Certificate under RSA93.

6.5. REVIEW AND ASSESSMENT FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

Public exposures as a result of radioactive waste discharges and protection of the environment are devolved matters, with the authorisations for radioactive substances activities being issued under the relevant environmental laws in England and Wales, Scotland and Northern Ireland.

Radioactive substances regulation covers a wide range of practices with significantly different levels of hazard and risk. The regulators use a proportionate approach to permitting and setting conditions, including a consideration of the scale of the operation, the hazards present and the level of risks involved. There are several stages where review and assessment are required: during the application for an authorisation, during periodic audits, when proposing modifications which may lead to a variation of the authorisation, and during decommissioning. Accordingly, the regulators review and assess the activities dependent on the stage of regulatory control, by requiring the authorised party to submit written demonstrations.

The environmental regulators require an authorised party to evaluate operating experience and perform reviews, specifically during the authorisation application process, during periodic reviews, when proposing modifications which require a permit variation, and during site decommissioning.

As part of the Authorisation process, applicants must demonstrate that they apply proportionate controls to their radioactive substances activities through optimisation and the use of BAT and BPM which is verified by the appropriate environmental regulator.

For example, SEPA review all information submitted as part of the application along with other relevant information such as government guidance and policies, past waste disposal data returns for the site, previous inspection findings, and environmental data such as river flows, wind speed and direction, and sewage treatment plant flows, before granting an authorisation. For some applications SEPA carries out consultations with other regulatory bodies, local authorities, water companies or persons who may be affected by the applications. SEPA may also carry out pre-authorisation inspections of the facilities and activities to ensure that they are ready to comply with regulatory requirements. For authorizations relating to High Activity Sealed sources (HASS) this readiness inspection may be done jointly with Police Scotland Counter Terrorism and Security Advisors (CTSA).

NIEA requests information to be supplied prior to authorisation and reviews all this information plus any other relevant information (e.g. radiological impact assessments, Habitats Regulations assessments, advice received from the Police Service of Northern Ireland Counter Terrorism Security Advisor) before issuing a certificate confirming NIEA considers that the facility or activity complies with regulatory requirements. NIEA's authorisation decisions are recorded in decision documents. The NIEA also carries out regular compliance inspections once an authorisation has been granted.

The EA provides guidance to applicants. It provides an overview of the principles of optimisation in the management and disposal of radioactive waste from radioactive substances activities, setting out the principles to be used, but it does not set specific standards.

NRW has issued operational guidance notes that describe the process that its staff should take when making and determining authorisation applications they have received.

Once an authorisation has been issued all four environmental regulators use a variety of means for carrying out routine compliance activities and audits over the lifetime of a facility or the duration of an activity (see Chapter 7). The findings of these audits are communicated back to the authorised party, in writing, in order to drive improvement and prevent future non-compliances. Reviewing the use of BAT/BPM, management systems and security measures are all key audit topics for the four environmental regulators.

Specific reporting requirements may also be included within authorisations, for example EA authorisations issued to cyclotrons include pre-operational conditions to submit a decommissioning plan within six months of the authorisation including an update of the decommissioning plan at least every five years.

Audit follow-up work can include review of submitted reports, as well as action reviews and recommendations. The environmental regulators require an authorised party to evaluate operating experience and perform reviews, specifically during the authorisation application process, during periodic reviews, when proposing modifications which require a permit variation, and during site decommissioning. The regulators can review the conditions of a permit, which may be prompted by a number of factors including operational changes on the site, inspection findings or changes in best practice.

The EA and NRW produce Site Environment Reviews (SER) for each nuclear site in England and Wales, pulling together all work-streams, including non-radiological, collating key evidence and information to support risk-based regulation. A regulatory plan is produced clearly showing how much effort is assigned to each task for all areas not just radiation. This then leads to the production of an Inspection Plan, identifying what topics will be looked at and when during the coming year. On an annual basis, a national Nuclear Environment Review is then carried out which pulls together the learning outcomes and achievements for the previous year, to inform future plans for overall nuclear site regulation.

The NIEA carries out an annual assessment of compliance for each of their authorised parties, taking into account all relevant sources of information, including data received from the authorised party, authorisation conditions, incident reports and results of compliance audits. SEPA compile information from inspections on lessons learned and related findings.

For the majority of reviews undertaken, EA and NRW regulators discuss the improvements necessary on-site during audits, requesting authorised parties to submit applications for authorisation changes as necessary. These changes may involve the inclusion of items in the Improvement Programme Requirements in authorisations, which include specific deadlines for completion based on the severity of risk. Enforcement Notices may also be used, usually in unusual circumstances (See chapter 8). SEPA and NIEA use letters or formal notices to require improvements. All the environmental regulators' assessment and review processes are within their respective management systems.

There is a requirement that food irradiation facilities must be authorised by the regulatory body before they can irradiate food. The Food Standards Agency in England, Wales and Northern Ireland and Food Standards Scotland in Scotland must review and assess the information submitted by the applicant against the requirements set out in the legislation.

The Food Standards Agency has a Working Together Agreement with the EA under the Environmental Permitting Regulations to provide advice on the impact to food and animal feed with respect to the disposal of radioactive waste. Food Standards Scotland has a similar arrangement with SEPA in Scotland and the FSA supports FSS in undertaking their role.

6.6. REVIEW AND ASSESSMENT FOR DECOMMISSIONING ACTIVITIES

As part of the UK government decommissioning policy, ONR is required to complete review of the decommissioning plans for each nuclear site licensee at least every five years except where 'equivalent arrangements' have been put in place. Equivalent arrangements have been put in place for Operating NPPs and NDA owned facilities. The licensed operators of these facilities provide their reviews to NDA, which consult with ONR on the review. NPPs under development produce decommissioning plans that ONR considers as part of the safety case assessment. For other facilities 'equivalent arrangements' are in place however these are not strictly in line with UK decommissioning policy.

The environment agencies have their own processes for nuclear operators to surrender their permits. This is detailed in GRR describing what operators need to do, when they are planning and carrying out their work to decommission and clean-up their sites. GRR makes reference to decommissioning plan but sets up requirements only on the RAW management plan and discharges. As an example, the Site Environmental Review of Bradwell NPP has been presented. The NPP site is now in its Care and Maintenance phase which will last 70-80 years. Annually EA reviews and assesses the status of the site against EA expectations considering RAW management and discharges to the environment and uses this information to inform future regulatory priorities at the site (taking into account planned activities such as any key decommissioning activities or milestones). Other components of

decommissioning plans, such as the selected decommissioning strategy; the schedule, type and sequence of decommissioning actions; the proposed end state etc. are reviewed and assessed by the ONR.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The ONR review of decommissioning plans is not in line with UK decommissioning policy.*	
(1)	**BASIS: GSG 47 para 7.11 states that** *"As stated in para. 7.5 of GSR Part 6 [1], the decommissioning plan is required to be updated by the licensee and is required to be reviewed by the regulatory body periodically (typically every five years or as prescribed by the regulatory body), or when specific circumstances warrant."*
S10	**Suggestion: The ONR should consider revising the relevant decommissioning guidance to provide clarity on how it undertakes periodic regulatory review of decommissioning plans.**

6.7. REVIEW AND ASSESSMENT FOR TRANSPORT

There are different Competent Authorities (CAs) for civil transport of Class 7 (radioactive material) dangerous goods within the UK, depending on mode and region. However, it is only ONR that issues approvals, including on behalf of other UK CAs. As a result, organisations apply to ONR for CA approval for new designs, renewal of existing approvals, validation of overseas approvals or modifications to approved designs.

ONR assess the application against the requirements of the modal texts:

- United Nations Economic Commission for Europe - European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)
- Intergovernmental Organisation for International Carriage by Rail - Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)
- International Maritime Organisation (IMO) International Maritime Dangerous Goods (IMDG) Code 2018 Edition incorporating Amendment 39-18 (IMDG Code)
- International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air 2019-2020 Edition (ICAO Technical Instructions)
- Depending on the transport modes requested which all replicate the requirements of IAEA SSR-6.

ONR's detailed process for assessment of applications for CA approval is set out in their guidance documentation.

The MCA has identified that it does not have the ability to conduct a survey to approve a Radiation Protection Program (RPP) required under the IMDG Code and INF Code. All the vessels currently requiring an approved RPP plan have an approved plan as required under the IMDG Code and INF Code, but the MCA does not have the ability, currently to assess and approve a new plan. The IRRS team noted that provisional arrangements are under consideration for ONR to assist the MCA in this work.

6.8. REVIEW AND ASSESSMENT FOR OCCUPATIONAL EXPOSURE

The regulations IRR17, IRR(NI)17 provide the framework for safety, however the requirements for the authorisation of occupational exposures does not include review and assessment of the safety assessment and the monitoring programme of occupationally exposed workers. The review of arrangements falling under the scope of the radiation protection programme, as outlined by Requirement 24 of the IAEA GSR Part 3, including the classification of controlled and supervised areas, local rules and procedures and protective equipment, along with workplace monitoring are not reviewed prior to authorisation. The applicant is not required by the HSE, HSENI and ONR to submit documentation in support of the request for authorization. This finding is valid for all of the four countries. The verification of compliance of an authorised party in relation to protection measures for the control of occupational exposures occur only during inspections, see also sub-chapter 5.8.

6.9. REVIEW AND ASSESSMENT FOR MEDICAL EXPOSURE

The review and assessment for medical exposure activities is performed by the CQC, HIS, HIW and the RQIA. Intelligence gathered by review and assessment is used to inform the authorities' work programmes and inspection programmes.

The IRRS team was informed that the vast majority of referrers have access to referral guidelines, which include dose information, established by The Royal College of Radiologists. RQIA has in conjunction with PHE performed a retrospective review of justification of computed tomography examinations undertaken on a single day in Northern Ireland. The study found that 94% of the computer tomography (CT) referrals reviewed were justified and that the majority of CT referrals had sufficient clinical information provided by the referrer to justify the examination.

UK National Diagnostic Reference Levels (NDRLs) for diagnostic and interventional radiology are established and updated by PHE after acquiring information about examinations and doses through relevant statistical surveys and questionnaires. The IRRS team was informed that five different surveys are currently on-going. The NDRLs can be found on the PHEs NDRLs website page at gov.uk. The NDRL was last updated in August 2019. There is, however, no requirements in the UK legislation that stipulates which organisation that has the responsibility to revise the NDRL and at what frequency. The NDRLs are based on body region examined and, where appropriate, the clinical requirement for the examination. NDRL for nuclear medicine are established by ARSAC and published in the ARSAC Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources.

The guidance to the Ionising Radiation (Medical Exposure) Regulations 2017, prepared by Department of Health and Social Care, requires the employer to regularly review and make available Local DRL (LDRL). The IRRS team learned that most of the larger hospitals have established LDRL. Review of compliance is included in the inspection programme for IR(ME)R by the relevant enforcing authorities.

The IRRS team was informed that during inspections, inspectors would expect to see that a clinical audit program as well as an audit programme covering IR(ME)R has been established at the site, and would look for evidence that these programmes are being followed and reviewed on a regular basis. The IRRS team was informed that RQIA request clinical audit reports pre-inspection. During 2018 CQC carried out a review and assessment of how radiology examinations are reported in NHS acute trusts, in response to serious concerns at a number of trusts about reporting backlogs and delegating clinical evaluations to non-radiology staff.

In 2017 RQIA commissioned the Medical Exposures Group (MEG) of PHE to design and compile an online survey and spreadsheet to build a picture of the nuclear medicine services and workload available at each site across Northern Ireland. Responses to the survey were received from eight centres across the region, seven HSC and one independent provider. A completed, or partially completed, spreadsheet was provided from seven centres, six HSC and one independent, giving workload information. A similar survey was also compiled to build a picture of the current CT equipment and services available across the five Northern Ireland Health and Social Care Trusts.

CQC maintains an electronic log of all serious accidental and unintended exposures reported under Regulation 8 of IR(ME)R . This log includes a summary of the incident, including the root cause and action taken by the provider to reduce the likelihood of similar incidents. Similar records are kept by HIS, HIW and RQIA. All the enforcing authorities analyse the reported accidental and unintended exposures and take enforcements if necessary. CQC also publishes annual reports where learning from incidents is shared with authorized parties.

6.10. REVIEW AND ASSESSMENT FOR PUBLIC EXPOSURE

There is a spectrum of non-nuclear sites that may give rise to public exposures. At most of these sites there are persons in close proximity that are not directly associated with the site. The provisions in the revised regulations of IRR17 and IRR(NI)17 include dose limits for members of public in the line with GSR Part 3. Where the non-nuclear site is authorized to discharge radioactive wastes by the relevant environment agency under EPR16, EASR18 and RSA93, that authorizsation will also have regard to ensuring impacts to the public are within relevant

dose limits and constraints. There is a further requirement of maintaining radiation exposures ALARA and risks ALARP and putting procedures in place to estimate the doses to members of public, when it is anticipated that they are likely to be exposed to direct radiation or contamination.

Where employers anticipate this could occur, they are required to apply a dose constraint that has been recommended to not exceed 0.3 mSv a year. This is especially important for healthcare employers to take note of, due to the chance of the public being exposed to ionising radiation, via a patient who has received ionising radiation treatment.

HSE is responsible for regulatory oversight of the "representative person" of public arising on site from the operation of the non-nuclear site (such as shielding evaluation, work practices etc). However, as HSE does not assess and review the safety assessment (already referred to in chapter 5) during authorisation, the effective implementation of the dose to the public is unsure.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *It is not always obvious for the operator to decide on the on-site "representative person" in the non-nuclear facility towards compliance of IRR17 requirements.*	
(1)	**BASIS: GSR Part 3 Requirement 29 states that:** *"The government or the regulatory body shall establish the responsibilities of relevant parties that are specific to public exposure, shall establish and enforce requirements for optimization, and shall establish, and the regulatory body shall enforce compliance with, dose limits for public exposure".*
S11	**Suggestion: HSE should consider making a guidance document on the identification of the on-site "representative person" in the non-nuclear practices. This would assist the operator and HSE to ensure appropriate implementation of the requirements with respect to public exposures.**

HSE and EA have complementary areas of responsibilities in discharging their regulatory functions. To address the interfaces, an MoU between HSE and EA has been established in 2012. This was before the transposition of the EU Basic Safety Standards Directive 2013 (BSSD13), which led to amendments to both IRR17 and EPR16. Therefore, the MoU should be reviewed to reflect the relevant changes.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The MoU and any other arrangements between the HSE and EA have not been updated to incorporate the overlap of responsibilities arising from revised IRR17 and EPR, 2016.*	
(1)	**BASIS: GSR Part 1 Requirement 7 para 2.18 states that:** *"Where several authorities have responsibilities for safety within the regulatory framework for safety, the responsibilities and functions of each authority shall be clearly specified in the relevant legislation. The government shall ensure that there is appropriate co-ordination of and liaison between the various authorities concerned in areas such as:(1) Safety of workers and the public; (2) Protection of the environment …;* *The co-ordination and liaison can be achieved by means of memoranda of understanding, appropriate communication and regular meetings. Such co-ordination assists in achieving consistency and in enabling authorities to benefit from each other's experience".*
S12	**Suggestion: HSE and EA should consider updating their MoU to ensure it reflects changes in relevant legislation and IAEA guidance since 2012.**

The UK Government has put in place a Radon action plan to address long-term health risks from any source of radon ingress to dwellings, buildings with public access and workplaces. This activity is being conducted by a number of organisations including Public Health England, HSE, HSENI, NIEA, Drinking Water Inspectorates and local authorities.

6.11. SUMMARY

The IRRS team has reviewed processes for review and assessment for nuclear and radiation facilities and activities. Although in general the review and assessment activities are carried out according to the IAEA standards, some areas for improvement have been defined:

- Revise the relevant decommissioning guidance to provide clarity on periodic regulatory review of decommissioning plans
- Provide guidance on the identification of the on-site “representative person” in non-nuclear practices.
- Review and update of the MoU between HSE and EA

One area for improvement on the review and assessment in the area of occupational exposure has been combined into chapter 5, sub-chapter 5.5.

7. INSPECTION

7.1. GENERIC ISSUES

All nuclear installations in the UK are subject to continuous regulatory inspection over their entire lifecycle from the start of construction to the end of decommissioning. The regulatory authorities carry out inspections of facilities and activities to verify that the authorized party is in compliance with regulatory requirements and with the conditions specified in the authorization. The regulatory authorities design and conduct their activities in a manner which reinforces the fundamental principle that the prime responsibility for control, supervision and verification activities for safety is the authorized party. For example, where appropriate, the regulatory authorities use sampling tools to assess the extent to which the authorized party complies with their own self-monitoring obligation.

The relevant environment agency is responsible for the regulation of facilities and activities involving radioactive substances for the protection of the public and the environment in England, Wales, Scotland and Northern Ireland. The Health and Safety Executive (and other regulatory authorities) inspectors carry out inspections to verify compliance with health and safety legislation.

As part of this responsibility, the agencies undertake independent inspections of regulated facilities and activities to verify compliance with regulatory requirements and any of the limitations and conditions specified in authorisations.

ONR's inspection program for nuclear facilities specifies the type of inspections to be conducted and stipulates the frequency and the areas and programs to be inspected. Most of the regulatory authorities conduct planned, announced and unannounced inspections, as deemed appropriate. Additionally, reactive inspections are carried out following reportable incidents or safety-relevant findings. Inspectors have unlimited access to authorized facilities and activities.

All inspection methods mentioned in the IAEA GSG-13 are utilized including monitoring, direct observation, discussions, reviews, examinations of procedures, records, and documentation. The regulatory authorities apply a graded approach that depends on the potential hazard associated with the facility or activity. For example, due to the high hazard potential of nuclear power plants, the regulatory effort and attention at these installations is generally greater than for other nuclear installations.

Some inspections are performed in cooperation with other authorities or institutions as necessary. These inspections are initiated on a case-by-case basis. The regulatory authorities record the results of their inspections. If any findings have been established during the inspections or important insights have been gained, these are also addressed and discussed for the purpose of exchanging information and developing improvements to the inspection program.

All results of inspections including the findings are communicated to authorized facility personnel at the end of the inspections. Results of inspections are recorded, and findings are tracked. If any non-compliance with regulatory requirements is identified during inspection, appropriate enforcement action is taken proportional to the significance of the non-compliance.

As a response to findings identified in the 2009 ICL Inquiry Report, ONR created the Regulatory Issues Database (RID) so that the necessary follow-up actions related to safety or security issues that are identified by ONR inspectors are not overlooked. The RID was put into practice in 2009 and has subsequently been revised and expanded over the years. The Site Summary Issues Report provides a very useful mechanism for sharing the current status and history of regulatory issues of concern from identification to final resolution. The IRRS team noted it to be an effective tool for knowledge management and to ensure accountability in the resolution of issues.

7.2. INSPECTION OF NUCLEAR POWER PLANTS

The IRRS team concluded that a comprehensive inspection program which implements a graded approach is in place for inspections at licensed nuclear facilities in the UK. The inspections conducted by ONR verify licensee compliance with non-prescriptive standard licence conditions (LCs). ONR sometimes carries out joint inspections with other enforcing authorities on licensed nuclear sites; these are mainly with inspectors from one of the three

national environment agencies (EA, NRW and SEPA), with whom ONR have formal MoUs. The IRRS team determined that the complementary inspection activities are generally well coordinated including the development of joint guidance where appropriate. Although inspections were being scheduled consistent with a graded approach, the IRRS team did identify a need for EA to develop guidance to specify how the graded approach should be used to determine the frequency of inspections to ensure the practice remains durable.

The IRRS team observed an onsite system-based inspection. The site inspector and specialist inspectors were highly competent and professional in their interactions with each other and the licensee. Their actions demonstrated a good understanding of the inspection programme policies and procedures and the practical application of a graded approach. They also demonstrated mastery of the technical areas being inspected. The IRRS team also noted that the use of the systems-based inspection approach appeared effective at enabling inspectors to identify insights and potential issues which otherwise might not be identified though individually conducted compliance inspections alone.

ONR does not deploy on-site resident inspectors and relies upon visiting nominated site inspectors and specialist inspectors to monitor the general condition of the facility. However, the IRRS team identified that ONR does not provide expectations regarding how much time should be spent by nominated site inspectors to perform general surveillance activities.

The IRRS team was informed by the SEPA that staffing challenges have not yet impacted its ability to accomplish nuclear plant inspections, however they expressed concern that it has the potential to impact if not properly managed. This is another example of the staffing challenges discussed in the Recommendation R5 included in sub-chapter 3.3.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ONR inspection program guidance does not establish expectations regarding how much general surveillance of facilities inspectors should be performing and how it should be accomplished.*	
(1)	**BASIS: GSG 13, Requirement 28, para. 3.271 states that** *"The regulatory inspection programme should provide time for general surveillance of the facility or activity by regulatory inspectors. Such surveillance is aimed at gaining an overall impression of the authorized party's capabilities and performance and is not restricted to specifically designated components and systems or designated scheduled activities and tests".*
S13	**Suggestion: ONR should develop clear expectations and associated guidance for inspection staff in how much time should be dedicated to general surveillance of facilities and how it should be accomplished independent of scheduled inspection activities.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *EA inspection program guidance does not stipulate how to determine the appropriate frequency of inspection in accordance with a graded approach for nuclear facilities.*	
(1)	**BASIS: GSR Part 1 Requirement 4.50 states that** "*The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach".*
R12	**Recommendation: EA should provide guidance on how to apply a graded approach in**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	determining the appropriate frequency of inspections for the areas and programs inspected for nuclear facilities.

7.3. INSPECTION OF FUEL CYCLE FACILITIES

The inspection framework for FCFs (both front-end and back-end fuel cycle facilities) is the same as for NPPs throughout the period of operation, from construction to decommissioning.

Regulating safe hazard and risk reduction activities on the Sellafield site is ONR's highest regulatory priority. For example, at some of the relatively low hazard licensed sites, inspectors may only visit two or three times a year for a few days. This is in contrast to the Sellafield site, where there is a dedicated team of 6 site inspectors delivering the annual inspection program, as well as a team of project inspectors providing regulation through giving permissions for highly safety significant projects.

There are other considerations which determine the extent of regulatory inspection at a site, these are termed as regulatory attention levels (RAL) and include: the magnitude and nature of the hazard; the licensee's safety performance; the extent of ageing and degradation; open regulatory issues; and the number and significance of incidents occurring on the site. The sites are assigned one of three RAL. Currently only legacy facilities at Sellafield are assigned at the highest level and receive significantly enhanced attention.

Additionally, inspections at FCFs focus on the criticality and chemical/toxicity hazards associated with these facilities. Inspectors with specialized training in nuclear criticality and chemical hazards accompany inspectors or conduct inspections in these areas of the facilities. Focus is applied on the "Defence in Depth" principle for accident sequences and the use of "Double Contingency" to prevent nuclear criticality. Relevant environment agencies undertake independent inspections of regulated facilities and activities to verify compliance with regulatory requirements and any of the limitations and conditions specified in authorisations.

The IRRS team observed a compliance inspection at a fuel reprocessing facility Highly Active Liquor Evaporation and Storage (HALES) at Sellafield. It was a jointly co-ordinated inspection undertaken by the ONR site inspector and an instrument and control specialist from ONR. There was good preparation and the inspectors followed an inspection plan. After the walk-down of the facility, the inspectors compiled their findings in private and presented them in an exit meeting in a clear and concise manner to the operator's representatives, specifying the relevant timeframes for response and the outcome of the focused compliance inspection. The inspectors provided advice in several areas that the operator representatives acknowledged would result in improvement to safety of the facility.

During discussion with the IRRS team, the operator representatives indicated that although they acknowledged the regulatory burden in dealing with multiple regulators, they all share the same objective to drive and improve safety for staff, the public and the environment.

The inspection concentrated on matters relevant to safety and was conducted in a professional manner.

7.4. INSPECTION OF WASTE MANAGEMENT FACILITIES

Inspection of waste management facilities is accomplished using the same general approach as described in sub-chapter 7.1 above.

To gain practical experience with ONR's and EA's inspection approach, two members of the IRRS team visited the Sellafield site and observed ONR and EA inspections. One member observed an ONR inspection of FCF and the second witnessed an EA inspection of a Sellafield facility.

The EA inspection was a reactive inspection in response to a series of mis-consignments reported by the permit holder. The inspection was executed following an inspection plan which provided details on the reasons for inspection, its objective, scope, format, programme and documentation required. The inspectors prepared for the

inspection by utilizing inspection templates. This preparation provided for a more effective and efficient inspection while onsite.

The IRRS team noted that the EA inspectors conducted a thorough inspection which included interviews with facility managers and operating staff on site. Even though it was the first time either of the EA inspectors had conducted an inspection at the facility, the inspectors were well prepared and arrived on site knowledgeable of the results of previous EA inspections and the history of reported events at the facility. At the debriefing, the EA inspectors effectively communicated findings to the authorized party in a clear and straightforward manner. The inspection records have to be delivered to the authorized party within a 20-day period. All EA inspection records of nuclear licensed sites are shared with ONR and vice versa.

The IRRS team has no findings specific to inspection of waste management facilities, however, an area for improvement was identified associated with clearance of waste material and is documented in chapter 9.

7.5. INSPECTION OF RADIATION SOURCES FACILITIES AND ACTIVITIES

HSE/HSENI can inspect any work with ionising radiation for which they are the enforcing authority. HSE takes a graded approach of any work with ionising radiation, which is described in guidance entitled: IRR17 Guidance for Notifications, Registrations and Consents.

The principal document assisting inspectors in their inspection is the Approved Code of Practice and Guidance to IRR17 'Work with ionising radiation' (L121). There are also various information documents describing standards of good radiological practice published on HSE's intranet and website. Where a Specialist Inspector (Radiation) is unfamiliar with a particular practice, this is identified via the competency matrix and appropriate training and instruction is given. IRRIs are given training for each inspection initiative and provided with information on enforcement expectations.

HSE/HSENI records the results of inspection in inspector notebooks and on a computerised system. Inspection results are always discussed with and reported to the employer. If there are none or only very minor breaches the inspection findings are conveyed verbally.

HSE/HSENI make no distinction between inspections of radiation sources, occupational or public exposures. All inspections and investigations will examine all these types of exposures.

HSE has 7 full-time equivalent Specialist Inspectors (Radiation) plus access to a proportion of 10 Ionising Radiations Regulatory Inspectors' (IRRIs) time, available to carry out inspections. In 2018-2019 the Specialist Inspectors (Radiation) and IRRIs carried out a total of 193 inspections against a target of 150.

HSE has a 3-year programme of inspections which stipulates the types and numbers of inspections. The Radiation Team's Plan of Work for 2019-2020 includes a target of 175 proactive inspections. However, HSE's programme of inspections does not cover all relevant authorized facilities and activities working with radiation sources. There is no predefined inspection frequency for the different types of practices and no evidence that a graded approach to inspections of activities involving radiation sources is applied. A summary of data collected by the IRRS team to support this conclusion is included in the tables below. The IRRS team was informed by HSE staff that as of July 2019, radiation specialists inspect all employers who have been granted new consents.

On nuclear licensed sites a similar approach is adopted for inspecting radiation safety. ONR's General Inspection Guide (ONR-INSP-GD-064) and Guidance for Inspection Planning and Reporting (ONR-INS-GD-059) set out information and guidance on inspection planning, preparing for and undertaking inspections. However, ONR's guidance does not specify the frequency of radiation sources safety related inspections for all relevant authorized facilities.

No. of consents	Type of practice	HSE Inspections					
		TOTAL	2018	2019	2019, JE	2018, JH	2019, JH
541	HASS (except industrial radiography)	6	1	5	1	0	1
	Industrial radiography (may be HASS)	32	18	14	1	n.a.	n.a.
62	Industrial irradiation	1	0	1	1	n.a.	n.a.
133	Particle accelerators	25	10	15	2	1	2
360	Administration of radioactive materials in vivo	17	9	8	1	2	2
281	Other (radiopharmacy, waste storage, discharge)	4	*	*	1	n.a.	n.a.

JE: Joint inspections with environment agencies (EA, NRW, SEPA)

JH: Joint inspection with health authorities (CQC, HIW, HIS)

*: Data not provided to IRRS team

n.a: Not Applicable

No. of consents	Type of practice	HSENI Inspections					
		TOTAL	2018	2019	2019, JE	2018, JH	2019, JH
*	HASS	7	6	1	n.a.	0	0
	Industrial radiography (generator)	0	0	0	0	n.a.	n.a.
1	Industrial irradiation	0	0	0	0	n.a.	n.a.
*	Particle accelerators	0	0	0	0	0	0
8	Administration of radioactive materials in vivo	0	0	0	0	0	0
*	Other (radiopharmacy, waste storage, discharge)	0	0	0	0	n.a.	n.a.

JE: Joint inspections with environment agencies (NIEA)

JH: Joint inspection with health authorities (RQIA)

*: Data not provided to IRRS team

n.a: Not Applicable

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES

Observation: *HSE, HSENI, and ONR do not have inspection programmes that covers all relevant authorized facilities and activities which stipulate the inspection frequency and the areas and programmes to be inspected, in accordance with a graded approach.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 29, para. 4.50 states that** *"The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections), and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach".*
R13	**Recommendation: HSE, HSENI and ONR should develop and implement a programme of inspection which stipulate the frequency of radiation sources safety related inspections and the areas and programmes to be inspected, in accordance with a graded approach.**

The environment agencies (EA, NIEA, NRW and SEPA) undertake independent inspections of regulated facilities and activities. Each agency develops its own inspection plans detailing the types of inspections to be undertaken and at which regulated facilities. Each agency has its own internal guidance and procedures detailing how inspections should be undertaken.

The environment agencies undertake independent inspections of non-nuclear facilities and activities to verify compliance with regulatory requirements and any of the limitations and conditions specified in authorizations. In order to undertake inspections, the environment agencies have the power to enter regulated facilities at any reasonable time or, in an emergency, at any time as specified in the Environment Act 1995 (EA95) Section 108 (4) for the EA, NRW and SEPA, and Radioactive Substances Act 1993 (RSA93) Section 31 for NIEA. This power allows the environment agencies to undertake planned and reactive inspections, both announced and unannounced, as required.

During development of inspection plans for radiation sources facilities and activities, each agency adopts a graded approach by taking into account the potential magnitude and nature of the hazard at the regulated facilities when preparing inspection plans The graded approach is reflected in inspection plans whereby the frequency of inspections is proportional to the hazard from the regulated facilities, determined in accordance with the internal procedures of each agency. For example, SEPA has assigned different types of regulated facilities to hazard bands, where higher hazard bands have higher associated inspections frequencies, allowing inspections to be undertaken in accordance with a graded approach.

In general, the environment agencies inspect HASS every year, open sources and waste permits every second year and smaller sources every four years. The IRRS team was informed that joint inspections of HASS are performed with the respective nations counter terrorism and security advisors.

For assisting in the delivery of inspection plans, each agency has its own internal guidance and procedures detailing how inspections should be undertaken. The IRRS team was also informed that SEPA has faced challenges to implement its inspection programme because of staffing shortages. This staffing challenge is discussed in a Recommendation R5 included in sub-chapter 3.3.

Following inspection activities, each agency records the results of inspections and communicates these to the regulated facility. Even though the inspection responsibilities are legally and operationally separate for each agency, the inspection of regulated facilities and activities is undertaken to the same standards and is consistent across the UK.

The IRRS team observed an inspection at an industrial NDT facility. It was a jointly co-ordinated inspection undertaken by HSE, ONR, NRW, Police (Extremism and Counter Terrorism Unit) and two IAEA team members. There was good preparation and the inspectors followed an inspection plan. After the walk-down of the facility, the inspectors compiled their findings in private and presented them in an exit meeting in a clear and concise manner to the facility representatives, specifying the relevant timeframes for response. As a whole, the inspection concentrated on matters relevant to safety and was conducted in professional manner.

The IRRS team also attended an inspection at a nuclear medicine department at an NHS Hospital. It was a jointly co-ordinated inspection undertaken by EA and HSE. The inspectors were well prepared and followed a clear plan for the inspection. Following the inspection, while the inspectors were compiling their findings, the IRRS team members collected insights from the authorized party regarding the regulatory system and processes. The IRRS team was informed that EA frequently inspects the hospital whereas the inspection from HSE was the first of its kind.

The IRRS team noted that the inspections were prepared well and performed in a professional manner by the EA and HSE inspectors, who demonstrated a high level of professionalism and understanding of all issues discussed during the inspections.

7.6. INSPECTION OF DECOMMISSIONING ACTIVITIES

Inspection of decommissioning safety for licensed nuclear sites is accomplished using the same, general approach as described in sub-chapter 7.1 above. During the review meetings with ONR staff, two Intervention Records were reviewed. The first report is an example of a compliance inspection report while the second one is an outcome of a system-based inspection verifying the implementation of a safety case at the site.

7.7. INSPECTION OF TRANSPORT

One of ONR's responsibilities is regulating the safe transport of civil nuclear material and waste by road, rail and inland waterway between licensed nuclear sites but also to and from other facilities using ionising radiation within Great Britain. ONR has established inspection programmes related to transport; some of these inspections are in support of transport package approval by the UK Competent Authority (CA).

ONR carries out typically between 30-40 proactive and reactive compliance inspections of consignors and carriers annually. The inspections are informed by risk and are planned and carried out in a similar way to ONR's nuclear safety inspections following the same inspection guidance.

Transport of radioactive material by road, rail and inland waterway is inspected under regulatory requirements imposed by The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 and the IRR 17. The regulations invoke the requirements of the relevant UNECE (ADR/RID/ADN) modal texts directly derived from IAEA SSR-6 as well as additional requirements for emergency preparedness and response derived from BSSD. Air and sea transport are regulated against the relevant UN modal texts (ICAO and IMDG) by the relevant competent authorities; Civil Aviation Authority (CAA) and the Maritime and Coastguard Agency (MCA). Customs checks are carried out by UK Border Force.

ONR has agreed MoUs with other transport, radiation safety and environmental competent authorities to facilitate inspection and clarify responsibilities at transport and regulatory interfaces. ONR has established agency agreements with a number of Police Constabularies to perform inspections of vehicles carrying Class 7 goods on public roads, on behalf of, but not to the exclusion of ONR.

The inspection technique employed by ONR for transport duty-holders is a sampling regime. Compliance in a range of areas relevant to the duty-holders transport operations is assessed including the transport radiation protection programme, management systems, compliance with package approval requirements for competent authority approved packages and the consignor's ability to demonstrate compliance with requirements for non-competent authority approved packages.

Results of inspections are reported to authorized parties through letters (non-nuclear authorized parties) and inspection reports (nuclear authorized parties). Actions are followed up and tracked through ONR's normal reporting and inclusion in the ONR regulatory issue database. Transport Inspection findings are reviewed by relevant staff to identify trends and refine inspection strategy.

NIEA carries out announced inspections on a number of companies carrying out radioactive transport by road in Northern Ireland under the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment

Regulations (Northern Ireland) 2010. The number of inspections to be carried out each year is determined by the Principal Radiochemical Inspector and recorded in the KPI spreadsheet.

NIEA has a quality procedure QA 012: Transport of Radioactive Substances (Inspections) which describes how to carry out and report on compliance assessment activities on companies carrying out radioactive transport. Compliance reports are prepared after each visit and a copy is sent to the operator. Compliance reports detail any non-compliances and actions required.

Civil Aviation Authority

Air transport regulations apply to shippers, freight forwarders, the designated postal operator, ground handling service providers and air operators; the regulations incorporate by reference the Technical Instructions for the Safe Transport of Dangerous Goods by Air 2019-2020 issued by the International Civil Aviation Authority (ICAO).

Inspection and enforcement powers for air transport enable independent audits and inspections concerning all activities associated with dangerous goods in air transport including acceptance, loading and carriage by the aircraft operator or its designated agent. The CAA also performs risk and performance-based oversight (audits) of shippers and freight forwarders. Where necessary, the CAA works with the ONR (which has the power to enter the premises of such organisations). The CAA is tasked by the Department for Transport to investigate and prosecute breaches of aviation safety rules.

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. There are documented procedures for the conduct of these activities including keeping records, informing the authorised party and tracking resultant outcomes. The output from safety oversight and occurrence data feeds into the Performance Based Oversight process thus informing the regulatory process.

Maritime and Coastguard Agency

The MCA carries out a programme of statutory surveys of UK registered ships carrying nuclear products in accordance with international requirements set out by the International Maritime Organisation (IMO). This includes a survey regime with set frequency and scope for internationally trading ships, including nuclear carriers; as well as requirements of the IMDG Code and INF Code which relate to the carriage of nuclear products. The surveys are linked to statutory certification issued by the MCA and Recognised Organisations (ROs). Actions as a result of surveys are documented and reported to the operator, followed by monitoring and close out by MCA/RO. The results of surveys are recorded and may be used indirectly to inform future policy lines to be adopted by UK flag state at IMO. Containment devices for carriage of nuclear products at sea are approved to IMDG standards by IMO and the surveys fully cover these requirements to confirm compliance with internationally agreed standards.

The MCA carries out safety management audits of the nuclear carrying vessels which focus on the operators own management system and how it is implemented both in the company offices and on-board the ship, thus providing assurance of the operator's commitment to safety and the environment. This is a statutory requirement under the International Safety Management (ISM) Code. It is a fundamental aspect of the ISM Code that the operator, and in particular the master, has primary responsibility for safety. The purpose of the audits is to ensure the company has policies and procedures in place to reflect this. Ships and companies cannot legally operate without ISM certification.

In addition, MCA have powers under the Merchant Shipping Act to inspect foreign flagged vessels entering a UK port under The Merchant Shipping (Port State Control) Regulations 2011, SI 2601. This requirement is a regime for enforcement in respect of shipping using UK Ports and their waters of international standards for ships safety and pollution prevention to ensure they comply fully with the requirements.

7.8. INSPECTION OF OCCUPATIONAL EXPOSURE

Responsibility to carry out inspections lies with the competent authority: the ONR for nuclear facilities and transport, the HSE for non-nuclear facilities and the HSENI for non-nuclear facilities in Northern Ireland under the jurisdiction of HSW74 and HSW(NI)O78.

HSE and HSENI inspectors rely on the Operational Guidance document: Inspection Procedure, while the ONR inspectors use the guidance documents: ONR Guidance for Intervention Planning and Reporting (ONR-INSP-GD-059) and ONR General Inspection Guide (ONR-INSPGD-064) to guide inspection plans and the conduct of inspections; reporting findings; and taking enforcement action. During inspections, the inspectors check compliance with the relevant regulation and approved codes of practice guidance document governing occupational exposures (IRR17 and IRR(NI)17). The preparation for the inspections may involve request of the safety assessment and further documents from the authorised practice in advance.

The procedure of the HSE and HSENI inspectors is outlined in the Inspection Procedure Document and guides the inspector in

- selecting the appropriate authorised facility or practice,
- gathering relevant information,
- identification of objectives,
- selection of appropriate inspection method,
- preparations for the inspection.

The inspection procedure includes a sampling regime. In accordance with a graded approach and depending on the specific circumstances of the workplace to be inspected, inspections may vary in scope.

The referenced ONR guidelines use a different terminology and are more detailed, however are based on similar principles, where the inspectors employ the same sample-based approach.

The inspection concludes with reporting and recording its results, where significant non-conformances are addressed with the appropriate notice (Notification of Contravention, Improvement Notice, Prohibition Notice). Depending on the outcome of the inspections, the inspector could carry out a follow-up.

Due to the current authorisation scheme of the HSE, HSENI and ONR concerning occupational exposures, the inspections have a very important role to verify the safety of workers, as they provide the opportunity for review optimisation and compliance along with all the relevant verifications of the existing arrangements for the control of such exposures.

The IRRS team observed that during the site visits, all inspectors carried out their duties according to the highest standards of proficiency and considered all relevant safety aspects. However, the IRRS team also noted the current HSE, HSENI and ONR inspection guidance does not provide adequate clarity to ensure inspection of all relevant safety aspects. The existing procedure relies heavily on the individual inspector's experience and expertise to cover all relevant safety aspects.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *HSE, HSENI, and ONR inspection guidance does not provide adequate clarity to ensure inspection of all relevant safety aspects associated with IRR17 inspections. The existing procedure relies heavily on the individual inspector's experience and expertise to cover all relevant safety aspects.*	
(1)	**BASIS: GSR Part 1 Requirement 29, para. 4.53 states that** *"In conducting inspections, the regulatory body shall consider a number of aspects, including:* *- Structures, systems and components and materials important to safety;* *- Management systems;* *- Operational activities and procedures;*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	- Records of operational activities and results of monitoring; *- Liaison with contractors and other service providers;* *- Competence of staff;* *- Safety culture;* *- Liaison with the relevant organization for joint inspections, where necessary".*
R14	**Recommendation: HSE, HSENI, and ONR should review their individual occupational exposure inspection guidance to ensure they adequately address the relevant safety aspects to be included in the scope of inspections.**

7.9. INSPECTION OF MEDICAL EXPOSURE

The most relevant statutes for the safety of patients exposed to radiation from medical equipment are the IR(ME)R17 (GB) and the IR(ME)R18 (in NI). Each of the four nations which comprise the UK has its own 'relevant enforcing authority' for these Regulations. These are the CQC, The Scottish Ministers, The Welsh Ministers and The Department of Health (Northern Ireland). In Scotland, Wales and Northern Ireland the 'relevant enforcing authorities' have written agreements whereby the respective quality regulators for health bodies undertake a range of these regulatory functions on their behalf. These bodies are: HIS; HIW and RQIA.

The HSWA74 and Health and Safety at Work (Northern Ireland) Order 1978 provides the inspectors appointed by the relevant enforcing authorities with the necessary enforcement powers including the power to enter premises at any reasonable time where there is reason to believe it is necessary to carrying out its inspection duties.

The inspections for medical exposures are performed in a similar way across the UK. Inspections usually last for one or two days and include a review of the required documentation, staff training records and patient records, as well as discussions related to management and governance systems, procedures outlining practices within the facility, and radiation safety culture. They also include inspectors interviewing clinical staff to evaluate their understanding of the regulatory requirements and employer's procedures within the department. Immediately following an inspection verbal feedback is provided to the authorized party's staff. Subsequently an inspection report is produced and sent to the authorized party outlining the structure of the inspection, identifying areas of good practice, areas for improvement and actions to be taken to improve compliance with regulations.

The IRRS team was informed that prior to announced inspections a comprehensive template for self-assessment is sent, by HIW, HIS and RQIA, to the organisation involved which then is used as a basis for the inspection process. A range of policies and procedures are also returned with the self-assessment. Self-assessment templates have been developed for radiology, nuclear medicine and radiotherapy.

The IRRS team observed an inspection at an NHS Trust, The IRRS team noted that the inspection was prepared well and performed in a professional manner by CQC inspectors who demonstrated a high level of professionalism and understanding of all issues discussed during the inspections.

Specific information regarding each regulators' inspection programmes and inspection policies is described below.

CQC

The CQC undertakes the relevant regulatory functions for both National Health Service (NHS) and private healthcare services. CQC carries out both planned and reactive inspections of facilities that undertake exposures with medical equipment involving exposure to ionising radiation and radioactive substances. CQC may also carry out joint inspections with the HSE who are responsible for enforcing the IRRs that cover occupational exposures and exposures of members of the public.

The IRRS team was informed that CQC has undertaken a total improvement of the inspection process during the last two years. An IR(ME)R17 inspection handbook has been developed, which describes the various steps in the inspection process. CQC has also included some medical exposures areas in their regular inspections of the healthcare inspections of NHS acute hospitals, performed by non-IR(ME)R17 inspectors. However, the IRRS team noted that there were no provisions to ensure that every facility and activity is regularly inspected and no set frequency for inspection of different areas of medical exposures with a graded approach based on the associated risk. The IRRS team was informed that due to CQC's staffing levels, it has faced challenges to implement an inspection programme that ensures that every facility and activity is regularly inspected, Recommendation R6 in sub-chapter 3.3 addresses this matter. The IRRS team was informed that CQC has developed short-term focussed inspection plans for interventional radiology, radiotherapy and nuclear medicine, which should be completed within two years, and 13 inspections have been performed so far during the financial year 2019/2020. Inspection themes during 2017 and 2018 included children's hospitals and orthopaedic hospitals. In June 2019 CQC published a report of their findings and conclusions from the inspection of the 12 NHS providers of specialist paediatric radiology services across England.

Reactive inspections are decided on the basis of notifications of unintended or accidental exposures reported to CQC or from intelligence provided by either CQC general hospital inspectors, whistle-blowers or other sources. Inspections are usually short-notice announced inspections (facilities are usually given at least 24 hours' notice) although on occasion inspections will be unannounced, usually in response to an incident being reported or information being provided by a whistle-blower.

HIW

HIW has an IR(ME)R17 inspection policy and a programme of inspections and reviews which are conducted across a wide range of health care services to ensure they meet the requirements of IR(ME)R17. However, neither the inspection policy nor the inspection programme clearly describes the rationale behind the inspection frequency or how appropriate inspection coverage is achieved over a period of time. HIWs programme of proactive IR(ME)R17 inspections is based on coverage of the seven Welsh health boards, two NHS Trusts and independent services that use ionising radiation. The inspection plan is reviewed and confirmed on an annual basis where the hospital site and modality are selected for inspection. Dental practices compliance with legislation is assessed through HIW's dental inspection programme which is a 5-year inspection cycle. The findings and conclusions from the inspections are published in an individual inspection report for the service inspected and a summary of findings is published in HIW's annual IR(ME)R17 report.

The inspections are carried out in conjunction with staff from the Medical Exposures Group in Public Health - England. Inspections are generally announced with up to 8 weeks' notice provided to the service being inspected. Where appropriate (e.g. in response to an incident), inspections may be unannounced. However, the IRRS team learned that no unannounced inspections have been performed during the last three years.

HIS

In consultation with Scottish Government, HIS has during the last year developed an IR(ME)R17 inspection policy for medical exposures. The IRRS team was informed that discussions between HIS and the Scottish Government on the annual number and the format of inspections are ongoing. However, the IRRS team learned that neither the inspection policy nor the inspection plan that has been developed to date states the rationale behind the number of inspections or sets out the frequency for inspections with a graded approach in terms of risk. The IRRS team also learned that unannounced inspections are not covered by the inspection plan that has been developed to date.

RQIA

RQIA has a policy which sets out the regulatory basis for inspections and outlines the inspection process. A graded risk-based approach is taken to inspection; radiotherapy centres, which are the areas of greatest risk, are inspected every three years. All other facilities are inspected as part of the rolling inspection programme. RQIA carries out

inspections in conjunction with staff from the Medical Exposures Group in Public Health England, who act as advisers to RQIA. Each yearly inspection programme is developed in advance with Public Health England staff. Inspections usually last one day and include a review of the required documentation, staff training records and patient records, as well as discussions around management and governance systems, practice within the facility and radiation protection culture. Generally, inspections are announced but where appropriate e.g. in response to a serious incident, inspections may be unannounced. However, the IRRS team has been informed that no unannounced inspections have been performed during the last three years. The IRRS team was informed that RQIA has good links with the HSENI. Information is shared where appropriate and joint inspections also take place where appropriate.

The IRRS team notes that while the CQC has undertaken improvement of the inspection process relating to radiation safety during the last two years, the new process does not include regular inspection of every facility and activity with a frequency for inspection determined based on the risk associated with facilities and activities in accordance with a graded approach. Both the HIW and HIS's policy and inspection programmes also do not establish a frequency of inspections for facilities and activities in accordance with a graded approach based on the associated risk. Additionally, the inspection process of HIW, HIS and RQIA does not include unannounced inspections and criteria for conducting unannounced inspections are not established.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *CQC, HIW and HIS do not have a programme of inspection that includes the frequency of inspections for all facilities and areas and programmes to be inspected, in accordance with a graded approach. This has been recognized in the action plan of CQC, HIW and HIS as applicable.*	
(1)	**BASIS: GSR Part 1 (Rev 1) Requirement 29 § 4.50 states that** *" "The regulatory body shall develop and implement a programme of inspection of facilities and activities, to confirm compliance with regulatory requirements and with any conditions specified in the authorization. In this programme, it shall specify the types of regulatory inspection (including scheduled inspections and unannounced inspections) and shall stipulate the frequency of inspections and the areas and programmes to be inspected, in accordance with a graded approach".*
(2)	**GSR Part 1 (Rev 1) Paragraph 4.52 states that** *"inspections shall cover all areas of responsibility of the regulatory body, and the regulatory body shall have the authority to carry out independent inspections. Provision shall be made for free access by regulatory inspectors to any facility or activity, at any time, within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences. These inspections may include, within reason, unannounced inspections. The manner, extent and frequency of inspections shall be in accordance with a graded approach".*
R15	**Recommendation: CQC, HIW, and HIS should develop a programme of inspection that includes the frequency of inspections for all facilities and areas and programmes to be inspected, in accordance with a graded approach.**

7.10. INSPECTION OF PUBLIC EXPOSURE

Inspection with respect to public exposure is essentially for planned exposure situations which consist of Inspections by environment agencies of the respective jurisdiction across UK with respect to Nuclear Licensed Sites (NLS) and non-NLS.

The environment agencies indicate the inspection frequency for each practice in their documents the frequency of which is based on general level of compliance and operator stability. Inspections include both site inspections and desk-based inspections. The majority of inspections carried out are announced, as this is more productive for the environment agencies and less disruptive for the authorized parties. However, they retain the ability to carry out unannounced inspections. The inspections are carried out in a graded approach with the General Binding Rules (in

Scotland). The environment agencies also periodically carry out themed inspections for NLS (around 5 in a year). Such inspections focus on a particular area of compliance with an authorization/ permit. On occasion, themed inspections may be carried out in conjunction with other regulators where there are areas of common interest. All other non-nuclear facilities are between once in five years to annual depending on the hazard potential.

7.11. SUMMARY

The IRRS team identified some areas for improvement for inspection in the following areas:

- Expectations on general surveillance of facilities through ONR inspection
- Guidance on inspection frequency to ensure a graded approach to EA inspections for nuclear facilities
- Guidance on inspection frequency and scope for HSE, HSENI, and ONR radiation sources safety related inspections covering all applicable facilities
- Guidance to ensure all relevant safety areas are addressed in HSE, HSENI, and ONR occupational exposure inspections
- Guidance on inspection frequency and scope for CQC, HIW and HIS medical exposure inspections covering all applicable facilities.

8. ENFORCEMENT

8.1. ENFORCEMENT POLICY AND PROCESS

Nuclear installations

The primary legislation providing the legal bases of enforcement by ONR in relation to nuclear licensed sites is through relevant provisions of the Nuclear Installations Act 1965 (NIA65), the Health and Safety at Work etc. Act 1974 (HSWA) and the Energy Act 2013. The Health and Safety (Enforcing Authority) Regulations 1998 (SI 1998/494) makes ONR the enforcing authority for HSWA and its relevant statutory provisions on New Nuclear Build (NNB) sites immediately adjacent to a nuclear licensed site. The enforcement powers in relation to ONR's nuclear site health and safety purposes or nuclear safety purposes are the same.

The regulatory landscape in the UK is complex, and other governmental bodies may need to be informed of ONR enforcement actions. ONR has memoranda of understanding with a number of governmental organisations. However, exchange of information in case of enforcement actions is not fully formalised, and not addressed in enforcement related guidelines.

ONR and the environmental regulators (EA, NRW, SEPA but not NIEA since there are no nuclear licensed sites in Northern Ireland) have all established and implemented enforcement policies, in line with the UK Regulators' Code, setting out the general principles and approach related to enforcement. These policies typically imply the use of a graded approach (proportionality), consistency, transparency, targeting and accountability.

ONR's guidance to inspectors on taking enforcement decisions is based on the ONR Enforcement Management Model (EMM), a guideline providing a systematic and logical approach to assist inspectors when considering and making enforcement decisions. Similar guidelines are in place at the environment agencies (EA Offence Response Options; SEPA Enforcement Guidance; NRW Guidance on Enforcement and Sanctions). The guidelines include criteria to define the appropriate level of enforcement. In deciding this level, the models assess the risk level considering actual or potential consequences as well as control measures in place. ONR also considers aspects related to the actions and attitude of the licensee, through the application of authorized party Factors or Public Interests Factors (environment agencies).

Generally, there is a somewhat lower level of formalisation in the work processes of the national environment agencies than within ONR. There are also some differences between EA/NRW and SEPA, but in practice, a high degree of coordination appears to have been achieved through frequent interaction, coordination and co-operation, e.g., through participation in the Nuclear Industry Liaison Group (NILG) and in regulatory fora for EDF and Magnox Limited. Guidance documents are often jointly developed and issued, which is seen by the IRRS team as a good performance. Transparency is, however, somewhat limited, with documentation available only at agency offices.

The application of a graded approach is the basis for enforcement for all regulators, i.e., the enforcement action taken shall be commensurate with the safety significance of the non-compliance. The levels of enforcement actions start with verbal advice (which is in practice documented) followed by a range of methods of formal enforcement, including Enforcement Letters, Improvement or Prohibition Notices, and prosecution. The enforcement processes in England and Wales are similar but those in Scotland differ. This applies especially to prosecution, where regulators have the power to prosecute in England and Wales but can only recommend prosecution to the Crown Office and Procurator Fiscal Service (COPFS) in Scotland. Another example concerns penalties, where SEPA has the powers to impose monetary penalties on authorized parties, which is not possible for the ONR or for environmental regulators in England and Wales.

The IRRS team was informed by both ONR and the Environment Agency that Sellafield is a special case with a high number of hazardous facilities and associated challenging regulatory issues. The ONR priority for Sellafield is high hazard and risk reduction, targeting the areas of highest risk. As a result, ONR and EA have introduced a new and innovative regulatory strategy to help drive improvements at Sellafield, aiming to facilitate and encourage hazard and risk remediation whilst maintaining adequate safety standards. One of the themes of this new strategy is the avoidance of distraction and diversions – removing unnecessary demands on the licensee, diverting attention away from the overriding priorities. This means that the graded approach to enforcement takes into account the unique nature of the challenges faced at Sellafield.

Enforcement actions are communicated with the licensees before being served, in order to get feedback on the timescale and to make sure required actions are understood. Appeal of enforcement Notices is included in TEA13 and HSWA74, but rarely done. For ONR Improvement or Prohibition Notices, appeal is possible through an Employment Tribunal. For ONR enforcement decisions and actions under NIA65, the formal appeal route is to the Chief Executive Officer of ONR.

For the environment agencies, appeal of enforcement decisions is possible through the Planning Inspectorate in England and Wales, in Scotland through the Scottish Ministers. Information received from licensees indicates that appeal is rarely done, even when there is a difference in opinion about whether or not an enforcement decision is justified. The potential gain of an appeal is said to be balanced against the possible impact on the relationship with the ONR and other factors.

Transport of radioactive material

The enforcement policy and procedures of HSE and HSENI are very similar to those applied by the ONR and the environment agencies (EA, NRW, SEPA and NIEA).

Enforcement of civil Transport Activities on road, rail or inland waterway in Great Britain is done by the ONR, under the same enforcement regime as for nuclear installations.

In Northern Ireland, NIEA is designated as the competent authority for the transport of radioactive material by road. Enforcement Guidance is by the NIEA Quality Procedure for Enforcement. If an inspector decides that a non-compliance requires enforcement action, quality procedure "Transport of Radioactive Substances (Inspections)" provides guidance on enforcement options and procedures. All investigations and enforcement action are recorded on the Schedule of Investigations.

The Civil Aviation Authority (CAA) is responsible for enforcement related to air transport. Inspection and enforcement powers for air transport derive from the Civil Aviation Act 1982 and European Commission Regulation No 965/2012. Where necessary, the CAA works with the ONR. The CAA is tasked by the Department for Transport to investigate and prosecute breaches of aviation safety rules. For dangerous goods offences the CAA is both the investigation and prosecuting body throughout the UK, except in Scotland where the prosecution would be the purview of the COPFS.

The Maritime and Coastguard Agency (MCA) is responsible for enforcement related to sea transport. The enforcement powers used by the MCA are set out in the Merchant Shipping Act (MSA) 1995 and the associated secondary legislation. The MCA takes action when deficiencies are found in relation to statutory requirements applicable to UK vessels and non-UK flagged vessels when in a UK port or UK waters, where these requirements are made under the MSA. There is a documented set of enforcement instructions for Marine Office surveyors and for Enforcement Branch if it is found that that the vessel has contravened UK requirements. The MCA can use Prohibition and Improvement Notices or in more serious cases, detention of the ship. At a national level, the enforcement team can take forward prosecutions when there are serious breaches of the regulations.

Radiation sources, occupational radiation protection and medical exposure

The approach on enforcement taken by HSE and HSENI is set out in the Enforcement Policy Statement, which lays out the general principles that HSE expects health and safety enforcing authorities to follow. Alongside these high-level principles, the Enforcement Management Model (EMM) has been developed for operational use by inspectors, which has also formed the basis for HSE/HSENI's specific EMM for ionising radiations. The EMM documents are a guide to inspectors on what enforcement action is appropriate for particular circumstances and provides a level of consistency on enforcement action. Enforcement actions available to HSE/HSENI inspectors include verbal advice, letters (in HSE these are known as Notifications of Contraventions), letters/compliance reports (HSENI), Improvement Notice, Prohibition Notice, and prosecutions. For Improvement Notice, the party on which the notice is served is required to remedy the deficiencies within a given timescale and to inform HSE/HSENI of the action taken. Enforcement actions are recorded and kept in registers by the respective regulatory body.

IR(ME)R17, IR(ME)R18, HSWA74 and HSWO(NI)O78 provide the relevant enforcement authorities with the legal framework for enforcement. When Improvement or Prohibition Notices are served, guidance notes accompanying the notice provide details of how to appeal to an employment tribunal.

CQC has established and implemented an enforcement policy statement to respond to non-compliance with regulatory requirements. Inspectors have the power to serve a formal notice such as an Improvement Notice or a Prohibition Notice. An Improvement Notice will require the employer or other authorized party to take remedial action, usually within a specified timeframe. Where a person's activities involve or may in the future involve a risk of serious personal injury, the inspector may serve a Prohibition Notice directing the employer to immediately interrupt the activity causing risk. Inspectors can also use criminal law procedures to initiate the process to prosecute authorized parties for failing to meet their legal requirements under HSWA74. To date, there have been no prosecutions under IR(ME)R17 or IR(ME)R18. The inspectors can also include recommendations in the inspection report. The employer is then required within 6 weeks to provide inspectors with an action plan addressing the issues highlighted in the inspection report. Follow-up of inspection findings will be dependent on the types of non-compliance and on the associated level of risk.

HIS has implemented the HSE's Enforcement Management Model as the basis for ensuring decisions are open and transparent.

HIW has established and implemented a general enforcement policy to respond to non-compliance with regulatory requirements, which is intended to support enforcement that is proportionate to the level of risk. At the end of every inspection, the inspection team will provide a summary of its findings, which will include advising the employer of any potential enforcement action. HIW's enforcement approach is split into three levels: business as usual, Improvement or Prohibition Notice, or prosecution. Depending on the nature of non-compliance, HIW will identify the most appropriate method to confirm that action has been taken. The method of follow-up will be dependent on the types of non-compliance and level of risk. Where immediate patient safety issues are identified these will be brought to the attention of the employer immediately and confirmed in writing within 48 hours of completing the inspection. The employer must confirm within one week what action has been taken to mitigate the risks identified.

RQIA has established and implemented a general enforcement policy to respond to non-compliance with regulatory requirements. RQIA also have an IR(ME)R17 and IR(ME)R18 policy and procedure which sets out guidance and criteria for different enforcement tools. For a more serious breach, an enforcement decision meeting will be held between the inspection team, the assistant director, and the director of the Improvement Directorate. An Improvement Notice may be used where a person is in breach of legislation and the notice will state the time by which matters must be remedied. In situations where an activity involves, or may in the future involve, a risk of serious personal injury the inspector may serve a Prohibition Notice.

CQC, HIW, HIS and RQIA inspectors have established criteria for corrective actions in their respective enforcement policies. There is a legal framework to issue enforcements on the spot and seal, cease or disarm equipment if the risk is considered to be serious and persistent. Enforcement actions are published; they are also recorded and kept in registers by respective regulatory body.

Fuel Cycle Facilities

For FCFs, as for other nuclear installations, the enforcement framework for both front-end and back-end fuel cycle facilities is the same as for nuclear installations throughout the period of operation, from construction to decommissioning. The ONR, as the nuclear licensing authority and regulator of nuclear safety on nuclear licensed sites, is responsible for enforcement of statutory and regulatory requirements for the FCFs. This is done using the same EPS and EMM that apply to other types of licensed nuclear installations.

The relevant environment agencies have powers to take enforcement action against regulated facilities and activities where there has been noncompliance with regulatory requirements and any limitations and conditions specified in authorisations. Each environment agency has enforcement policies and guidance detailing the different steps in the enforcement process.

Public Exposure

EA95 allows EA, NRW and SEPA to investigate breaches of conditions or limits set in an environmental permit, and the agencies have the power to remove radioactive waste from any premises. Similar powers are given to NIEA by RSA93. EA and NRW have a range of powers under EPR16 to take enforcement action, including variation and variation and surrender of an Environmental Permit as well as to issue Enforcement Notices and Suspension Notices. EA and NRW may specify the steps that must be taken to remedy the contravention or remove the risk when issuing a notice. EA95 also gives powers of entry and powers to deal with causes of imminent danger of serious pollution.

SEPA has a range of powers under EASR18 enabling it to fulfil its regulatory functions including powers to require the provision of information, to impose authorisations, to escalate and deescalate authorisations and to dispose of radioactive waste in circumstances where there is reason to believe this will not be done lawfully otherwise.

NIEA has a range of powers under RSA93, allowing the Chief Inspector to revoke or vary the conditions of an authorisation granted. NIEA may also issue an Enforcement Notice requiring the holder of an authorisation to take steps to remedy matters constituting a failure to comply with the limitations or conditions, and issue a Prohibition Notice requiring the holder of an authorisation to take steps to remove a risk of imminent pollution of the environment or harm to human health.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Other governmental bodies may need to be informed about ONR enforcement actions. Exchange of information on enforcement actions is not fully formalised, and not addressed in enforcement related guidelines.*	
(1)	**BASIS: GSG-13 para. 3.46 states that** *"…Guides should also indicate which other governmental organizations, if any, are to be informed in the event of enforcement actions".*
(2)	**BASIS: GSG-13 para. 3.314 states that** *"Procedures should stipulate which other governmental bodies, if any, should be informed in the event of enforcement actions being taken".*
S14	**Suggestion: The ONR should consider improving its guidance to indicate which other governmental organizations are to be informed of its formal enforcement actions.**

8.2. ENFORCEMENT IMPLEMENTATIONS

Non-compliances can be revealed in a number of ways by inspectors when carrying out their core assessment and inspection activities and may be related to safety risks or based on compliance or administrative shortfalls. When it is judged that it is proportionate to do so, these non-compliances may then be investigated in accordance with ONR's process for conducting investigations. The ONR EMM is used to consider the level of risk or compliance gap and to identify proportionate enforcement actions to secure compliance.

ONR inspectors utilise a variety of enforcement tools to deal with safety risks and to secure compliance. These range from regulatory advice (18 in period April 2018 to September 2019), an Enforcement Letter (33), to issuing Specifications (none), Directions (1), Improvement Notices (8) and Prohibition Notices (none). Inspectors can also institute proceedings (England & Wales) or recommend prosecution (Scotland) where the circumstances warrant it (9 investigations initiated resulting in 3 prosecutions). Enforcement decisions are periodically reviewed for consistency across all ONR regulatory divisions. The latest review, issued in March 2019, gives recommendations on, e.g., strengthening of training, improvement of the CNI Office's Enforcement Database, and sharing of enforcement decisions among different inspectors (nuclear safety, security, safeguards).

For ONR it is worth noting that a substantial proportion of enforcement actions are related to conventional safety, especially for higher-level actions. Thus, almost all prosecutions have been due to workplace accidents where actual harm has occurred.

On-the-spot enforcement by ONR inspectors in case of a risk of serious personal injury is possible. This is typically done using a Prohibition Notice. Inspectors from the environment agencies have similar powers based on the Environmental Act, which gives the authority to intervene immediately.

Effective implementation of the necessary corrective actions is tracked by ONR through the Regulatory Issue (RI) database, with the Level of the RI being graded (e.g. Level 2 for an Improvement Notice and Level 3 for an Enforcement Letter). The RI(s) raised cannot be closed until the licensee has complied with the requirements of the formal enforcement action.

In addition, the Chief Nuclear Inspector's Office Enforcement Database has been developed in April 2018. The database tracks all enforcement actions, ranging from Advice from the inspector, through Enforcement Letters, Notices (Improvement or Prohibition Notice) up to Investigations and Prosecutions. Background, progress and closeout are tracked for all database items. The introduction of the CNI Office's Enforcement Database to document the initiation, progress and closure of all ONR enforcement actions is seen by the IRRS team as a notable improvement, allowing an efficient overview of the status of open items, and supporting consistency over time in the application of enforcement.

At the environment agencies, systems are in place to record, track and close out formal enforcement actions. The EA Compliance Classification Scheme Database (CCS) records enforcement actions proposed and the Case Management System CMS (database) records enforcement actions taken. NRW captures non-compliances on a dedicated database that tracks the non-compliance and the related enforcement activity. The tracking systems include the CCS, the Wales Incident Recording System (WIRS) and the Contravention Offence Legal Information Notification system (COLINS). At SEPA, formal enforcement actions, including potential reports to the Crown Office and Procurator Fiscal Services (COPFS) for consideration of prosecution and monetary penalties, are recorded on a SEPA-wide spreadsheet, which is held and maintained by SEPA's Legal Department. Authorisation contraventions are recorded by the relevant site inspector within SEPA's Compliance Assessment Scheme (CAS). The completion of operator actions to address contraventions is verified by the site inspector, and the compliance status of contraventions are monitored by the site inspector.

A graded approach is taken at ONR to managing regulatory issues, where the most significant issues receive the most senior management control and scrutiny. If there are concerns regarding the timescales and/or quality of delivery of corrective actions, regular reviews by the appropriate management group will identify that sub-standard performance and may decide to elevate the enforcement level of that issue such that it receives a suitable increase in management attention, both by ONR and the authorized party.

Training on enforcement of ONR inspectors is part of mandatory inspector training (including an e-learning module). A limited warrant, which does not allow formal enforcement, is issued to new inspectors when they join ONR. Full warrants are only issued to inspectors who 'are judged by ONR to be suitably qualified to carry out the functions that ONR authorises the person to carry out'. Attaining a full warrant typically takes 12-18 months. At EA and NRW, training on enforcement tools and approaches are part of the requirements to obtain a warrant, and a Level 2 warrant is needed to be allowed to enforce formally. For SEPA the training approach is more ad hoc, based on the new inspector's background, supplemented by onsite training together with an experienced inspector, which includes training in enforcement. The need for a more structured competence process and training programme has been identified as a gap.

For the environment agencies, the regulatory emphasis is on prevention of non-compliance. Higher-level enforcement cases are infrequent and maintaining formal investigation and enforcement experience is therefore seen as a challenge. However, expertise can be utilised from their wider organisations, which deal with enforcement on a more routine basis. EA regulatory officers are also trained in formal investigation processes under the Police and Criminal Evidence Act (PACE) and the Criminal Procedures and Investigations Act (CPIA).

ONR will typically have a relatively high number of lower level enforcement decisions but identifies it as a significant challenge to build up and maintain core competence for investigation, which might follow preliminary enquiries. Whilst many notifications are received, there are (as expected) far fewer cases in which, perhaps following preliminary enquiries, an inspector is of the opinion that an investigation should be conducted. This means that inspectors will rarely be involved in an investigation making on the job training for investigation a

challenge. A number of actions are ongoing to remedy the situation, including the formation of an Investigation Governance Resources Group (IRG) receiving special training in conducting investigations. However, the ONR sees a need for further work to be done to establish investigation as a core competency and hence reduce the risk of a prosecution authorised by the ONR to proceed following an investigation failing because of non-compliance with the requirements of the CPIA (the Criminal Procedure and Investigations Act 1996).

8.3. SUMMARY

The nuclear safety regulator (ONR) and the relevant environment agencies (EA, NRW, SEPA, NIEA), as well as the regulators involved for other types of facilities and activities, have all established and implemented enforcement policies, in line with the UK Regulators' Code. The application of a graded approach is the basis for enforcement for all regulators, and guidance documents have been developed to assist inspectors when considering and making enforcement decisions. The legal framework and its implementation are in general judged to be in line with IAEA safety standards and guidelines. However, the following area for improvement in enforcement was identified:

- It is suggested to the ONR to consider improving its guidance to indicate which other governmental organizations are to be informed of enforcement actions.

9. REGULATIONS AND GUIDES

9.1. GENERIC ISSUES

The legal basis for health and safety at work regulation in the UK is HSWA74 and the Health and Safety at Work (Northern Ireland) Order 1978 in conjunction with TEA13 and NIA65. HSWA creates a number of general health and safety duties upon employers and individuals as well as providing for the creation of regulations. HSWA, the Order and regulations that sit beneath them, including IRR17/IRRNI17, apply to all sectors. Regulations are made by the Government and are legally binding.

The UK regulatory regime is generally goal-setting which means the authorized party has to determine and justify how to adequately achieve the legally-required goals. An example is the legal duty upon authorized parties to reduce risks to health and safety in so far as is reasonably practicable (SFAIRP) which is analogous to reducing risks to be ALARP or radiation doses to be ALARA.

Nuclear sites are required to have a licence which is granted by ONR in line with NIA65. ONR attaches LCs to all site licences covering the range of activities across the lifecycle of a facility. The LCs are also generally goal-setting and mostly require a nuclear site licensee to make and implement adequate arrangements. It is a legal requirement that any licence condition must be adhered to and ONR can undertake enforcement action against non-compliance. Environmental and public protection legislation (e.g. EA95, EPR16) requires that permits or authorisations be obtained to store, use or dispose of radioactive materials and/or wastes. Conditions may be attached to these permits or authorisations by the appropriate environmental regulatory body.

Internal guidance that is used by regulatory bodies to judge the adequacy of an authorized party's approach is not legally binding but describes in more detail what is required to comply with the law. The guidance specifies criteria against which the regulatory bodies will judge compliance against the relevant legislation. It is the basis for regulatory assessment and enforcement and is admissible in a court of law. The guidance is considered to be relevant good practice (RGP); that is, it describes what actions and measures are generally considered to achieve the ALARP objective with regard to a particular topic based on what has been undertaken in similar circumstances and is already known to comply with legal requirements. RGP is not static: guidance is updated as national and international safety standards change and as new technologies and techniques emerge.

The hierarchy of regulatory health and safety guidance includes approved codes of practice (ACOPs), established guidance and interpretative guidance. ACOPs are documents written by the regulators, subject to consultation with various parties, that set out the details of an approach that meets legal requirements (for example, compliance with UK legislation relating to the risks from asbestos exposure at work). ACOPs are issued by the regulator subject to consent from the Minister. Codes of practice proposed under TEA13 must also be laid before Parliament. ACOPs are not regulations in themselves but have a special legal status; if an authorized party chooses not to follow the advice set-out in the ACOP, the onus falls upon it to demonstrate how it has achieved compliance with the law through an equally-good alternative approach.

Regulatory bodies have established guidance that is regarded as RGP but this does not have the special legal status of an ACOP. The ONR SAPs, SyAPs, TAGs and TIGs are examples.

Other relevant interpretative guidance is not authored by the regulatory bodies themselves but by national and international expert bodies (such as standard-setting or professional organisations) and the industry itself (such as discussion fora or cross-industry working parties).

The UK's legislative framework, with a hierarchy of high-level principle documents and more detailed guidance documents as RGP, enables the use of graded approach depending on the hazard and risks. For example, ONR guidance documents are mostly applicable to all nuclear facilities (any restrictions are mentioned in the introduction), but the detailed applicability can be discussed case by case depending on the size of the hazard. An example of this is provided by ONR's SAPs numerical targets which become more onerous as the potential consequences increase. This in turn will require more, and/or better, engineering and operational safety features. Another example is ONR's regulatory expectations on the safety function categorisation and structure, system and component classification (NS-TAST-GD-094).

The BSS Directive advises that its provisions should be implemented in line with a graded approach, which should take into account the potential magnitude and nature of risks posed by the installation. IRR17/IRRNI17 apply this graded approach. The transport regulations apply a graded approach with higher-hazard transport subject to an authorisation regime in which designs and activities require approval from the appropriate competent authority.

The UK's approach is that changes in the law are needed only infrequently. Such changes are typically resulting from a need to make legally-binding changes to the regulatory regime – for example, the replacement of the Radiation (Emergency Preparedness and Public Information) Regulations 2001 by the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR) which have been revised to align with the EU BSSD – or from a need to put into effect changes in the regulatory bodies – for example TEA13 which, amongst other things, established the ONR. There are parliamentary procedures to provide information to the public on the proposals, debating and passing of legislation. Primary legislation also provides rules for consultation when preparing regulations. A specific communication plan was prepared for the transposition and implementation of the BSSD into IRR and REPPIR.

Regulatory bodies have processes in place to review and revise regulatory guidance. Review and revision can be needed because of, for example:

- Changes in the overarching legislation that need to be reflected;
- Evolution in regulatory expectations against goal-setting requirements. For example, in the evolution of applicable RGP, or in the evolution of best available techniques for environmental and public protection;
- Changes in relevant national or international standards.

Regulatory bodies have processes in place to keep the public and authorized parties informed of new or revised guidance and to make such guidance available via websites. The exact processes and procedures vary between the regulatory bodies and the nature of the guidance. ONR processes for developing and updating its regulatory guidance explicitly include consideration of relevant international safety standards and all their guidance documents have a dedicated section in the beginning of the document. Due to SEPA's wide ranging role, SEPA's document control and review procedures are generic across all SEPA's environmental responsibilities and therefore the processes and procedures need to be generic to a certain extent. However, for the development of radioactive substance specific guidance, there is a review group (the Radioactive Substances Regulatory and Policy Support Group, RASRAP) whose task is to provide a focus for the co-ordination of the development and maintenance of policies, procedures, templates and guidance. Although RASRAP takes into account the IAEA Safety Standards when reviewing guidance, the terms of reference for RASRAP do not explicitly mention this. The same applies to other organisations (EA, NRW, NIEA, HSE, HSENI, and CQC), where the process to keep national regulatory guidance consistent with safety standards as they evolve is not yet formalized.

The UK is implementing a new process to improve co-operation between regulatory bodies and government in the development of IAEA Safety Standards. This will be co-ordinated by BEIS and monitored via regular meetings between the relevant bodies. The UK representatives on each Safety Standards Committee, supported by the relevant RBs, are responsible for understanding the implications of the guidance before it is finalized. This process will feed into an internal ONR guidance review process and the relevant document owners (primarily TIG and TAG owners). This is considered to be a good development, but it still needs to be ensured that the cooperation process feeds into every relevant regulatory body's guidance review process.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Regulatory bodies' processes do not explicitly consider the review and update of the regulatory guidance to include applicable IAEA safety standards.*	
(1)	**BASIS: GSR Part 1 Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained."*
R16	**Recommendation: The EA, NRW, SEPA, NIEA, HSE, HSENI and CQC should further develop processes and procedures for the establishment, review and update of regulatory guidance to**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	include applicable IAEA safety standards.

The environment agencies (EA, NRW, SEPA, NIEA) and health and safety agencies (HSE, HSENI and CQC) in accordance with applicable legislative or regulatory requirements, consult interested parties using variety of engagement methods. For example, the environment agencies hold public consultations concerning new authorizations or significant changes to them, and also make judgements on a case by case basis concerning the updated regulatory guidance depending on the scope of the guidance under review and the potential significance for regulatory decision making. Many examples exist on their websites. There is further discussion on how ONR could develop its approach to public consultation in sub-chapter 3.8.

9.2. REGULATIONS AND GUIDES FOR NUCLEAR POWER PLANTS

UK occupational health and safety legislation applies to all workplaces, including nuclear sites licensed under NIA65, which must also adhere to the LCs which are publicly available via the ONR website. Many LCs are also goal-setting, requiring a licensee to "make and implement adequate arrangements" in respect of different topics. Altogether, the legislation and the 36 LCs provide the basis for ONR's regulation of nuclear safety.

The EA, NRW and SEPA regulate public exposures and protection of the environment at NPPs in England, Wales and Scotland, respectively (see sub-chapter 9.10). There are no nuclear sites in Northern Ireland. The legislation governing radioactive substances and the accumulation and disposal of radioactive waste is EPR16 in England and Wales, and EASR18 in Scotland. Environment agencies publish more detailed guidance and they have also produced a number of joint guidance documents.

ONR has established SAPs that guide its regulatory judgments when undertaking technical assessment of licensees' safety submissions. They are also used to inform ONR pre-licensing assessments and generic design assessments from requesting parties. The SAPs provide overarching nuclear safety principles and are benchmarked against the higher-level principles in IAEA Safety Standards. The SAPs are goal-setting and are supported by a suite of around 70 TAGs that expand upon the RGP, taking into account IAEA safety standards. ONR also has a suite of TIGs that complement the TAGs and provide guidance on the planning and conduct of inspection activities.

The UK regulatory system was discussed during the review with the conclusion that the SAPs are used as a reference for technical judgments on the adequacy of licensees' safety cases to determine whether the law has been met. The level of detail in the SAPs is generally equivalent to that provided by the regulations of other countries and covers the IAEA safety requirements. Although the TAGs and TIGs are not directed at licensees, these are made available via the ONR website and provide non-mandatory guidance on how to comply with regulatory requirements. TAGs and TIGs can also be referenced in ONR's decisions and regulatory observation documents as stating regulatory expectations for such things as the review of safety cases. The level of detail provided by TAGs and TIGs is generally equivalent to regulatory guides published in other countries and IAEA Safety Guides. They are expected to be followed unless differences are separately stated (for example higher level expectations coming from WENRA reference levels for operating NPPs and safety objectives for new reactors). The updated European Nuclear Safety Directive (2014) was implemented in the UK mainly by updating TAGs.

ONR undertakes regular reviews of its LCs (last completed in 2018) and its SAPs (last completed in 2014). Reviews of supporting TIGs and TAGs are undertaken approximately every 3 years.

The LCs were fundamentally reviewed and rearranged into a standard set in 1990 and LC36 was added in 2000. ONR then reviewed the LCs in 2015-2018 with a view to developing options for streamlining, and removal of ambiguities, to ensure that their condition was relevant to the modern nuclear industry. This review was done internally by ONR and discussed with the industry and other relevant organisations. At the end of the review project, ONR decided that since none of the findings were urgent and in view of the cost and effort (both to the industry and to ONR) that a revision of the LCs would entail, the project should be placed on hold. The IRRS team was however informed that the project will resume in the near future. ONR's target is to review the LC around

every ten years but this target is not documented in the management system. In the next revision of the LCs, it is recommended that interested parties should be consulted, including the public (see sub-chapter 3.8).

The 2006 revision of the SAPs drew from earlier ONR (and predecessor organisations) publications from 1979 to 1992, and taking into account the evolution of RGP, developments in regulation and operational experience, both internationally and nationally. The 2014 revision was initiated by the lessons learnt from the TEPCO Fukushima Daiichi accident and the changes in the IAEA safety standards. The draft document was made available for public consultation on the ONR website.

ONR has a general process for developing regulations and guides which applies to SAPs, SyAPs, TIGs, TAGs and other regulatory guidance. ONR's KPI target is that at least 90% of the TIGs and TAGs should be reviewed and updated every 3 years, and the target is currently being met. The process also describes consultation with industry and other relevant regulatory bodies when considered necessary. There is no consultation with the public when drafting TIGs and TAGs, although the final documents will be published on the ONR website with the opportunity for authorized parties and members of the public to provide feedback.

Updated regulatory guidance is taken into account in the routine permissions that are issued by ONR and licensees are expected to make an assessment of reasonably practicable safety improvements in the short term PSRs and in PSRs carried out every 10 years (see chapter 6).

9.3. REGULATIONS AND GUIDES FOR FUEL CYCLE FACILITIES

The regulations and guides for FCFs (both front-end and back-end fuel cycle facilities) are the same as for NPPs throughout the period of operation, from construction to decommissioning. The EA, NRW and SEPA regulate environmental and public protection at fuel cycle facilities in England, Wales and Scotland, respectively. These agencies work closely with ONR to ensure a consistent regulatory approach in areas of mutual interest – such as the storage and release of radioactive materials. There are no fuel cycle facilities in Northern Ireland.

9.4. REGULATIONS AND GUIDES FOR WASTE MANAGEMENT FACILITIES

ONR regulation of nuclear safety during the design, construction, commissioning and operations of RAW management facilities at nuclear sites is similar to that described earlier for NPPs, utilising the SAPs, LCs, TIGs and TAGs. ONR guidance specifically relating to the RAW management includes SAPs RW.1-7, TAG NS-TAST-GD-024; LCs 32, 33 and 34 and the TIGs for LCs 32-34 (NS-TAST-GD-032, -033 and -034, respectively). For higher activity waste, ONR is responsible for ensuring that it is managed safely and securely by the operator in an appropriate manner for storage and eventual disposal. The environment agencies are responsible for ensuring that the resulting waste packages are suitable for disposal, with environmental protection considered. GDF is expected by the Government to be a nuclear licensed site.

The environment agencies issue permits/authorisations to operators managing RAW. These permits/authorisations contain conditions which must be adhered to and provide the basis for the regulatory regime. E.g. the licensees are expected to have their own RAW management plan, however following the graded approach principle, the extent of such a plan may be limited to few pages. EA, NRW and SEPA require operators of RAW management facilities to have in place a waste management plan. This is not currently a requirement of NIEA. All the environment agencies use standard application forms (with accompanying guidance) and authorisation templates which apply to different types of RAW management activities, whether on a nuclear or non-nuclear site.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *In Northern Ireland, operators accumulating RAW do not have in place a waste management plan identifying the interdependencies in RAW management. This finding was also identified by the NIEA in their Action Plan.*	
(1)	**BASIS: SSG 45, para. 3.30 states that** *"Depending on the complexity of the operations and the*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	magnitude of the hazards associated with the facility or the activities concerned, the operator has to ensure an adequate level of protection and safety by various means" (GSR Part 5 [3], para. 3.11). These means should include: … *(d) Establishment of a radioactive waste management strategy that includes all waste under the control of the operator, including waste that has arisen from past practices, taking into account interdependences among all steps in waste management, the available options and the national radioactive waste management policy and strategy, as far as applicable."*
S15	**Suggestion: The NIEA should consider requiring permit holders of non-nuclear sites to have in place RAW management plans identifying the interdependencies in RAW management including the disposal option.**

The environment agencies consider RAW in closed disposal facilities, once the permit has been surrendered, not to be classed as radioactive waste for the purpose of regulation, and so be out of the scope of the legislation. However, the disposed waste becomes subject to regulation again by the environment agencies if it is subjected to a process which causes an increase in radiation exposure. However, disposal facilities aim to provide isolation of RAW for at least hundreds of years and institutional control needs to be performed up to 300 years. The provisions of the guidance document may release the permit holder from its duties after closure of a disposal facility.

The document "Principles for the Assessment of Prospective Public Doses arising from Authorised Discharges of Radioactive Waste to the Environment" provides guidance on the assessment of doses to members of the public for the purposes of permitting or authorising discharges of RAW to the environment. However, the disposal facility has to provide containment of RAW until radioactive decay has significantly reduced the hazard it poses. Any significant releases of radioactive substances from the disposal facility during the operational phase requires immediate action by the licensee.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The environment agencies do not consider RAW in closed disposal facility, once the permit has been surrendered, is no longer "radioactive waste" although it may still be radioactive. Also, the concept of discharges of liquid and gaseous radioactive waste into the environment indicate, that environment agencies consider that planned and controlled release of (usually gaseous or liquid) radioactive substances to the environment occurs during the operational and post-closure phase of disposal facility lifetime.*	
(1)	**BASIS: SSR 5 Requirement 8 states that** *"The engineered barriers, including the waste form and packaging, shall be designed, and the host environment shall be selected, so as to provide containment of the radionuclides associated with the waste. Containment shall be provided until radioactive decay has significantly reduced the hazard posed by the waste…".*
(2)	**BASIS: SSR 5 Requirement 9 states that** *"The disposal facility shall be sited, designed and operated to provide features that are aimed at isolation of the radioactive waste from people and from the accessible biosphere. The features shall aim to provide isolation for several hundreds of years for short lived waste and at least several thousand years for intermediate and high level waste …".*
R17	**Recommendation: The environment agencies should make more direct reference to the requirements for isolation and containment of radioactive waste and should clearly indicate in their guidelines that no radioactive discharges are expected from disposal facilities.**

Near-surface Disposal Facilities on Land for Solid Radioactive Wastes, Guidance on Requirement for Authorisation 2009 (NSD-GRA), Requirement 5, contains detailed expectations of environment agencies with regard to dose constraints during the period of authorisation and active institutional control. Passive institutional

control arrangements were discussed with environment agencies during the mission; however the process is not captured in NSD-GRA.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The environment agencies NSD-GRA do not consider passive institutional control period as a specific stage of disposal facility lifetime.*	
(1)	**BASIS: SSR-5 Requirement 22 states that** *"The period after closure and institutional controls Plans shall be prepared for the period after closure to address institutional control and the arrangements for maintaining the availability of information on the disposal facility. These plans shall be consistent with passive safety features and shall form part of the safety case on which authorization to close the facility is granted".*
(2)	**BASIS: SSR-5 Requirement 22, Para. 5.7 states that** *"The risk of intrusion into a disposal facility for radioactive waste may be reduced over a longer timescale than that foreseen for active controls by the use of passive controls, such as the preservation of information by the use of markers and archives, including international archives".*
R18	**Recommendation: The environment agencies should further develop their guide NSD-GRA to clarify the role of and its expectations for passive safety in providing additional assurance of the safety of a disposal facility.**

At the Sellafield site the LLW management facility (see chapter 7.5) was visited and it was observed that soft bags with declared surface dose rates of 2 μSv/h are transferred to the on-site incinerator plant. There is no procedure to clear this waste stream so the operator cannot minimise the amount of waste managed as RAW. Only pre-defined activity concentrations available in guidance document Scope of and Exemptions from the Radioactive Substance Legislation in England, Wales and Northern Ireland are implemented in practice. The authorized party cannot derive case and site-specific activities of radionuclides in its waste stream based on the limitation of effective doses to individuals (in the order of 10 μSv or less in a year and 1 mSv/y for low probability events). The authorized party should have the option to perform calculations to derive case/site specific clearance levels and present those calculations to EAs for permission.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The EA does not have guidance in place to facilitate the clearance of waste material, using case and site-specific activity concentrations, as an effective tool to minimise the amount of waste that needs further management as RAW.*	
(1)	**BASIS: GSR Part 5 Requirement 8 states that** *"… Radioactive waste arisings shall be kept to the minimum practicable".*
(2)	**BASIS: GSR Part 5 Requirement 8, para. 4.9 states that** *"The authorized discharge of effluent and clearance of materials from regulatory control, after some appropriate processing and/or a sufficiently long period of storage, together with reuse and recycling of material, can be effective in reducing the amount of radioactive waste that needs further processing or storage. The operator has to ensure that these management options, if implemented, are in compliance with the conditions and criteria established in regulations or by the regulatory body…".*
(3)	**BASIS: RS-G-1.7, para. 3.4 states that** *"The primary radiological basis for establishing values of activity concentration for the exemption of bulk amounts of material and for clearance is that the effective doses to individuals should be of the order of 10 μSv or less in a year. To take account of the occurrence of low probability events leading to higher radiation exposures, an additional criterion*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	was used, namely, the effective doses due to such low probability events should not exceed 1 mSv in a year …".
(4)	**BASIS: GSR Part 3 Requirement 8 states that** *"The government or the regulatory body shall determine which practices or sources within practices are to be exempted from some or all of the requirements of these Standards. The regulatory body shall approve which sources, including materials and objects, within notified practices or authorized practices may be cleared from regulatory control".*
(5)	**BASIS: GSR Part 3 Schedule I, para I-13 states that** *"Clearance may be granted by the regulatory body for specific situations, on the basis of the criteria of paras I-10 and I-11, with account taken of the physical or chemical form of the radioactive material, and its use or the means of its disposal. Such clearance levels may be specified in terms of activity concentration per unit mass or per unit surface area."*
R19	**Recommendation: The EA should review its approach to clearance, to consider the use of case and site-specific activity concentrations in helping enable the minimisation of radioactive waste production.**

9.5. REGULATIONS AND GUIDES FOR RADIATION SOURCES FACILITIES AND ACTIVITIES

IRR17 and IRRNI17 implement the EU BSSD's occupational aspects. It is based upon IAEA GSR Part 3 and ICRP and Euratom recommendations and specifies the principles, requirements and associated criteria for safety upon which regulatory judgements, decisions and actions are based.

The implementation of the BSSD was a four-year process during which time extensive consultation took place with stakeholders. Various consultation groups were established, and employer groups consulted. An HSE Project Board was established to oversee the introduction of the new IRR and HSE's Board and Regulation Committee sanctioned their recommendations prior to the new regulations being laid before Parliament. Extensive consultation also took place over the new ACOP to the IRR17/IRRNI17, L121 'Work with Radiation'. It is UK government policy that new regulations be reviewed after five years to make sure they are still required and fit for the purpose for which they were intended. IRR17/IRRNI17 are thus due for review in 2022.

The implementation of the BSSD led to the development and revision of the regulations. IRR17/IRRNI17 apply to all work with ionising radiations and control all exposures resulting from work activities. They apply the graded approach through a system of notifications and authorisation via registration and consent. Compliance with these regulations is inspected and enforced by inspectors appointed under the HSWA/HSW(NI)O78.

L121 contains ACOP guidance which was approved by the HSE Board, with the consent of the Secretary of State. It was also approved for use in NI in accordance with Article 18 of the HSW(NI)O78 and with the consent of the Department for the Economy. It gives practical advice on how to comply with legal requirements. If employers follow the ACOP advice they will be doing enough to comply with IRR17/IRRNI17 in respect of those specific matters on which the Code gives advice. If an employer is prosecuted for a breach of the IRR17/IRRNI17, and it is proved that the employer did not follow the relevant provisions of the Code, they will need to show that they have complied with the law in some other equally effective way or a Court will find them to be at fault.

HSE/HSENI produce further guidance for authorized parties when there is a need, an example being the 'Guidance for Notifications, Registrations and Consents' which advises employers how to notify, register or gain consent. HSENI provides equivalent guidance on its website although in many instances it directs authorized parties to more detailed guidance on the HSE website.

IRR17/IRRNI17 are readily available free of charge on the government website and the radiation protection community is fully aware of their existence because of the extensive consultation and publicity prior to their

introduction. Before publishing any additional guidance, HSE first consults with the radiation protection community and relevant professional institutions. HSE also operates an on-line community which is used to communicate with those involved in occupational radiation protection. The BSSD requires IRR17/IRRNI17 to be kept up to date taking into account international standards and particularly the recommendations produced by the ICRP. Thus, if any new exposure criteria, conversion factors, weighting factors etc. are produced by the ICRP it will usually result in an amendment to the regulations IRR and/or associated guidance to take account of these new recommendations. The regulations and guides cover all requirements on safety of radiation sources applications.

Environmental and Public Protection

The environment agencies regulate environmental and public protection aspects associated with the use, storage and disposal of radiation sources. Except where out of scope or exempt from the regulations, the use, storage and disposal of radiation sources requires an appropriate authorisation from the relevant environment agency. All the environment agencies use standard application forms (with accompanying guidance) and authorisation templates which apply to different types of radioactive substances activities and whether on a nuclear or non-nuclear site. In England, Wales and Northern Ireland, guidance is available which outlines if a radioactive substance's activity is out of scope (not subject to regulation) or exempt (where a permit is not required but users will need to comply with the conditions set out in legislation). The BEIS/Defra/NRW/DAERA guidance document, 'Scope of and Exemptions from the Radioactive Substances Legislation in England, Wales and Northern Ireland', August 2018 sets out the rationale underpinning the exemptions regime, the Government's intentions for the legislation, and how Government intends the regime to be interpreted and implemented. In Scotland, Schedule 9 of the Environmental Authorisations (Scotland) Regulations 2018 sets out which radioactive substances' activities are subject to general binding rules and are therefore exempt from notification so long as the rules are followed. All the environment agencies produce a range of guidance, both for operators and for their inspectors, which is made available through the environment agencies' websites.

EA and NRW have both raised actions regarding the need for guidance relating to financial provision for both HASS and non-HASS sites. The environment agencies plan to review their operational instructions and associated guidance for financial provision with a view to explaining more clearly when financial provisions can be applied to non-HASS sites. NRW plans to review the arrangements for financial provision for HASS and where necessary and appropriate, develop and implement formal procedures and guidance related to the existing arrangements. EA intends to review operational instructions and associated guidance for financial provision, with a view to explaining more clearly when financial provision can be applied to non-HASS sources. This is expected to be undertaken in 2020.

Food Irradiation

The Food Irradiation (England) Regulations 2009 and Food Irradiation (England) (Amendment) Regulations 2010, and equivalent legislation as applicable in each of the countries in the UK, require that food irradiation facilities be authorised by the regulatory body before they can irradiate food. FSA is the regulatory body for England, Wales and Northern Ireland whilst FSS is the regulatory body for Scotland.

Review of Regulations and Guides

The UK environment agencies undertake review and revision of guidance when regulations or policies change. EA and NRW also have in place policies and procedures covering the issuing of guidance (EA OI 26_01 and NRW OGN1). SEPA operates RASRAP which produces policy and guidance that are intended to capture decisions that affect SEPA's regulation of radioactive substances and which may result in a change to guidance. All procedures authorised by RASRAP are held on SEPA's document management systems (QPulse) and are subject to routine review in accordance with SEPA policy. Where practicable, consultation with stakeholders is carried out on new and revised guidance, e.g. when changes were made recently to the joint guidance covering the Radioactive Waste Adviser scheme.

Availability and Promotion of Guidance

The environment agencies publish guidance on their respective websites. These documents and any revisions made to them are widely publicised via electronic means such as websites, eBulletins, communities of interest etc. and, if appropriate, via press releases, newsletters etc.

9.6. REGULATIONS AND GUIDES FOR DECOMMISSIONING ACTIVITIES

Nuclear safety during the decommissioning of licensed nuclear sites is regulated by ONR. The environment agencies regulate environmental and public protection during the decommissioning, working closely with ONR.

Despite not being explicitly considered as a planned exposure situation in the IRRs, decommissioning is subject to regulation under IRRs. ONR regulation of nuclear safety during decommissioning utilises the SAPs, LCs, TIGs and TAGs, such as SAPs DC.1-9, TAG NS-TAST-GD-026; LC 35 and the LC35 TIG NS-INSP-GD-035.

All regulations and guides require that there is "no danger" from ionising radiations from anything on the site once the decommissioning is completed. This expectation for delicensing is explained in HSE/ONR guidance. Residual radioactivity above the average natural background, which can be satisfactorily demonstrated to pose a risk of death to the most exposed individual of less than one in a million per year is "broadly acceptable" to ONR and such a site can be de-licensed. It is acknowledged that once legislation is changed, ONR will need to develop guidance on delicensing a future GDF site or other nuclear licensed site which cannot be brought to "green field" status.

Non-nuclear sites (such as low-level waste facilities, hospitals, factories or oil rigs), are regulated by the HSE (in England, Wales and Scotland) or HSENI (Northern Ireland) using general UK health and safety legislation. Environmental and public protection at non-nuclear sites is managed as part of the normal regulation of radioactive substances sites carried out by the relevant environment agency. EA has developed environmental principle DEDP1-5, SEPA has published a guidance note covering non-nuclear decommissioning and NIEA still has to develop guidance on the decommissioning of facilities.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *There is no guidance on the decommissioning of non-nuclear facilities in Northern Ireland. This finding was also identified by the NIEA in its Action Plan.*	
(1)	**BASIS: GSR Part 6 Requirement 5 states that** *"…The regulatory body shall establish the safety requirements for decommissioning, including requirements for management of the resulting radioactive waste, and shall adopt associated regulations and guides…".*
R20	**Recommendation: The NIEA should continue with its effort to develop a guide on decommissioning of non-nuclear facilities.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The ONR guidance does not include provisions for release of the nuclear site from initial regulatory control with restrictions on the future use. This finding was also identified by the ONR in its Action Plan.*	
(1)	**BASIS: GSR Part 6 Requirement 15 states that** *"On the completion of decommissioning actions, the licensee shall demonstrate that the end state criteria as specified in the final decommissioning plan and any additional regulatory requirements have been met. The regulatory body shall verify compliance with the end state criteria and shall decide on termination of the authorization for decommissioning."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 6 Requirement 15 para 9.3 states that** *"If the approved decommissioning end state is release from regulatory control with restrictions on the future use of the remaining structures, appropriate controls and programmes for monitoring and surveillance shall be established and maintained for the optimization of protection and safety, and protection of the environment. These controls shall be subject to approval by the regulatory body.*
R21	**Recommendation: Once relevant legislative changes have been implemented, the ONR should review and update the decommissioning guidance to reflect the requirements on release of the nuclear site from their regulatory control with restrictions on the future use.**

9.7. REGULATIONS AND GUIDES FOR TRANSPORT

The Competent Authority (CA) for the civil transport of Class 7 (radioactive material) dangerous goods varies within the UK dependant on mode and region. The following are the relevant competent authorities:

- ONR for road, rail and inland waterways in GB (in practice inland waterways are not used);
- HSENI for rail and inland waterway in Northern Ireland (in practice neither are used);
- NIEA – for road in Northern Ireland;
- MCA for British registered ships and all other ships under Port State Control legislation whilst in UK territorial waters and ports;
- CAA for air transport.

The regulations apply a graded approach with higher-hazard transport subject to an authorisation regime in which designs and activities require approval from the appropriate CA. ONR provides advice to and, in applying its authorisation regime, acts on behalf of the other CAs and agencies (with the exception of HSENI, as rail and inland water transports are not undertaken in Northern Ireland).

The above international standards/agreements are implemented in UK law through legislation that is based on the requirements of IAEA SSR-6. The guidance given in IAEA SSG-26 is adopted as a key guidance document that is considered to represent RGP for safe transport.

IRR17 also applies to the transport of radioactive material. In addition, specific transport guidance relating to reporting criteria for incidents/accident, guides for users and applicants is published on the transport page of the ONR website.

ONR collects operational experience through its permissioning and inspection regimes and through its regulatory intelligence function, which gathers information relating to incidents using the INF1 process. ONR also consults with industry to identify areas for improvement. ONR also shares and gathers information through attendance at the European Association of Competent Authorities to identify wider international issues.

Proposals for amendment of IAEA safety standards (e.g. SSR-6) are fed back to the IAEA via ONR, where they are discussed at TRANSCC which ONR attends on behalf of the UK. If consensus is reached at TRANSCC, the IAEA safety standards are updated and promulgated into the modal texts ADR, RID etc. which then effectively become UK law.

NIEA has identified that they do not currently have guidance documents for transport of radioactive material. ONR has given DAERA permission to use their guidance, altering it to make it appropriate for the NI Regulations and rebranding it as necessary. NIEA will then publish its guidance on the DAERA website in 2020.

9.8. REGULATIONS AND GUIDES FOR OCCUPATIONAL EXPOSURE

The regulatory bodies responsible for the supervision of occupational exposures are ONR in the case of practices carried out at nuclear facilities and transport activities, and HSE/HSENI in the case of non-nuclear facilities. CAA

monitors compliance with air transport regulations which address the protection of aircrew exposed to cosmic radiation.

IRR17 and IRR(NI)17 are supplemented by guidelines or approved codes of practice to give appropriate advice on the fulfilment of the requirements. Since the regulations came into force in 2018, not all of the guidelines relevant to ensuring the safety of workers have been updated.

IRR17 and IRR(NI)17 establish requirements for the optimised protection of workers and require the setting of dose constraints as appropriate. This requires the effective cooperation between relevant parties (workers, employers and technical services) and provides the same level of protection whether an authorised party is the employer of the worker or not. The dose limits for workers, set by IRR17 and IRR(NI)17 regulations are in line with the ones set by IAEA GSR part 3 Schedule III. Special arrangements for the protection of workers under the age of 18 and for pregnant and breastfeeding workers are addressed in the regulations. The HSW74 and HSW(NI)O78 prohibit employers from offering benefits to workers as a substitute for measures for the protection and safety of those workers. In addition to being an offence under HSW74 and HSW(NI)O78, such an action may constitute a criminal offence.

The regulations delegate the responsibilities for safety appropriately, mandating the employers to have appropriate arrangements for the protection of workers and also requiring the workers to comply with the requirements.

The requirements for the protection of aircrew occupationally exposed to cosmic radiation are in line with the requirements of IAEA GSR Part 3.

The regulatory bodies responsible for authorisation apply the graded approach principle for their authorisation procedures. However, before granting authorisation, be it under the scope of notification, registration or consent, no review occurs of the design features related to the exposure of workers according to the legal framework.

IRR17 and IRR(NI)17 set requirements for the protection of workers in cases where they are exposed to radon and its daughter elements, if their work involves NORM or they work at remediation sites.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Since the IRR17 and IRR(NI)17 came into force on 1 January 2018, not all of the guidelines relevant to ensure the safety of workers have been updated.*	
(1)	**BASIS: GSG-13 3.11, states that** "*As part of its integrated management system, the regulatory body should establish a process for the development of regulations and guides. This process should ensure that the regulations and guides: …* *(c) Are consistent and comprehensive; …* *(h) Are reviewed and revised as necessary and are kept up to date."*
S16	**Suggestion: The HSE and HSENI should consider updating their guidelines relevant to the approval of technical services and establishing, developing and maintaining further appropriate guidelines.**

9.9. REGULATIONS AND GUIDES FOR MEDICAL EXPOSURE

CQC, HIW, HIS and RQIA provide information and guidance on radiation protection matters, including changes in regulations and new requirements, through a number of platforms to the health services.

IR(ME)R17 and IR(ME)R18 are supported by the publication 'Guidance to the Ionising radiation (Medical Exposure) Regulations' giving authorized parties information on how to comply with the legislation. The guidance is reviewed and, if necessary, revised from time to time. Additional guidance is provided to authorized parties via professional bodies with input from regulators. Extensive consultation took place before the IR(ME)R17 and IR(ME)R18 guidance was finalised. As part of UK government policy all new legislation must be reviewed five

years after its publication. Thus, the IR(ME)R will be reviewed in 2022 to ensure that it is achieving its objectives and aligns with international standards. The existence of these documents and any revisions made to them are publicised widely via electronic means such as websites, provider bulletins etc. and via press releases, newsletters and other publications.

ARSAC publishes guidance for applicants and good practice in nuclear medicine. The ARSAC 'Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources' covers issues relating to pregnancy, conception, and breastfeeding with regards to the administration of radioactive substances to patients. Guidance relating to the release of patients following nuclear medicine examinations can be found in the medical and dental guidance notes published by the Institute of Physics and Engineering and Medicine.

CQC, HIW, HIS and RQIA have produced and published a guidance document for employers and duty-holders regarding notification of significant accidental and unintended exposures under IR(ME)R17 and IR(ME)R18. CQC also publishes annual reports where learning from inspections and incidents is shared with authorized parties. Furthermore, CQC and HIS takes an active and continuing role in the radiation protection community's conferences and events and communicates regularly with relevant professional institutions.

The Institute of Physics and Engineering in Medicine (IPEM) produces guidance around equipment QA testing and DRLs.

The British Institute of Radiology has published advice on the timing of the release of patients, who have been administered with radiopharmaceutical, from hospital and the use of appropriate precautions.

9.10. REGULATIONS AND GUIDES FOR PUBLIC EXPOSURE

The environment agencies (NIEA, SEPA, EA in England and Wales), HSE, PHE, local authorities. FSA etc., have developed the necessary guidance required for implementation of authorisation requirements and general understanding in the area of public exposure due to planned exposures and existing exposures. The broad areas covered are public dose assessment owing to radioactive discharges, land contamination, radon assessment in dwellings and public places, dose assessment to public, NORM etc.

However, many of the regulatory guidance documents published by EA are out of date. Each document has a target date for the review and update and many of them are overdue, some documents are withdrawn.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *Many of the regulatory guidance documents published by the EA are beyond due date of revision. This has been identified in the Action Plan.*	
(1)	**BASIS: GSR Part 1, Rev 1, Requirement 33 states that** *"Regulations and guides shall be reviewed and revised as necessary to keep them up to date, with due consideration of relevant international safety standards and technical standards and of relevant experience gained".*
R22	**Recommendation: The EA should review and revise as necessary its regulatory guidance to keep it up to date with due consideration of relevant international safety standards, policy and current regulatory framework.**

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *NIEA does not currently have guidance in place to cover the Radioactive Contaminated Land (RCL) regime. This has been identified in the Action Plan.*	
(1)	**BASIS: GSR Part 3 Requirement 49 states that:** *"Responsibilities for remediation of areas with*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
	residual radioactive material. The government shall ensure that provision is made for identifying those persons or organizations responsible for areas with residual radioactive material; for establishing and implementing remediation programmes and post-remediation control measures, if appropriate; and for putting in place an appropriate strategy for radioactive waste management".
S17	**Suggestion: The NIEA should consider developing guidance to cover the RCL regime.**

9.11. SUMMARY

The UK regulatory regime is generally goal-setting which means that the authorized parties have to determine and justify how to achieve adequately the goals. The guidance that is used by regulatory bodies to judge the adequacy of an authorized party's approach is not legally binding but describes in more detail what is required to comply with the law.

The IRRS team identified further needs to develop processes for the establishment, review and update of regulatory guidance to include applicable IAEA safety standards. In addition, some areas for improvement related to developing and revising the guidance were identified in the following areas:

- requirement for the licensees of non-nuclear sites in Northern Ireland to have in place RAW management plans identifying the interdependencies in RAW management including the disposal option;
- revision of the approach to containment and isolation of RAW in disposal facilities and clearly indicating that no radioactive discharges are expected from disposal facilities;
- inclusion of passive institutional control period as a stage of disposal facility lifetime;
- introducing clearance based on case and site-specific activity concentrations derived by permit holder as an effective tool contributing to the RAW minimisation;
- decommissioning of non-nuclear facilities in Northern Ireland;
- reflecting restrictions on the future use in the requirements on release of the nuclear site from regulatory control;
- approval of technical services;
- covering of the RCL regime in Northern Ireland; and
- ensuring that regulatory guidance is kept up to date and consistent with IAEA safety standards.

10. EMERGENCY PREPAREDNESS AND RESPONSE REGULATORY ASPECTS

10.1. AUTHORITY AND RESPONSIBILITIES FOR REGULATING ON-SITE EPR OF OPERATING ORGANIZATIONS

TEA13 and NIA65 define ONR as the competent authority for civil nuclear safety activities including on-site EP&R.

For Great Britain, the HSWA defines ONR and HSE as the competent authorities for the regulation of safety and occupational health respectively at sites where either is the relevant authority. This means ONR is the competent authority for on-site EP&R for radiation activities in the nuclear sector, while HSE regulates medicine, industry and education. Equivalent legislation exists in Northern Ireland, which has no nuclear facilities, and designates HSENI as the single competent authority.

To ensure effective coordination between ONR and HSE, TEA13 requires arrangements to be made and maintained for the cooperation and exchange of information. These arrangements are brought into effect by an MoU.

TEA13 defines ONR as the competent authority for transport of civilian radioactive materials by road, rail and inland waterways in Great Britain. In Northern Ireland, the NIEA regulates radioactive transport on road under CDG(NI) 2010 and includes provisions for EP&R. The Merchant Shipping Act 1995 defines the Maritime and Coastguard Agency (MCA) as the competent authority for the legal framework and enforces the international regulations for transport by sea. The competent authority for transport of dangerous goods by sea within UK waters and on UK ships is the Secretary of State for Transport (SoS), who would also coordinate the regulatory response for sea transport emergencies in the UK. In case of emergency, the "Secretariat of States Representatives for Maritime Salvage and Intervention" would act on behalf of the Department of Transport and BEIS, which were authorized by the SoS to deal with the emergency. The Civil Aviation Authority (CAA) is established as the competent authority for air transport.

10.2. REGULATIONS AND GUIDES ON ON-SITE EP&R OF OPERATING ORGANIZATIONS

The UK framework for on-site EP&R consists of comprehensive, well established legislation with the Civil Contingencies Act (CCA) being supported by specific regulations including REPPIR 2019, and the preceding REPPIR 2001 (which will be phased out in May 2020) to deliver an emergency response framework for the civil nuclear, defence licensed, and authorised nuclear and radiological sectors. In addition to the main legislative framework there is substantial Government guidance related to EP&R underpinning the CCA.

The Approved Code of Practice (ACOP) and Guidance for REPPIR 2019 was jointly produced by ONR and HSE. It was published in September 2019 to assist the authorized party's compliance with the new regulations.

IRR17 requires operating organizations to undertake emergency planning for reasonably foreseeable radiological accidents. In Northern Ireland, HSENI regulations are applied. This includes REPPIR(NI) 2001, the draft REPPIR(NI) 2019, the Ionising Radiations Regulations (Northern Ireland) 2017 (IRR(NI)17) and Schedule 2 of CDG(NI) 2010 (amended 2019).

For nuclear installations, LC 11 requires the licensee to make and implement adequate arrangements for dealing with any accident or emergency arising on the site and its effects. The LC 11 is supplemented by more detailed guidance (i.e. ONR TIG NS-INSP-GD-011). There are other relevant LCs requiring the licensee to ensure that every person authorised to be on site receives adequate instructions regarding the actions to be taken in the event of an accident or emergency.

The transport of radioactive materials is regulated by the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (CDG) Regulations 2009, which authorizes use of international instruments such as ADR, RID, ADN (e.g. road, rail, sea and inland waterways respectively), which adequately address the EP&R arrangements.The sea and air transport are regulated with the respective international organizations (IMO, ICAO) provisions.

IAEA Safety Standards recommend emergency action levels (EALs) and operational intervention levels (OILs) be used for the efficient initiation of emergency plans and for taking protective actions and other response actions. The

IRRS team could not verify the existence of the regulatory requirements for the EALs nor its implementation by the operator. The UK does not use OILs in accordance with IAEA safety standards but has instead established a system of criteria expressed in terms of dose, which existed before the adoption of the reference levels concept. The equivalent, criteria derived, quantities, used instead of OILs, do not match those in IAEA GSG-2 in terms of which quantities are required or with the methodology (scenarios) needed for calculation of "OIL equivalents".

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The EALs and OILs are not established in the regulatory requirements in accordance with IAEA GSR Part 7 and GSG-2.*	
(1)	**BASIS: GSR Part 7, Requirement 5, para. 4.28 (4) states that** *"Once the protection strategy has been justified and optimized and a set of national generic criteria has been developed, pre-established operational criteria (conditions on the site, emergency action levels (EALs) and operational intervention levels (OILs)) for initiating the different parts of an emergency plan and for taking protective actions and other response actions shall be derived from the generic criteria".*
(2)	**BASIS: GSG-2 para. 3.4 states that** "…*Generic criteria are provided in terms of dose that can be projected or dose that has already been received. The operational criteria are values of measurable quantities or observables that include operational intervention levels (OILs), emergency action levels (EALs), specific observables and other indicators of conditions on the scene that should be used in decision making during an emergency. The operational criteria can be used immediately and directly to determine the need for appropriate protective actions and other response actions".*
(3)	**BASIS: GSG-2 para. 5.3 states that "***The EALs are the specific, predetermined, observable operational criteria used to detect, recognize and determine the emergency class of an event at facilities in threat categories I, II and III [2]. The EALs are used for classification and for decisions on the implementation of precautionary urgent protective actions corresponding to the emergency class. These criteria should be predefined as stated in Ref. [2] and implemented as described in Refs [7, 8]. Appendix III provides a discussion of the EAL development process and gives examples of EALs for the classification of emergencies at a light water reactor nuclear power plant".*
(4)	**BASIS: GSR Part 7 para. 5.16 states that** *"The emergency classification system for facilities and activities in categories I, II, III and IV shall take into account all postulated emergencies, including those arising from events of very low probability. The operational criteria for classification shall include emergency action levels and other observable conditions (i.e. 'observables') and indicators of the conditions at the facility and/or on the site or off the site. The emergency classification system shall be established with the aim of allowing for the prompt initiation of an effective response in recognition of the uncertainty of the available information".*
R23	**Recommendation: The Government should review the UK EP&R framework to explain how the requirements of GSR Part 7 are met in terms of EALs and OILs, and if any gap exists develop appropriate regulatory requirements.**

GSR Part 7 defines two zones (PAZ, UPZ) and two distances (EPD, ICPD). The REPPIR 2019 (ACOP) provides guidance on the determination and planning within the two protective actions planning zones (i.e. the detailed planning zone and the outline planning zone). However, while this approach is comprehensive, the two planning zones established under the REPPIR 2019 are not fully aligned with the GSR Part 7. In addition, there are differences in the protective actions needed to be implemented in the REPPIR 2019 defined zones compared to those protective actions required by the GSR Part 7 defined zones.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The emergency planning zones established under REPPIR 2019 are not fully in alignment with the requirements of GSR part 7.*	
(1)	**BASIS: GSR Part 7 para. 5.38 (a) states that** *"The specification of off-site emergency planning zones and emergency planning distances25 for which arrangements shall be made at the preparedness stage for taking protective actions and other response actions effectively. These emergency planning zones and emergency planning distances shall be contiguous across national borders, where appropriate, and shall include:* *(i) A precautionary action zone (PAZ), for facilities in category I, for which arrangements shall be made for taking urgent protective actions and other response actions, before any significant release26 of radioactive material occurs, on the basis of conditions at the facility (i.e. conditions leading to the declaration of a general emergency; see para. 5.14), in order to avoid or to minimize severe deterministic effects.* *(ii) An urgent protective action planning zone (UPZ), for facilities in category I or II, for which arrangements shall be made to initiate urgent protective actions and other response actions, if possible before any significant release of radioactive material occurs, on the basis of conditions at the facility (i.e. conditions leading to the declaration of a general emergency; see para. 5.14), and after a release occurs, on the basis of monitoring and assessment of the radiological situation off the site, in order to reduce the risk of stochastic effects.27 Any such actions shall be taken in such a way as not to delay the implementation of precautionary urgent protective actions and other response actions within the precautionary action zone.* *(iii) An extended planning distance (EPD) from the facility, for facilities in category I or II (beyond the urgent protective action planning zone), for which arrangements shall be made to conduct monitoring and assessment of the radiological situation off the site in order to identify areas, within a period of time that would allow the risk of stochastic effects in the areas to be effectively reduced by taking protective actions and other response actions within a day to a week or to a few weeks following a significant radioactive release.* *(iv) An ingestion and commodities planning distance (ICPD) from the facility, for facilities in category I or II (beyond the extended planning distance), for which arrangements shall be made to take response actions (1) for protecting the food chain and water supply as well as for protecting commodities other than food from contamination following a significant radioactive release and (2) for protecting the public from the ingestion of food, milk and drinking water and from the use of commodities other than food with possible contamination following a significant radioactive release".*
R24	**Recommendation: The Government should review the UK EP&R framework to explain how the requirements of GSR Part 7 are met in terms of planning zones and distances, and if any gap exists develop appropriate regulatory requirements.**

10.3. VERIFYING THE ADEQUACY OF ON-SITE EP&R OF OPERATING ORGANIZATIONS

The IRRS team was informed that emergency demonstration exercises are one of the most important verification tools for operating organizations' EP&R arrangements and are verified by ONR during licensing and inspection. Nuclear licensed sites are required to demonstrate their on-site emergency plan on a regular basis proportionate to the risk and hazard from the site. A formal Level 1 exercise is held at each nuclear site once a year to demonstrate compliance with the requirements and concentrates primarily on the operating organization's actions. ONR inspectors observe, make regulatory judgements and provide feedback on the adequacy of these demonstrations. The emergency exercise programme for all nuclear sites ensures that each year all operational NPP sites run

demonstration exercise (Level 1) with a pre-defined set of scenario types. The exercise programme contains a set of objectives, which are all exercised within a pre-defined cycle. This programme is made public by publishing it on the ONR website. Level 2exercises alsodemonstrate the adequacy of the arrangements of the local authorities and Level 3 exercises additionally include the Government response, including international liaison.

Both REPPIR 2019 and LCs allow for the submission of the operator's emergency plan or arrangements to ONR, which considerssconsiders whether the plan is adequate and take appropriate regulatory actions.

The HSE regulated sites must provide details of their assessment of the risk to HSE who will inspect these sites. Since the introduction of REPPIR 2001, no HSE sites have been identified as meeting the criteria requiring the development of an off-site plan. In Northern Ireland, HSENI adopted the same approach as HSE and the NIEA also review emergency plans of transported radioactive materials.

ONR's inspection and assessment of operating organizations' EP&R arrangements are supported by regulatory guidance such as: (a) the ACOP and Guidance for REPPIR 2019, (b) technical inspection guides (TIGs) related to on-site EP&R, and (c) safety assessment principles (SAPs), which refer to the control and mitigation of large radioactive release consequences. The IRRS team noted that in the action plan ONR identified that technical inspection guide NS-INSP -GD-011 in relation to LC 11 should be updated.

The data from the HSE system, together with responses to the ONR questionnaire, reports on the test of emergency plans, and other intelligence, shape ONR's annual inspection plan. The IRRS team verified that the ONR inspection plan includes inspections of LC 11 – emergency arrangements, as well as the other licence conditions.

ONR inspects EP&R arrangements of transported radioactive materials using guidance based on the CDG Regulations 2009 and the relevant TIGs comprising EP&R in transport of dangerous goods. In Northern Ireland, the NIEA inspects EP&R arrangements for the transport of radioactive materials.

10.4. ROLES OF THE RB IN A NUCLEAR OR RADIOLOGICAL EMERGENCY

The ONR's and HSE's primary roles during emergencies are to provide advice to support the local and national EP&R arrangements, in addition to the regulatory roles of investigating and collecting evidence. Both competent authorities are Category 2 responders and are not front-line responders in implementing protective actions. However, they assume the advisory role as explained above. During an emergency, both ONR and HSE provide around-the-clock accurate and up-to-date advice, as well as for further regulatory investigative actions. In addition, ONR is the UK's National contact point for the International Nuclear Event Scale (INES) as delegated by BEIS.

The response centre, the Redgrave Court Incident Suite (RCIS), supports the collation of information, provides the interpretation of the collected information, and is the central hub of information exchange for ONR. The RCIS co-ordinates the overall ONR response. ONR fulfils its advisory role in many locations. This includes sending inspectors from ONR and other regulatory bodies to the Strategic Coordination Centre (SCC), usually located at the county or higher level, to provide timely and authoritative advice to the central and devolved government. In addition, a team, led by the ONR Chief Nuclear Inspector and other regulatory bodies, are sent to the Scientific Advisory Group for Emergencies (SAGE), which advises the Prime Minister in COBR. Other ONR teams are deployed to the affected nuclear site and to the licensee or operator's off-site facility established to provide technical support for their on-site emergency response.

ONR also supports the preparation of the IAEA notification messages via BEIS, and vice versa, if an emergency is abroad, the information from the IAEA would be received via FCO. BEIS and FCO are the respective emergency competent authorities for notifying the IAEA concerning emergencies in the UK and responding to emergencies abroad. Since the on-site response and technical information are to be provided to the IAEA throughout the emergency, the team's opinion is that it would be more efficient if the ONR were the contact point or were more involved in the notification process with the IAEA. This would eliminate the additional technical consultation step between BEIS and ONR.

In case of emergency, during office hours, nominated inspectors are contactable via a dedicated emergency telephone line which is answered by the Divisional Directorate Support (DDS) staff. Out of office hours the on-call duty officer takes the call and alerts the on-call inspector who makes the decision on the appropriate initial action,

e.g. whether to set up the RCIS. The IRRS team noted that the decision about RCIS activation is not directly based on the emergency class, but also on additional factors considered by the on-call inspector.

HSE has guidance for its response to a major incident. The guidance provides detailed instructions for each position within the HSE response organisation, and describes response to any emergency within the scope of HSE authority (not only radiological) and clearly demonstrates an all-hazards approach. The IRRS team noted that HSE may benefit from developing additional specific guidance for dealing with radiation emergencies to make this guidance even more useful.

ONR does not have an agreed upon format for licensees to transfer on-site information promptly to the RCIS. Having access to predetermined on-site information such as the status of certain critical safety systems and key plant parameters (i.e. radiation reading, pressure and temperature) is necessary for the technical staff to have a current understanding of the reactor state and accident progression. Currently, RCIS's technical staff rely on inspectors at the licensee's emergency response centres for the required plant information for their assessment. During the ONR self-assessment process, ONR has also identified the need to improve resilience in the hardware and software arrangements within the RCIS.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *ONR does not have previously agreed format for plant data and information transfer during an emergency.*	
(1)	**BASIS: GSR Part 7, Requirement 9, para. 5.36 states that** *"Arrangements shall be made such that information on emergency conditions, assessments and protective actions and other response actions that have been recommended and have been taken is promptly made available, as appropriate, to all relevant response organizations and to the IAEA throughout the emergency".*
(2)	**BASIS: GSR Part 7, Requirement 24, para. 6.22 states that** *"Adequate tools, instruments, supplies, equipment, communication systems, facilities and documentation (such as documentation of procedures, checklists, manuals, telephone numbers and email addresses) shall be provided for performing the functions specified in Section 5…."*
S18	**Suggestion: ONR should consider establishing pre-defined communication with the operating organizations in terms of plant data and other information during emergencies.**

The RCIS provides ONR with adequate infrastructure to respond in emergencies and its staff has been increased significantly in recent years. However, ONR does not have an overarching emergency response plan that defines its response objectives, the organizational response structure and functions, how the response actions are coordinated within the RCIS and its external stakeholders, etc. There are RCIS procedures for each position; however, these procedures are not linked together with an overarching document. The new ONR management system, under development, does not currently include a sub-process of ONR EP&R capability maintenance.

In addition, the systematic training and qualification of RCIS team has not been formally implemented. The action plan also identified that IT and training in EP&R area should be improved. A RCIS documentation control system including hardcopies needs to be strengthened. There are RCIS procedures for each position; however, the accident analysis does not provide any specific technical guidance and rely exclusively on the competence and previous experience of the expert.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES
Observation: *The ONR does not have an overarching emergency response and preparedness plan to coordinate the response functions and maintain response capability within the RCIS. The action plan identified the ONR does not have a formal training and qualification programme for its staff responding to an emergency.*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(1)	**BASIS: GSR Part 7 para. 6.16 states that:** *"Plans, procedures and other arrangements for effective emergency response, including coordinating mechanisms, letters of agreement or legal instruments, shall be made for coordinating a national emergency response".*
(2)	**BASIS: GSR Part 7 para. 6.30 states that:** *"Exercise programmes shall be developed and implemented to ensure that all specified functions required to be performed for emergency response".*
(3)	**BASIS: GSR Part 7, Requirement 25 states that: "***The government shall ensure that personnel relevant for emergency response shall take part in regular training, drills and exercises to ensure that they are able to perform their assigned response functions effectively in a nuclear or radiological emergency.«*
(4)	**BASIS: GSR Part 7, Requirement 21 states that:** "*The government shall ensure that overall organization for preparedness and response for a nuclear or radiological emergency is clearly specified and staffed with sufficient personnel who are qualified and are assessed for their fitness for their intended duties."*
S19	**Suggestion: The ONR should consider integrating its response arrangements into a response and preparedness plan and formalize training and qualification of emergency response staff.**

The Department for Environment, Food and Rural Affairs (Defra) is the Lead Government Department in England for recovery from radiological and nuclear emergencies and would work closely with government agencies, including EA, ONR and HSE, to coordinate longer-term remedial action, including decontamination.

In Northern Ireland the response to a nuclear incident elsewhere with impacts on its territory would be led by DAERA, equivalent of Defra. HSENI's main role in emergency response to a nuclear or radiological event would be to provide technical expertise and advice to support the multi-agency response and emergency planning process. The NIEA responds to transport emergencies.

BEIS has recently implemented the Joint Agency Modelling (JAM) dose prognosis and environmental impact modelling system. JAM provides a national capability to estimate, forecast and provide expert advice on the scale and uncertainties associated with a radiological release from a nuclear emergency to decision makers responsible for early protective actions. This includes providing advice on the likely extent of public health countermeasures including sheltering, evacuation, distribution of stable iodine, food and water and whether automatic countermeasures need to be extended. This new and important capability has been exercised with positive outcome. The IRRS team considers this good performance and the lessons learned from its development and operations should be shared with other states.

10.5. SUMMARY

The UK legislative framework defines the regulatory mandate and responsibilities of all competent authorities for EP&R. The EP&R legislation is comprehensive and provides for a robust and consistent regulatory framework for all facilities and activities. However, some elements of the GSR Part 7 still need to be clearly demonstrated in the UK legislative framework.

The IRRS team encourages the UK government to consider hosting an IAEA EPREV mission, since in recent years substantial legislative changes have been made (IRR17, REPPIR 2019).

The areas for improvement are:

- Review of the UK EP&R framework to explain how the requirements of GSR Part 7 are met in terms of EALs and OILs and filling out any identified gaps,

- Review the UK EP&R framework to explain how the requirements of GSR Part 7 are met in terms of planning zones and distances and filling out any identified gaps,
- Establish pre-defined communication with the operating organizations in ONR emergency response centre,
- Overarching ONR emergency response plan and formalization of training and qualification of ONR emergency response staff.

11. INTERFACE WITH NUCLEAR SECURITY

11.1. LEGAL BASIS

The UK government has established the legal framework for oversight and enforcement of nuclear security. This includes a state system of accounting for, and control of, nuclear material and arrangements for interfaces between safety and security.

The TEA13 has created ONR as a statutory organisation with purposes covering nuclear safety and nuclear security for civil nuclear licensed sites and transport. Security Assessment Principles (SyAPs) and the Safety Assessment Principles (SAPs), are derived from the IAEA's fundamental principles for safety and security. SAPs and SyAPs contain regulatory expectations for the integration of safety and security arrangements by authorised parties.

For transport, the UK Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG) are based on those of the IAEA and incorporate ADR and RID for road and rail respectively. In terms of interface, both the safety and security requirements are for each mode of transport (i.e. ADR for road and RID for rail) captured in a single set of regulations, which in relation to class 7 (radioactive) dangerous goods are regulated by a single competent authority (ONR).

For non- nuclear sites, enhanced security arrangements are in place for category 1 to 4 sources. The UK environmental laws provide the legislative basis for these security measures. The "Security Requirements for Radioactive Sources" is a classified document produced by UK National Counter Terrorism Security Office (NaCTSO) and based on IAEA standards (e.g. Categorisation of Radioactive Sources (RS-G-1.9); Nuclear Security Series No.11). Counter Terrorist Security Advisers (CTSAs) trained in radiological matters advise the environmental regulators on security measures for category 1 to 4 sources and this includes preauthorisation inspections to confirm security arrangements are implemented as part of permit /authorisation conditions. This provides a graded approach to security whereby the most stringent security measures are required for the most dangerous sources.

Authorisations issued by the environmental regulators for category 1 to 4 sources include requirements on operators to provide and maintain security arrangements to an appropriate standard. Security requirements for category 5 sources and unsealed sources are not prescriptive. The security requirements are aligned with requirements for safety under the IRR regulations.

The IRR17 and IRRNI17 also impose requirements in relation to storage, record keeping and the accounting of radioactive substances. Further, the record keeping must be of such a nature to allow any reasonably foreseeable loss or theft of those substances to be identified within a reasonable amount of time. The regulations also require authorised parties to report theft or losses of radioactive sources. There is also guidance provided on accounting and storage of radioactive substances which may be enforced during inspections and investigations.

Within the UK framework, the interface of safety with nuclear security involves the advice from security experts, i.e. CTSAs in establishing and monitoring security measures for category 1 to 4 radioactive sources and are based on a statutory requirement. This includes joint and independent inspections as well as pre-authorization inspections.

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
Observation: *The UK's regulatory framework for the interface between safety and security requires counter terrorist security advisers trained in radiological matters to advice the environmental regulators on security measures for category 1 to 4 sources. This includes preauthorisation inspections, security arrangements as well joint inspections.*	
(1)	**BASIS: GSR Part 1 Requirement 12 states that** *"The government shall ensure that, within the governmental and legal framework, adequate infrastructural arrangements are established for interfaces of safety with arrangements for nuclear security and with the State system of accounting for, and control of, nuclear material."*

RECOMMENDATIONS, SUGGESTIONS AND GOOD PRACTICES	
(2)	**BASIS: GSR Part 1 Requirement 2, para 2.39 states that** *"Specific responsibilities within the governmental and legal framework shall include:* *(a) Assessment of the configuration of facilities and activities for the optimization of safety, with factors relating to nuclear security and to the system of accounting for, and control of, nuclear material being taken into account;* *(b) Oversight and enforcement to maintain arrangements for safety, nuclear security and the system of accounting for, and control of, nuclear material;* *(c) Liaison with law enforcement agencies, as appropriate".*
GP2	**Good Practice: The UK government has implemented effective interface between safety and security for category 1 to 4 radioactive sources through the requirement for security experts to advise and inspect security requirements with environmental regulators.**

11.2. REGULATORY OVERSIGHT ACTIVITIES

ONR is responsible for the regulation (oversight and enforcement) of nuclear safety, security and conventional health and safety at civil licensed nuclear sites and during transport of radioactive materials. ONR inspectors use SAPs and SyAPs as the basis for making judgements with regards to the adequacy of authorised parties' arrangements. Fundamental Security Principle 10 of SyAPs states that authorised parties must implement and maintain effective security emergency preparedness and response arrangements which are integrated with the wider safety arrangements.

In the case of non- nuclear sites, officers from the relevant environmental regulatory body inspects the premises to confirm the security arrangements before a permit/authorisation/certificate as required under EPR16, EASR18 or RSA93, is issued.

The CTSAs also visit premises before a permit/authorisation is issued to advise on the adequacy of security arrangements and any necessary improvements so that the regulatory body can include appropriate security conditions.

All employers who undertake work with ionising radiations are required to either, notify or gain a registration, or obtain consent from HSE or HSENI.

Compliance with authorisation conditions is enforced by relevant regulatory bodies during inspections which include assessment of premises, reporting of source holdings and notifications to the regulator. The sources are also subject to periodic joint inspection for safety and security by the environmental regulator and CTSAs.

11.3. INTERFACE AMONG AUTHORITIES

The current legal framework for oversight and enforcement of nuclear safety and security establishes infrastructural arrangements to create an effective interface. ONR is the regulatory body for both safety and security for civil nuclear licensed sites and transport. ONR's security informed nuclear safety specialist team is experienced with aspects such as radiation protection and external hazards in addition to nuclear security aspects such as blast effects. ONR inspectors interact with the Civil Nuclear Constabulary (CNC) deployed at certain high hazard sites. One example is joint attendance at the Exercise Governance Group, for the exchange of counter terrorist exercise operational experience across the industry.

There are a number of regulators including security and emergency response agencies responsible for safety and security of radioactive sources. The coordination between the environmental regulators and the CTSAs are based

on a statutory requirement and interaction between the two is regular and structured via the review and assessment procedures.

Arrangements to integrate offsite nuclear and radiological emergency arrangements have also been made. Joint Emergency Services Interoperability Principles programme has been established to improve the way the Police, Fire & Rescue and Ambulance services work together when responding to major multi-agency incidents.

The IRRS team was informed both independent and joint inspections are carried out by the environmental regulators and CTSAs. CTSAs provide feedback to the regulatory body as appropriate.

SEPA is in the process of developing a formal agreement with CTSA in Scotland but such an arrangement does not exist in England, Wales or NI. There is also no formal coordination in place between CTSA, HSE and EA. The IRRS team was advised that HSE inspectors are not aware of the "Security Requirements for Radioactive Sources" document. The IRRS team noted that there is also no harmonisation of safety and security requirements between HSE and environment agencies in terms of requirements or checklist to identify and mitigate any conflicts between safety and security. The requirements are applied and inspected independent of each other. The IRRS team was advised that conflicts between safety and security aspects are managed at an operational level and have not created any issues to date. Examples of safety and security issues resolved at an operational level were provided to the IRRS team.

A Radioactive Substances Security Regulators Liaison Group has been established to provide interface between the different organisations with responsibility for security regulation of radioactive substances. The IRRS team has been informed that this group has not been functional since May 2015.

The UK would benefit from reinvigorating previous arrangements to enhance coordination and cooperation between all relevant agencies to ensure that safety and security measures are implemented in an integrated way. The UK action plan has identified two actions to enhance safety and security in Northern Ireland with regard to carrying out joint inspections between Police Service Northern Ireland (PSNI) and HSENI. Regular meetings between (PSNI, HSENI and NIEA) to discuss any issues, to review findings from inspections and resolve any conflicts between safety and security are also proposed. The IRRS team agrees with the proposed action and recommends such an arrangement for adoption in Great Britain. A recommendation in this regard has been made in sub-chapter 1.5

11.4. SUMMARY

The UK government has established the legal framework for oversight and enforcement of nuclear and radiation security. The interface between the environmental regulators and national counter terrorism security agencies for category 1 to 4 sources is recognised as a good practice.

However, liaison between safety and security agencies could be further enhanced to improve coordination and cooperation between all relevant agencies to responsible for safety and security.

IRRS UK REVIEW TEAM

APPENDIX I - LIST OF PARTICIPANTS

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APPENDIX II - MISSION PROGRAMME

United Kingdom IRRS Mission Schedule 14 – 25 October 2019

Initial Mission First Week

Time	SAT	SUN	MON	TUE	WED	THU	FRI	SAT	SUN	
9:00-10:00	Arrival of Team Members		Entrance Meeting	Interviews / Visits	Interviews / Visits	Interviews / Visits / DTC writes introductory parts	TM write Report TL and DTL review introductory part **Draft text to TL**	• Discussing and improving Draft Report • Cross-Reading • TL, DTL, TC and DTC read everything	Free day, Social Tour	Reading, Cross-reading of the Report
10:00-11:00										
11:00-12:00										
12:00-13:00			Lunch with Host	Standing lunch	Standing lunch	Standing lunch	Standing lunch	Standing lunch		
13:00-14:00		Initial Team Meeting: • Welcome • 5 minutes /TM self-intro • Refresher training • Meet host liaison officer • Mission logistics • Discussion of first impressions • Closing	Interviews	Interviews + in-group discussions / Visits	Interviews + in-group discussion / Visits	Interviews + in-group discussions Secretariat edits the report **1st version of the report ready** / Visits / DTC writes introductory parts	3 Policy Discussions (13:00 to 16:00) Secretariat edits the report **Preliminary Draft Report Ready**	Finalisation of the Draft Report		
14:00-15:00										
15:00-16:00										
16:00-17:00					**Written preliminary findings delivered**		Cross-reading by TM			
17:00-19:00			Daily Team Meeting	Daily Team Meeting	Daily Team Meeting: Discussion of findings	Daily Team Meeting	Daily Team Meeting			
19:00-20:00	Informal dinner	Team Dinner	Dinner	Dinner	Dinner	Dinner	Dinner	Dinner		
20:00-24:00			Writing of the report	Writing of the report	Daily Team Meeting: Discussion of findings	Writing of the report	TM Read Draft	Secretariat edits the report		

United Kingdom IRRS Mission Schedule 14 – 25 October 2019

Initial Mission Second Week

<table>
<tr><th></th><th>MON</th><th colspan="2">TUE</th><th colspan="3">WED</th><th>THU</th><th>FRI</th></tr>
<tr><td>9:00-10:00</td><td rowspan="2">Discussion of Recommendations, Suggestions and Good Practises with counterparts by module</td><td colspan="2" rowspan="2">Cross-Reading of the Report TL, DTL, TC and DTC read everything
Finalisation</td><td colspan="3">Common read through and finalisation of the Report by the Team</td><td rowspan="2">Host reads Draft Report and Executive Summary</td><td>Submission of the Preliminary Report</td></tr>
<tr><td>10:00-12:00</td><td colspan="3">Submission of the Draft to the Host</td><td>Exit Meeting
Publication of Press Release</td></tr>
<tr><td>12:00-13:00</td><td>Standing lunch</td><td colspan="2">Standing lunch</td><td colspan="3">Lunch</td><td>Standing Lunch</td><td>Lunch</td></tr>
<tr><td>13:00-15:00</td><td>Policy Discussions</td><td rowspan="3">Discussion of the Report by the Team</td><td rowspan="3">TC, DTC prepare Executive Summary and exit presentation</td><td rowspan="3">Host reads Draft Report</td><td rowspan="3">TL finalises Executive Summary and Exit Presentation</td><td rowspan="3">TC Drafts the Press Release</td><td>Written comments provided by the Host

Team meeting to discuss and resolve Host comments</td><td rowspan="4">Departure</td></tr>
<tr><td>15:00-17:00</td><td>Individual discussions of Recommendations, Suggestions and Good Practises with counterparts</td><td>Plenary (Team + Host) to discuss Host comments and finalize the report</td></tr>
<tr><td>17:00-19:00</td><td>Daily Team Meeting</td><td colspan="3">Discussion of Executive Summary and delivery to the Host</td><td>Briefing of the Senior IAEA Manager; Finalisation of the press release and of the Preliminary Report</td></tr>
<tr><td>19:00-20:00</td><td>Dinner</td><td colspan="2">Dinner</td><td colspan="3">Dinner</td><td rowspan="2">Farewell Dinner</td></tr>
<tr><td>20:00-21:00</td><td rowspan="2">Secretariat updates Report</td><td colspan="2" rowspan="2">Secretariat finalises Report</td><td colspan="3" rowspan="2">Free</td></tr>
<tr><td>21:00-24:00</td><td>Free</td></tr>
</table>

APPENDIX III – IRRS MISSION COUNTERPARTS

	IRRS Experts	Lead Counterpart	Support Staff
1.	**RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT**		
	Felix ALTORFER Uma RAMASAMY	Alison Jeynes (DAERA) Donald McGillivray (Scottish Government) Huw Davies (BEIS) Matthew Ager (Welsh Government)	Arthur Johnson (Scottish Government) Emma Darkins (BEIS) Helen North (DfT) Joe Magee (DoH NI) Richard Dimelow (Scottish Government) Sarah Peters (DHSC)
2.	**GLOBAL NUCLEAR SAFETY REGIME**		
	Felix ALTORFER Uma RAMASAMY	Alastair McGown (HIS) Alison Jeynes (DAERA) Alison Kentuck (MCA) Andrew Pryse (HIW) Christopher Thomas (FSA) Colette Grundy (EA) Eric Gillett (CAA) Hall Graham (RQIA) Joanne Stewart (PHE) Mina Golshan (ONR) Paul Dale (SEPA) Rachael Ward (CQC) Sally Nicholson (HSE)	Alan Holmes (MCA) Clare McNicholas (HSE) David MacRae (MCA) David Owen (ONR) Jo Browne (RQIA) Linda Murphy (HSE-NI) Mohammed Hussain (BEIS) Rebecca Upson (BEIS)
3.	**RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY**		

	IRRS Experts	Lead Counterpart	Support Staff
	Philip WEBSTER	Clare McNicholas (HSE) Ian Streatfield (EA) Michael Finnerty (ONR) Nigel Acheson (CQC)	Adam Brown (CQC) David Nicholson (EA) Holly Warriner (CQC) Katie Day (ONR) Rachael Ward (CQC)
4.	**MANAGEMENT SYSTEM OF THE REGULATORY BODY**		
	Cantemir CIUREA-ERCAU	Ian Barlow (ONR) Ian Streatfield (EA) Nigel Acheson (CQC) Sally Nicholson (HSE)	Adam Brown (CQC) Charlotte Cooper (ONR) Holly Warriner (CQC) Neil Pearson (HSE) Paul Murphy (ONR) Rachael Ward (CQC) Richard Broughton (HSE) Steve Hardy (EA)
5.	**AUTHORIZATION**		
	Olivier LAREYNIE	Anthony Hart (ONR) Donald Urquhart (ONR) Eirian MacDonald (NRW) Isabelle Watson (SEPA) Nancy Lawton (EA) James Taylor (HSE)	Fiona Hunter (ONR) Llinos Owen (NRW) Paula Atkin (EA) Tanya Montgomery (EA)
5.-9.	**FUEL CYCLE FACILITIES**		

	IRRS Experts	Lead Counterpart	Support Staff
	Thomas VUKOVINSKY	Andrew Fairhurst (EA) Linda Buchan (SEPA) Peter Hughes (ONR)	John Rogers (ONR) Jonathan Evans (ONR)
5.-9.	**RADIOACTIVE WASTE MANAGEMENT FACILITIES AND DECOMMISSIONING**		
	Peter LIETAVA	Gillian Wasson (NIEA) Juliet Long (EA) Nicholas Blackburn (ONR) Richard McLeod (SEPA) Robert Price (NRW)	Angela Wakefield (EA) Beth Davies (NRW) David Brazier (EA) Karl Littlewood (EA) Louise Gray (ONR)
5.-.9.	**RADIATION SOURCES APPLICATIONS**		
	Carl BLADH Jarlath DUFFY	Alastair McGown (HIS) Alison Jeynes (DAERA) Amber Bannon (EA) Andrew Pryse (HIW) Angela Wright (SEPA) Gareth Richards (NRW) Hall Graham (RQIA) James Taylor (HSE) Louise Fraser (PHE) Rachael Ward (CQC) Richard Dimelow (Scottish Government) Tim Randles (ONR)	Adam Brown (CQC) Arthur Johnston (Scottish Government) Holly Warriner (CQC) Isabelle Watson (SEPA) Jo Browne (RQIA) Linda Murphy (HSE-NI) Nigel Acheson (CQC) Richard Lee (EA)
5.-9.	**TRANSPORTATION**		

	IRRS Experts	Lead Counterpart	Support Staff
	Jarlath DUFFY	Alison Kentuck (MCA) Eric Gillett (CAA) Gavin Smith (ONR) Gillian Wasson (NIEA) James Taylor (HSE) Linda Murphy (HSE-NI)	Alan Holmes (MCA) David MacRae (MCA) Simon Clark (ONR)
5.-9.	**OCCUPATIONAL RADIATION PROTECTION**		
	Richard ELEK	James Taylor (HSE) Tim Randles (ONR)	Linda Murphy (HSE-NI) Sally Nicholson (HSE)
5.-9.	**PUBLIC PLANNED AND EXISTING EXPOSURE**		
	Anuradha VANGALA	Alison Jeynes (DAERA) Andy Mayall (EA) Arthur Johnston (Scottish Government) Christopher Thomas (FSA) Gillian Wasson (NIEA) James Taylor (HSE) Neil McColl (PHE) Paul Dale (SEPA) Penny Dunbabin (BEIS) Robert Price (NRW) Tim Randles (ONR)	Corynne McGuire (SEPA) Linda Murphy (HSE-NI) Tiberio Cabianca (PHE) Trevor Howard (EA) Wayne Oatway (PHE)
6.	**REVIEW AND ASSESSMENT**		

	IRRS Experts	Lead Counterpart	Support Staff
	Rob JANSEN	Anthony Hart (ONR) Eirian MacDonald (NRW) Isabelle Watson (SEPA) Nancy Lawton (EA)	Llinos Owen (NRW) Paula Atkin (EA) Robert Exley (ONR) Tanya Montgomery (EA)
7.	**INSPECTION**		
	Michael KING	Julia Frost (NRW) Linda Buchan (SEPA) Michael Ainsworth (EA) Rob Campbell (ONR) James Taylor (HSE)	Kulvinder McDonald (ONR) Shaun McKenna (ONR)
8.	**ENFORCEMENT**		
	Michael KNOCHENHAUER	Julia Frost (NRW) Linda Buchan (SEPA) Michael Ainsworth (EA) Rob Campbell (ONR) James Taylor (HSE)	Kulvinder McDonald (ONR) Vince Green (ONR)
9.	**REGULATIONS AND GUIDES**		
	Kirsi ALM-LYTZ	Anthony Hart (ONR) Gillian Wasson (NIEA) James Taylor (HSE) Julia Frost (NRW) Keith Hammond (SEPA)	Matthew Worsley (ONR) Rebecca Favager (NRW)

	IRRS Experts	Lead Counterpart	Support Staff
		Peter Brember (EA)	
10.	**EMERGENCY PREPAREDNESS AND RESPONSE REGULATORY ASPECTS**		
	Igor GRLICAREV	Adam Stevens (BEIS) Carol Attwood (EA) Christopher Thomas (FSA) Clare McNicholas (HSE) Corynne McGuire (SEPA) Gillian Wasson (NIEA) Graeme Thomas (ONR) Jo Evans (NRW)	Adam Lang (Defra) Charles Stapleton (BEIS) Gavin Smith (ONR) Linda Murphy (HSE-NI) Liz Thomas (ONR) Paul Barrett (BEIS) Richard Broughton (HSE) Simon Clark (ONR)
11.	**INTERFACE WITH NUCLEAR SECURITY**		
	Felix ALTORFER Uma RAMASAMY	Alison Jeynes (DAERA) Angela Wright (SEPA) James Taylor (HSE) Paul Fyfe (ONR) Peter Brember (EA) Robert Price (NRW)	Linda Murphy (HSE-NI) Matt Sims (ONR)
	SPECIFIC DISCUSSIONS		
	Ramzi JAMMAL Fabien FÈRON	David Snowball (HSE) Helen Shirley-Quirk (BEIS) Jamey Johnson (DWP) Mark McAllister (ONR)	

	IRRS Experts	Lead Counterpart	Support Staff
		Philip White (HSE) Sarah Albon (HSE)	

APPENDIX IV - RECOMMENDATIONS (R), SUGGESTIONS (S) AND GOOD PRACTICES (GP)

AREA	R: Recommendation S: Suggestion GP: Good Practice	Recommendations, Suggestions or Good Practices
1. RESPONSIBILITIES AND FUNCTIONS OF THE GOVERNMENT	R1	Recommendation: The UK Government should publish a single, formalized statement of its national policy and strategy for safety to include all relevant elements of GSR Part 1, Rev 1.
	S1	Suggestion: The UK Government should consider improving the coordination among the regulatory bodies and with Government departments to ensure effective delivery of their regulatory functions including by addressing gaps in existing coordination arrangements.
	R2	Recommendation: The UK Government should revise: • the Nuclear Installation Regulations 1971 such that GDF is defined as a nuclear licensed site and is subject to ONR authorization; and • the Nuclear Installation Act 1965 to include requirements on release of nuclear licensed sites from regulatory control with restrictions on the future use.
2. THE GLOBAL SAFETY REGIME	S2	Suggestion: The UK Government should consider notifying the IAEA of its commitment to the Supplementary Guidance on the Management of Disused Radioactive Sources.
	R3	Recommendation: The UK government, in consultation with regulatory bodies should formalise and improve existing processes and arrangements for sharing of operating and regulatory experience to ensure systematic analysis and feedback on measures taken in response to information received.
3. RESPONSIBILITIES AND FUNCTIONS OF THE REGULATORY BODY	GP1	Good Practice: ONR has developed its matrix management structure that effectively allocates resources to need. It has also improved its hiring, training and strategic planning practices so as to develop new hires and to effectively anticipate and fill future needs.
	R4	Recommendation: The HSE should increase the number of both Specialist Inspectors (Radiation) and Ionising Radiations Regulatory Inspectors.
	R5	Recommendation: SEPA should continue to develop and implement a competence

		framework and develop a human resources and training plan in its department of radioactive substances, including related procedures.
	R6	**Recommendation: CQC should allocate resources to regulate relevant IR(ME)R activities, commensurate with the radiation risks associated and in accordance with a graded approach. CQC should also seek to increase its number of inspectors so as to be able to increase the frequency with which facilities are inspected.**
	S3	**Suggestion: The HSE should consider reviewing the operational aspects of CIDI to receive data more frequently and enhance its capabilities to facilitate its own and other regulatory bodies' activities.**
	R7	**Recommendation: The HSE, HSENI and ONR should establish and maintain a single register of radiation sources and radiation generators which contain information about their exact numbers, characteristics and location to enable adequate regulatory oversight by the relevant regulatory authorities.**
	R8	**Recommendation: ONR should establish provisions for interested parties and the public to be appropriately consulted in its process for making significant regulatory decisions, establishing regulatory guidance or when updating licence conditions.**
4. MANAGEMENT SYSTEM OF THE REGULATORY BODY	**R9**	**Recommendation: ONR should further develop and implement its Integrated Management System to fully comply with the IAEA safety standards.**
	R10	**Recommendation: EA should further develop and implement its Integrated Management System to fully comply with the IAEA safety standards.**
	S4	**Suggestion: Within its Integrated Management System, CQC should consider enhancing its processes for oversight of radiation safety.**
	S5	**Suggestion: HSE should consider improvement of its Integrated Management System with respect to the clear visibility of the process owners.**
5. AUTHORIZATION	**R11**	**Recommendation: The ONR, HSE and HSENI should request the applicants seeking authorization for the safety significant activities and facilities to submit a safety assessment in accordance with IRR17, which should be reviewed before granting the authorization. When deemed necessary, the ONR, HSE and HSENI should be able to impose limits, conditions and controls on the authorized party's subsequent activities.**

	S6	**Suggestion: The HSE should consider setting up appropriate mechanisms for either the formal recognition or accreditation of training and educational service providers.**
	S7	**Suggestion: The HSE should consider providing, in addition to the UKAS, approval to certain calibration services or individuals.**
	S8	**Suggestion: The UK Government should consider establishing a licensing regime for radiation therapy facilities, facilities performing image guided interventional procedures and diagnostic radiology facilities with regards to medical exposures.**
	S9	**Suggestion: The UK Government should consider including information on the regulation of "Consumer Products" in its draft "Framework for Radiation Protection and Nuclear Safety". In addition to that, the OPSS and the HSE should consider developing further guidance pertaining to "Consumer Products" regulations.**
6. REVIEW AND ASSESSMENT	**S10**	**Suggestion: The ONR should consider revising the relevant decommissioning guidance to provide clarity on how it undertakes periodic regulatory review of decommissioning plans.**
	S11	**Suggestion: HSE should consider making a guidance document on the identification of the on-site "representative person" in the non-nuclear practices. This would assist the operator and HSE to ensure appropriate implementation of the requirements with respect to public exposures.**
	S12	**Suggestion: HSE and EA should consider updating their MoU to ensure it reflects changes in relevant legislation and IAEA guidance since 2012.**
7. INSPECTION	**S13**	**Suggestion: ONR should develop clear expectations and associated guidance for inspection staff in how much time should be dedicated to general surveillance of facilities and how it should be accomplished independent of scheduled inspection activities.**
	R12	**Recommendation: EA should provide guidance on how to apply a graded approach in determining the appropriate frequency of inspections for the areas and programs inspected for nuclear facilities.**
	R13	**Recommendation: HSE, HSENI and ONR should develop and implement a programme of inspection which stipulate the frequency of radiation sources safety related inspections and the areas and programmes to be inspected, in accordance with a graded approach.**

	R14	**Recommendation: HSE, HSENI, and ONR should review their individual occupational exposure inspection guidance to ensure they adequately address the relevant safety aspects to be included in the scope of inspections.**
	R15	**Recommendation: CQC, HIW, and HIS should develop a programme of inspection that includes the frequency of inspections for all facilities and areas and programmes to be inspected, in accordance with a graded approach.**
8. ENFORCEMENT	**S14**	**Suggestion: The ONR should consider improving its guidance to indicate which other governmental organizations are to be informed of its formal enforcement actions.**
9. REGULATIONS AND GUIDES	**R16**	**Recommendation: The EA, NRW, SEPA, NIEA, HSE, HSENI and CQC should further develop processes and procedures for the establishment, review and update of regulatory guidance to include applicable IAEA safety standards.**
	S15	**Suggestion: The NIEA should consider requiring permit holders of non-nuclear sites to have in place RAW management plans identifying the interdependencies in RAW management including the disposal option.**
	R17	**Recommendation: The environment agencies should make more direct reference to the requirements for isolation and containment of radioactive waste and should clearly indicate in their guidelines that no radioactive discharges are expected from disposal facilities.**
	R18	**Recommendation: The environment agencies should further develop their guide NSD-GRA to clarify the role of and its expectations for passive safety in providing additional assurance of the safety of a disposal facility.**
	R19	**Recommendation: The EA should review its approach to clearance, to consider the use of case and site-specific activity concentrations in helping enable the minimisation of radioactive waste production.**
	R20	**Recommendation: The NIEA should continue with its effort to develop a guide on decommissioning of non-nuclear facilities.**
	R21	**Recommendation: Once relevant legislative changes have been implemented, the ONR should review and update the decommissioning guidance to reflect the requirements on release of the nuclear site from their regulatory control with restrictions on the future use.**

	S16	**Suggestion: The HSE and HSENI should consider updating their guidelines relevant to the approval of technical services and establishing, developing and maintaining further appropriate guidelines.**
	R22	**Recommendation: The EA should review and revise as necessary its regulatory guidance to keep it up to date with due consideration of relevant international safety standards, policy and current regulatory framework.**
	S17	**Suggestion: The NIEA should consider developing guidance to cover the RCL regime.**
10. EMERGENCY PREPAREDNESS AND RESPONSE REGULATORY ASPECTS	**R23**	**Recommendation: The Government should review the UK EP&R framework to explain how the requirements of GSR Part 7 are met in terms of EALs and OILs, and if any gap exists develop appropriate regulatory requirements.**
	R24	**Recommendation: The Government should review the UK EP&R framework to explain how the requirements of GSR Part 7 are met in terms of planning zones and distances, and if any gap exists develop appropriate regulatory requirements.**
	S18	**Suggestion: ONR should consider establishing pre-defined communication with the operating organizations in terms of plant data and other information during emergencies.**
	S19	**Suggestion: The ONR should consider integrating its response arrangements into a response and preparedness plan and formalize training and qualification of emergency response staff.**
11. INTERFACE WITH NUCLEAR SECURITY	**GP2**	**Good Practice: The UK government has implemented effective interface between safety and security for category 1 to 4 radioactive sources through the requirement for security experts to advice and inspect security requirements with environmental regulators.**

APPENDIX V - REFERENCE MATERIAL PROVIDED BY THE COUNTERPARTS

The references below are those provided to the IRRS Team in advance of the mission and during the mission itself for information.

Reference	Reference Title
1.	EA Operational Instruction 247_10, Environmental permitting: handling and determining applications for radioactive substances activities on nuclear sites, Version 7, 07/03/2018
2.	NIEA – QA 007: Radioactive Substances: Compliance Assessment Report
3.	NIEA - QA 012: Transport of Radioactive Substances (Inspections), version 12, May 2017
4.	NIEA – QA 022: Agreement of Work Scope for Northern Ireland Environment Agency
5.	NIEA Framework Document, December 2018
6.	NS-PER-GD-013 - Administrative Arrangements for Delegated Authorities within ONR
7.	NS-PER-GD-014 - Permissioning Guidance
8.	NS-PER-GD-015 - Guidance on Production of Reports
9.	ONR-ENF-GD-006 Enforcement
10.	ONR-HPC-PAR-12-043 Assessment of NNB GenCo Application for a Nuclear Site Licence, November 2012
11.	ONR-HR-GD-001 – Application of ONRs Equivalence Process – Revision 1
12.	ONR-HR-GD-003 – Competence Framework and Training and Development for ONR Staff – Revision 5
13.	ONR-HR-GD-005 – Issue and Control of ONR warrants and AVO identification cards - Revision 5
14.	ONR-HR-GD-009 ONR Regulatory Competency Framework
15.	ONR-RI-GD-003 Management of Regulatory Issues
16.	SEPA Code of Conduct for Staff, BP-HR-009, Version 9.0, Feb 2017
17.	SEPA Commercial Services Strategy
18.	SEPA Complaints Handling Procedure, BP-008, Version 14.0, Apr 2018
19.	SEPA Constitution of the Regulatory Review Teams, OBP-RRT-01, Version 31, Apr 2018
20.	SEPA Dignity and Respect at Work Procedure, BP-HR-001, Version 7.0, Jun 2015
21.	SEPA Environmental Events Guidance: Radioactive Substances, RS-G-011, Version 4.0, Nov 2016
22.	SEPA Grievance Procedure, BP-HR-014, Version 6.0, Aug 2017
23.	SEPA Guidance for Managing Performance, BP-HR-099, Version 4.0, Apr 2017
24.	SEPA Guidance on SEPA's involvement in different types of event involving radioactive substances, RS-G-012, Version 1.0, Sep 2013
25.	SEPA Hazard Bands & Inspection Frequencies for Radioactive Substances Activities under EASR, RASPAN 2018-02, Version 2.0, Mar 2019
26.	SEPA Information & Evidence Strategy
27.	SEPA Managing Performance Procedure, BP-HR-102, Version 3.0, Apr 2017
28.	SEPA Procedure for the Authorisation of SEPA Officers, OBP-054.08, Version 12, Sep 2015
29.	SEPA Procurement Guidelines, BP-084, Version 15.0, May 2018
30.	SEPA Procurement Strategy 2016 - 2022, BOS-015, Version 6.0, Jan 2017
31.	SEPA Radioactive Substances Emergency Response Plan, ER-CA-7, Version 3.0, Sep 2018

32.	SEPA RASRAP Terms of Reference, RS-P-025, Version 2.0, Apr 2018
33.	SEPA Regulatory Evidence Strategy
34.	SEPA Review of Authorisations and Registrations, RS-P-019, Version 4.0, Apr 2015
35.	SEPA Scheme of Delegation to the Chief Executive, BP-116, Version 3.0, Jul 2011
36.	SEPA Specific Scheme of Delegation, BP-062, Version 14, Mar 2013
37.	SEPA Standby arrangements for radioactive substances, RS-P-009, Version 5.0, Nov 2014
38.	SEPA Training, Learning and Development, BP-TLD-001, Version 5.0. Apr 2013
39.	Transport Permissioning – Example of a Package Design Approval (template)
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41.	TRA-MS-GD-003 Revision 0, GB Competent Authority (Radioactive Materials Transport) Manual
42.	TRA-PER-GD-001 Revision 1, Transport Permissioning Assessment, December 2016
43.	TRA-PER-GD-002 Revision 1, Safety Case Requirements Assessment, December 2016
44.	TRA-PER-GD-003 Revision 1, Pre-Permissioning Review, December 2016
45.	TRA-PER-GD-004 Revision 1, TSC support to Transport Permissioning, December 2016
46.	TRA-PER-GD-005 Revision 1, Extensions to Approvals, December 2016
47.	TRA-PER-GD-006 Revision 2, Non-European B (U) Validations, December 2016
48.	TRA-PER-GD-007 Revision 1, Transit Approvals, December 2016
49.	TRA-PER-GD-008 Revision 1, Publication of Project Assessment Reports, August 2016
50.	TRA-PER-GD-009 Revision 2 Preparation of Approvals, January 2019
51.	TRA-PER-GD-010 Revision 1, Application Receipt and Allocation, December 2016
52.	TRA-PER-GD-011 Revision 1, Shielding Assessment, December 2016
53.	TRA-PER-GD-012 Revision 1, Criticality Assessment, December 2016
54.	TRA-PER-GD-013 Revision 1, Engineering Assessment, December 2016
55.	TRA-PER-GD-017 Revision 1, Assessment Scope and Pre-Job Brief, December 2016
	Legislative References (alphabetical)
56.	Air Navigation (Dangerous Goods) (Amendment) Regulations 2019
57.	Anti-Terrorism, Crime and Security Act 2001
58.	Aviation Safety (Amendment etc.) (EU Exit) Regulations 2019
59.	Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010
60.	Civil Aviation Act 1971
61.	Civil Aviation Act 1982 and the associated Regulations (the Air Navigation Order 2016 SI 2016 No 765
62.	Civil Contingencies Act 2004
63.	Control of Major Accident Hazards (COMAH) Regulations 2015
64.	Dangerous Vessels Act 1985
65.	Disposal of Documents Order 1925
66.	Energy Act 2013
67.	Environment Act 1995
68.	Environment Wales Act 2016
69.	Environmental Authorisations (Scotland) Regulations 2018 (EASR)
70.	Environmental Permitting (England and Wales) Regulations 2016

71.	Environmental Protection Act 1990
72.	Food (Scotland) Act 2015
73.	Food and Environment Protection Act 1985 (FEPA)
74.	Food Irradiation (England) Regulations 2009
75.	Food Irradiation (Scotland) Regulations 2009
76.	Food Irradiation (Wales) Regulations 2009
77.	Food Irradiation Regulations (Northern Ireland) 2009
78.	Food Safety Act 1990
79.	Food Standards Act 1999
80.	Freedom of Information Act 2000
81.	Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999
82.	Health and Safety at Work etc. Act 1974 (HSWA)
83.	Health and Social Care Act 2008
84.	Ionising Radiation (Basic Safety Standards) (Miscellaneous Provisions) Regulations 2018
85.	Ionising Radiation Regulations 2017 (IRR17)
86.	Ionising Radiations Regulations (Northern Ireland) 2017 (IRRNI17)
87.	Legislative and Regulatory Reform Act 2006
88.	Marine Safety Act 2003
89.	Merchant Shipping Act 1995
90.	Merchant Shipping Act 1995 as Amended by Marine Safety Act 2003
91.	Merchant Shipping and Maritime and Security Act 1997
92.	National Health Service (Scotland) Act 1978
93.	NHS Act 2006
94.	Nuclear Industries Security Regulations 2003
95.	Nuclear Installations Act 1965
96.	Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999
97.	Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999 (EIADR)
98.	Offshore Installations (Emergency Pollution Control) Regulations 2002
99.	Police and Criminal Evidence Act 1984
100.	Pollution and Prevention and Control Act 1999, Section 3
101.	Public Bodies (Joint Working) (Scotland) Act 2014
102.	Public Records Act (NI) 1923
103.	Public Service Reform Scotland Act 2010
104.	Radioactive Contaminated Land (Enabling Powers) (England) Regulations 2005
105.	Radioactive Contaminated Land (Modification of Enactments) (Wales) Regulations 2006
106.	Radioactive Contaminated Land (Scotland) Regulations 2007 and their amendments
107.	Radioactive Substances Act 1993 (RSA93)
108.	The Air Navigation (Dangerous Goods) Regulations 2002 SI 2002 No 2786
109.	The Air Navigation Order 2016
110.	The Building (Scotland) Regulations 2004
111.	The Building Regulations (Northern Ireland) 2012

112.	The Building Regulations 2010 Approved Document C (England)
113.	The Building Regulations 2010 Approved Document C (Wales)
114.	The Carriage of Dangerous Goods (Amendment) Regulations 2019
115.	The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009
116.	The Economic Growth (Regulatory Functions) Order 2017
117.	The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003
118.	The Health and Safety (Enforcing Authority) Regulations 1998
119.	The Health and Safety at Work (Northern Ireland) Order 1978 (HSW(NI)078)
120.	The High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005
121.	The Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018
122.	The Ionising Radiation (Medical Exposure) Regulations 2017 (IR (ME)R) in Great Britain
123.	The Management of Health and Safety at Work Regulations (Northern Ireland) 2000
124.	The Management of Health and Safety at Work Regulations 1999
125.	The Merchant Shipping (Carriage of Packaged Irradiated Nuclear Fuel etc.) (INF Code) Regulations 2000
126.	The Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997
127.	The Merchant Shipping (International Safety Management (ISM) Code) Regulations 2014
128.	The Merchant Shipping (Reporting Requirements for 2498 Ships Carrying Dangerous or Polluting Goods) Regulations 1995
129.	The Natural Resources Body for Wales (Establishment) Order 2012
130.	The Natural Resources Body for Wales (Functions) Order 2013
131.	The Public Water Supplies (Scotland) Regulations 2014
132.	The Radiation (Emergency Preparedness and Public Information) Regulations 2001
133.	The Radiation (Emergency Preparedness and Public Information) Regulations (Northern Ireland) 2001
134.	The Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR19)
135.	The Radioactive Contaminated Land (Modification of Enactments) (England) Regulations 2006
136.	The Radioactive Contaminated Land Regulations (Northern Ireland) 2006
137.	The Radioactive Substances (Basic Safety Standards) Regulations (Northern Ireland) 2003
138.	The Radioactive Substances (Modification of Enactments) Regulations (Northern Ireland) 2018
139.	The Radioactive Substances Exemption (Northern Ireland) Order 2011
140.	The Transfrontier Shipment of Radioactive Waste and Spent Fuel Regulations 2008
141.	Transitional (Provisions and Savings) Order 2014 (SI 2014 No 469)
142.	Water Industry (Scotland) Act 2002
143.	Water Supply (Water Quality) Regulations (Northern Ireland) 2017
144.	Water Supply (Water Quality) Regulations 2016 as amended by the 2018 Amendment Regulations
145.	CQC Commercial Strategy
146.	CQC Health and Safety Policy
147.	CQC People Directorate Business Plan

148.	CQC Procurement Policy
149.	EA Document 1044_14, Incident Management Handbook, March 2018
150.	EA Document 1401_12 Guide to Development of RSR Fully Capable Regulators v4 Apr-2018
151.	EA Document 212_04 Non-Financial Scheme of Delegation (NFSoD) version 38 7 June 2018)
152.	EA Document 389_09, Our role and response to a radiation incident, v3, 29 March 2018
153.	EA Document 44_14, Managing performance well-a guide for managers and team members, v8, 25 May 2018 Environment Agency, Document 724_11 (LIT 16368)
154.	EA Document 763_14, Workforce Planning guidance
155.	EA Document 785_14, Succession Planning guidance
156.	EA Document LIT 15647, Controlled content - how to plan, produce, review and withdraw content, v4
157.	EA Nuclear Delivery Plan 2018 - 2023 V1.0
158.	EA Operational Instruction 150_10, Periodic review of non-nuclear RSR permits under EPR2010, Version 3, 24/06/11
159.	EA Operational Instruction 156_10, Assessing compliance for radioactive substances (RSR) facilities under the Environmental Permitting Regulations (EPR)
160.	EA Operational Instruction 26_01, How to plan, produce, publish and maintain Quality Management System documents v32 Issued 1 February 2018
161.	EA Operational Instruction 338_04, RSR permitting – prospective radiological assessments for human health and wildlife (habitats) v8, Version 8, 01/06/2015
162.	EA Operational Instruction 353_03, Investigations Manual, version 26, issued 31 July 2018
163.	EA Operational Instruction 416_07 Code of Conduct, issued 25 May 2018)
164.	EA Operational Instruction 487_10, Whistleblowing - dealing with a concern, v16, 26 July 2018
165.	EA Operational Instruction 514_10, Environmental permitting: determining applications for radioactive substances on non-nuclear sites, Version 3, 15/03/2016
166.	EA Operational Instruction 590_11, Obtaining and maintaining your personal authorisation (warrant) version 11, 02 May 2018
167.	Environment Agency Document 212_04 Non-Financial Scheme of Delegation (NFSoD) version 38 7 June 2018)
168.	Framework Document between the Department for Work and Pensions and the Health and Safety Executive
169.	HIS Quality of Care Approach – Evaluating and Improving
170.	HIS Quality of Care Approach – Quality Assurance
171.	HIS Strategy
172.	HSE Employee Guidance
173.	HSE Health and Safety Policy Statement
174.	HSE Info for employees
175.	HSE Inspectors – regulatory & discipline specialists
176.	HSE Responsibilities
177.	HSE Self-enforcement policy statement
178.	HSE/HSENI Inspection and Investigation Policies, Procedures and Guidance
179.	HSE's approach to its own risk assessments required as part of its duties as an employer to reduce risks ALARP

180.	HSE's Intranet (Inspection and Investigation)
181.	HSENI's Compliance Handbook
182.	HSENI's Major Incident Response Plan, Version 7
183.	Incidents Index, Reporting Health, Safety and Wellbeing Incidents in HSE
184.	Inspectors – Regulatory & Discipline Specialists
185.	Instructions for the Guidance of Surveyors - Marine Surveyor Development Scheme MSIS 40 Issue 1 Rev 12-2018
186.	International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air 2019-2020 Edition (ICAO Technical Instructions)
187.	NRW nnRSR Sector Plan
188.	NRW OGN 55. Environmental permitting: handling and determining applications for radioactive substances activities on nuclear sites. Version 1 April 2017
189.	ONR - Corporate Business Plan and the business plans for each directorate
190.	ONR - Emergency Arrangements Handbook
191.	ONR-GEN-POL-009 Management of Organisational Change Process
192.	ONR-PROC- 001, Control of Management System Documented Information
193.	Reporting Health, Safety and Wellbeing Incidents in HSE
	Hyperlinked References (alphabetical)
194.	A Guide to Emergency Planning Arrangements in Northern Ireland (September 2011)
195.	A guide to Nuclear Regulation in the UK – 2016 update
196.	A guide to the Radiation (Emergency Preparedness and Public Information) Regulations 2001
197.	ADR 2019 (Files) – European Agreement concerning the International Carriage of Dangerous Goods by Road
198.	Annual Report and Statement of Accounts, 2017/18, HSE
199.	Approved Dosimetry Services, HSE Guidance
200.	BRE Good Building Guides GG 73 "Radon protection for new domestic extensions and conservatories with solid concrete ground floors" and GG 74 "Radon protection for dwellings".
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203.	Business Classification Scheme and Disposal
204.	Cabinet Office Guidance dated October 2011
205.	CD282 - the implementation of Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure arising to ionising radiation
206.	CDG19 non-statutory guidance, Transporting radioactive material - Guidance on emergency planning and notification for the transport of class 7 goods, June 2019
207.	Central Index of Dose Information (CIDI)
208.	Civil Service Code
209.	Civil Service Management Code
210.	Civil Service Recruitment Principles
211.	Clean Air Strategy
212.	Clean Growth
213.	Commission Regulation (EU) No 139/2014 pursuant to Regulation (EC) No 216/2008

214.	Commission Regulation (EU) No 965/2012 of 5 October 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
215.	Commission Staff Working Document – Evaluation of Regulation (EC) No 2111/2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating carrier
216.	Committee on Radiological Protection and Public Health (CRPPH)
217.	Consultation on the REPPIR Approved Code of Practice
218.	Convention on Nuclear Safety - IAEA
219.	Council Directive 2011/70/EURATOM of 19 July 2011 – Establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste
220.	Council Directive 2013/51/Euratom of 22 October 2013 – Laying down requirements for the protection of the health and the general public with regard to radioactive substances in water intended for human consumption
221.	Council Directive 2014/87/EURATOM of 8 July 2014 – Amending Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations
222.	Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation
223.	CQC Annual Report
224.	CQC Enforcing IR(ME)R - website
225.	CQC Five Year Plan
226.	CQC Provider Information Request: independent healthcare services
227.	CQC website
228.	DAERA - Environment, Marine & Fisheries Group Enforcement Policy
229.	Defra 25 Year Environment Plan
230.	Defra Environmental Permitting Guidance
231.	Defra Environmental Permitting Guidance Radioactive Substances Regulation for the Environmental Permitting (England and Wales) Regulations 2010, version 2.0, September 2011
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233.	Defra Environmental Permitting Guidance, Core guidance for the Environmental Permitting (England and Wales) Regulations 2010, March 2013 (relevant to all EPR regimes)
234.	Defra Environmental Permitting Guidance, Core guidance for the Environmental Permitting (England and Wales) Regulation 2010
235.	Department for Transport - Moving Dangerous Goods - A guide to the international regulations on the transportation of dangerous goods by air, sea, road, rail or inland waterway
236.	Department of Health - Northern Ireland - Good Management Good Records, advice and guidance on records management - website
237.	Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (Recast)
238.	Drinking Water Quality Regulator for Scotland
239.	DWP Framework Agreement 2018
240.	EA – Consultation Principles Guidance

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242.	EA Enforcement and Sanctions Policy
243.	EA Guidance on near surface disposal facilities
244.	EA Principles of optimisation in the management and disposal of radioactive waste, version 2, April 2010
245.	EA Process and Information Document for Generic Assessment of Candidate Nuclear Power Plant Designs v3, October 2016
246.	EA Public Participation Statement
247.	EA Regulatory Guidance Series No RSR 1 Radioactive Substances Regulation – Environmental Principles, April 2010, Version 2.0
248.	EA Regulatory Guidance Series, No RSR 2 The regulation of radioactive substances activities on nuclear licensed sites, Version 2.0, August 2012
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250.	EA, SEPA, NIEA, Near Surface Disposal Facilities on Land for Solid Radioactive Wastes, Guidance on Requirements for Authorisation, February 2009
251.	Emergency Response and Recovery
252.	Enforce Prosecutions
253.	Enforcement Guidelines
254.	Enforcement Guidelines for health and safety at work in Northern Ireland, 28 March 2008
255.	ENSREG - Basic Safety Standards Directive – EU Legislation in the field of safety - 2013/59/Euratom
256.	Environmental Protection – Radon
257.	Environmental Protection Act 1990 Part IIA Contaminated Land - The Radioactive Contaminated Land (Scotland) Regulations 2007 - Statutory Guidance
258.	Environmental Protection Act 1990: Part IIA - Radioactive Contaminated Land Statutory Guidance, Radioactive Contaminated Land Statutory Guidance for Wales 2012
259.	European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2019 Edition
260.	European Union – The European Radio Equipment Directive 2014/53/EU
261.	European Union (Withdrawal) Act 2018
262.	Example of Public Guidance - What is Radon?
263.	Executive Summaries of Improvement Notices, Prohibition Notices and prosecutions - on HSENI's website
264.	Explanatory Memorandum to REPPIR 2019 (SI 2019 No. 703)
265.	FSA Incident Management Plan for Non-Routine Incidents
266.	FSA Strategic Plan 2015-2020
267.	FSA Website
268.	FSS Incident Management Plan for Non-Routine Incidents
269.	FSS Records Management Plan
270.	FSS Regulatory Statement
271.	FSS Website
272.	General Safety Requirements - IAEA
273.	Government Consultation outcome Revised requirements for radiological protection: emergency preparedness and response

274.	Guidance for Notifications, Registrations and Consents
275.	Guidance on requirements for release of nuclear sites from radioactive substances regulation (GRR document)
276.	Guidelines for Drinking-water Quality – World Health Organization
277.	Health and Safety Executive Inspector Warrants
278.	Health and Safety Guidance (HSG) publications
279.	Healthcare Inspectorate Wales - Website
280.	HERCA – Heads of the European Radiological Protection Competent Authorities
281.	HIS Operating Framework: Healthcare Improvement Scotland and Scottish Government
282.	HIS The Operational Plan for 2019–2020
283.	HIS The Regulation of Independent Healthcare in Scotland
284.	HIW Memorandum of Understanding between Welsh Ministers and HIW's Chief Executive.
285.	HIW Strategic Plan
286.	HSE – Information about Health and Safety at Work
287.	HSE – Plan, Do, Check, Act
288.	HSE - What are the Management Standards?
289.	HSE (Industry) Sector Plans
290.	HSE Agency agreements, memoranda of understanding and concordats, and working arrangements protocols
291.	HSE Agency agreements: 2001 - to date
292.	HSE Annual Report 2017/18
293.	HSE Board – Organisation Chart
294.	HSE Board Biographies
295.	HSE Business Plan 2018/19
296.	HSE Business Plan 2019/20
297.	HSE Competency Framework
298.	HSE Enforce
299.	HSE Enforcement Policy Statement, 1
300.	HSE Guidance (Emergency planning relating to radiation)
301.	HSE Ionising Radiation Index
302.	HSE Learning Management System
303.	HSE Major Incident Response Plan (MIRP)
304.	HSE Management Board
305.	HSE Measuring Performance
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307.	HSE Public Register of Prosecutions
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309.	HSE Radiation Index
310.	HSE Radiation Protection Advisers
311.	HSE Radon in the Workplace
312.	HSE Records Management Policy
313.	HSE Register of prosecutions and notices
314.	HSE Statement on radiation protection advisers

315.	HSE Statement on the Approval of Dosimetry Services
316.	HSE Strategies and Plans
317.	HSE's Enforcement Management Model
318.	HSE's Leadership Programme (In-company course only)
319.	HSE's Statement on RPAs
320.	HSENI - Public Register of Convictions
321.	HSENI - Radon Information Leaflet
322.	HSENI - What to expect when a Health and Safety inspector calls
323.	HSENI Annual Reports
324.	HSENI Corporate Plan 2018-2023
325.	HSENI Operating plans
326.	HSENI Profile webpage
327.	HSENI Senior Management Team
328.	HSENI's Enforcement Guidelines
329.	HSENI-Board
330.	HSG65 Managing for Health and Safety
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368.	NRW - People and Teams Strategy 2016-2020
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371.	NS-INSP-GD-009 Revision 4 – Instructions to Persons on Site - Licence Condition 9
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373.	NS-INSP-GD-011 Revision 5 – Emergency Arrangements - Licence Condition 11
374.	NS-INSP-GD-012 Revision 1 – Duly authorised and other suitable qualified and experienced persons - Licence Condition 12
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377.	NS-INSP-GD-017 Revision 4 – Management Systems - Licence Condition 17
378.	NS-INSP-GD-018 Revision 5 – Radiological Protection – Licence Condition 18
379.	NS-INSP-GD-019 Revision 5 – Construction or Installation of New Plant - Licence Condition 19
380.	NS-INSP-GD-020 Revision 4 – Modification to Design of Plant under Construction - Licence Condition 20
381.	NS-INSP-GD-021 Revision 5 – Commissioning - Licence Condition 21
382.	NS-INSP-GD-022 Revision 4 - Modification or Experiment on Existing Plant - Licence Condition 22
383.	NS-INSP-GD-023 Revision 5 - Operating Rules - Licence Condition 23
384.	NS-INSP-GD-024 Revision 4 – Operating Instructions - Licence Condition 24

385.	NS-INSP-GD-025 Revision 5 - – Operational Records - Licence Condition 25
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388.	NS-INSP-GD-033 Revision 5 - Disposal of Radioactive Waste - Licence Condition 33
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402.	NS-PER-GD-014 - ONR Guide - Purpose and Scope of Permissioning - November 2016 Revision 6
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406.	NS-TAST-GD-005 - Guidance on the Demonstration of ALARP (As Low As Reasonably Practicable) Revision 9
407.	NS-TAST-GD-018 – Criticality Warning Systems Revision 7
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409.	NS-TAST-GD-026 – Decommissioning Revision 4
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411.	NS-TAST-GD-038 - Radiological protection Revision 8
412.	NS-TAST-GD-041 - Criticality Safety Revision 6
413.	NS-TAST-GD-043 - Radiological Analysis Normal Operation Revision 5
414.	NS-TAST-GD-045 - Radiological Analysis - Fault Conditions Revision 4
415.	NS-TAST-GD-050 – Periodic Safety Review (PSR) Revision 7
416.	NS-TAST-GD-051 – The Purpose, Scope, and Content of Safety Cases Revision 4
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418.	NS-TAST-GD-080, 'Challenge Culture, Independent Challenge Capability (including an Internal Regulation function), and the provision of Nuclear Safety Advice''

419.	NS-TAST-GD-082 – The Technical Assessment of REPPIR Submissions and the Determination of Detailed Emergency Planning Zones Revision 4
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423.	NS-TAST-GD-101 Geological Disposal
424.	NS-TAST-GD-103 Emergency Power Generation
425.	Nuclear Skill Strategic Plan in December
426.	Nuclear Workforce Assessment (NWA)
427.	OC 130/11 - Enforcement management model (EMM): application to ionising radiations
428.	ONR - Behaviour Framework
429.	ONR - Calendar for Emergency Exercises
430.	ONR - Corporate Plan 2019/20
431.	ONR - Direction to Dungeness B Power Station to Carry Out a Review and Reassessment of Safety Addressing the Corrosion of Concealed Systems
432.	ONR - Enforcement - website pages
433.	ONR - Enforcement Management Model
434.	ONR - Enforcement Management Model (EMM)
435.	ONR - Enforcement Policy Statement
436.	ONR - Example Validation of an Approval of Package Design for the Carriage of Radioactive Material
437.	ONR - Graded Approach
438.	ONR - Holding to Account and Influencing Improvements – a Guide to Enabling Regulation in Practice.
439.	ONR - Inspection Rating Guide
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441.	ONR - Licence Condition Handbook
442.	ONR - Licencing Nuclear Installations
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444.	ONR - Memorandum of Understanding with HSE
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449.	ONR - Quarterly Local Liaison Committee/Site Stakeholder Group Reports
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453.	ONR - Scheme of Delegation
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456.	ONR - Self-assessment of performance against the Regulators' Code 2018
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463.	ONR-DFW-PAR-14-011 ONR Assessment of the Hinkley Point A Site PSR 2015-25 Submission
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466.	ONR-HYA-PAR-18-007 Heysham 1 Consent to Start-Up Reactor 2 Following Periodic Shutdown 2018
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475.	Partnerships with arm's length bodies: code of good practice
476.	PHE – Radiation Emergency Preparedness Service - Training courses
477.	PHE CRCE radiation emergency response arrangements
478.	Preparing Scotland Scientific and Technical Advice Cell (STAC) Guidance
479.	Preparing Scotland: Scottish Guidance on Resilience
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482.	Radsafe - website
483.	Regulation (EC) No 1008/2008 of the European Parliament and of the Council of 24 September 2008 on common rules for the operation of air services in the Community (Recast)
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500.	RQIA Standing Orders
501.	RQIA Website
502.	Scotland Higher-activity radioactive waste: implementation strategy
503.	Scotland's Higher Activity Radioactive Waste Policy 2011 (published in January 2011)
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505.	Scottish Government Statutory Guidance on the Purpose of SEPA
506.	Scottish Public Finance Manual
507.	Scottish Regulators' Strategic Code of Practice
508.	Sellafield - Licence Condition 36 (Organisational Capability) Arrangements Inspection, IR Executive Summary
509.	SEPA & ONR MoU on matters of mutual interest in Scotland, Jan 2019
510.	SEPA Annual Operating Plan 2019 - 2020
511.	SEPA Corporate Plan 2017 - 2022
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513.	SEPA Enforcement Guidance (OPS-21)
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534.	TRA-PER-GD-014 Applications Guide
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541.	Welsh Government - Geological Disposal of Higher Activity Radioactive Waste: Working with Communities
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The below table refers to additional references provided to the IAEA IRRS mission team during module specific discussions by the regulatory bodies.

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Justification Process
Scotland HAW Policy
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ONR DWP Framework Document Oct 18
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Partnership Between Departments and arms length bodies code of good practice
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Framework Agreement between DHSC and PHE 2018 Annex A Statutory Functions
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Module 2
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MOU between the UK and the Devolved Administrations
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Module 3
None
Module 4
CQC
The CQC Guardian and the Freedom to Speak Up
CQC What do our values mean? A guide to putting the values at the root of what we do
HSE
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EA
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Sellafield RASCAR CAR Log
Cyclife UK Ltd Permit
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16098C45 Environmental Permitting: Handling and Determining Applications for Radioactive Substances Activities on Nuclear Sites
Environment Agency Document 763-14 Workforce planning guidance
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Environment Agency Document 1401-12 Guide to Development of RSR Fully Capable Regulators
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Principles of Optimisation V2 2010
RSR Workforce Plan 2019
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Template Decision Document for Nuclear Permit Determination
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Enforcement Implementation - Nuclear Safety - Improvement Notice Served on Sellafield Limited Relating to LC101, LC122 and LC243 & Enforcement Letters to Exposure of a Worker to Plutonium
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Memorandum Of Understanding Between The Office For Nuclear Regulation And The Natural Resources Body For Wales On Ma Tiers Of Mutual Interest In Wales
Memorandum Of Understanding Between The Office For Nuclear Regulation And The Scottish Environment protection Agency (SEPA) On Matters of Mutual Interest In Scotland
Guidance To Support The Joint Regulatory Memorandum Of Understanding Between The Office For Nuclear Regulation And The Environment Agency On Matters Of Mutual Interest In England
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Module 9
NIEA
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Radioactive Waste Advisor Scheme guidance
Guidance on the scope of and exemptions from the radioactive substances legislation in the UK
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Schedule of SAPs Project Boards
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Draft of new ONR RGP internal guidance
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DAERA

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HASS Security Certificate Template
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EA
SEL-18-042-O- Enforcement Notice
Regulation of none nuclear sites
RSL Guidance update BEIS format V5
RASCAR-SEL-015-MSSS
Hinkley Point C Permit
LIT 12427 Assessing Compliance for Radioactive Substances Facilities under EPR
Heysham 1 SER V7 2019
RASCAR-HART-18-003 Outage Waste Management
Selcia Varied Permit

Environment Agency, Installation Sector Activities 2018-19 v1.5
Canterbury Hosp Visit Report 2018 008 Non Compliance
RIFE data for EA
NORM Strategy
RS-JG-018 Rad Mon Guidance Note 02 Environmental Review
LIT 11141 Regulating contaminated land under part 2a EPA 1990 Remediating Special Sites
LIT 11248 Preparation of a remediation notice under part 2A of the EPA 1990
Halsemere Permit PB3091 DX
HSE
MOU between HSE and EA on the Regulation of Radioactive Substances on Non Nuclear Sites
SEPA
Outline Inspection Programme v6
Occupation Exposures
HSENI
Questions for ionising radiation consent applications
Questions for ionising radiation notification and registration applications
Registration certificate, Number: IR201909-0008
Consent certificate - industrial radiography practices: IC201909-0001
Questions for ionising radiation notification and registration applications
ONR
IRR99 Regulation 15 vs irr17 Regulation 16 Co-operation between employers
IRR17 Inspection of the Active Handling Facility
Notification – Acknowledgement or Receipt
Notification for Work With Ionising Radiation on the Certain Nuclear Premises
Certificate of Registration of Registrable Practice(s)
Application for Certification of Registration of Registrable Practice(s)
Certificate of Consent to Carry out Specified Practices
Application for Certificate of Consent to Carry out Specified Practices
Responding to a CBRN(e) Event: Joint Operating Principles for the Emergency Services
NS-TAST-GD-002 (Rev 7) June 2022 Radiation Shielding PDF
NS-TAST-GD-004 (Rev 7) April 2022 Fundamental Principles PDF
NS-TAST-GD-005 (Rev 9) March 2021 Guidance on the Demonstration of ALARP (As Low As Reasonably Practicable) PDF
NS-TAST-GD-038 (Rev 8) November 2020 Radiological protection PDF
NS-TAST-GD-041 (Rev 6) June 2022 Criticality Safety PDF
NS-TAST-GD-043 (Rev 5) July 2022 Radiological Analysis Normal Operation PDF
NS-TAST-GD-045 (Rev 5) July 2022 Radiological analysis Fault conditions PDF
NS-TAST-GD-097 (Rev 0) October 2020 Criticality Safety Assessment of Transport Packages PDF
NS-TAST-GD-100 (Rev 0) April 2020 Shielding and Dose Rate Safety Assessment of Transport Packages PDF
Transport
NIEA
AWE transport inspection report
Agency Agreement between DAERA and ONR
Radiation Sources

DAERA
RSA1 c (Sealed Sources) Application for registration of premises for sealed sources
RSA1 o (Open Sources) Application for registrations of premises for open sources
RSA3 (Authorisation) Application for authorisation to accumulate and dispose of radioactive waste
Section 7 Open Sources Certificate template
Section 7 HASS Security Certificate template
Section 13 & 14 Certificate of authorisation
Example of variation of certificate – Altnagelvin
QA 006 – Application process
QA 007 – Inspection process
RSA Inspection Plan 2019 – 2020
RSA list of registered sites
IPRI Schedule of Investigations
Scope of and exemption from the radioactive substances legislation in England, Wales and Northern Ireland
NIEA
HASS record form Justification of practices involving ionising radiation 2004 - Guidance on their application and administration
Medical Exposures
HIS
IRMER Enforcement Policy Updated
HSE EMM
IRMER Inspection Methodology
Inspection Programme 2019-20
NRW
IRMER Governance and Enforcement V8 Working Draft
IRMER History
RQIA
Ionising Radiation Policy Final
RQIA Inspection Policy
RQIA Enforcement Policy
IR(ME)R Schedule
IR(ME)R Schedule
Existing Exposures
EA
MOU between ONR and EA on matters of Mutual Interest in England

APPENDIX VI - IAEA REFERENCE MATERIAL USED FOR THE REVIEW

1.	**IAEA SAFETY STANDARDS SERIES No. SF-1** – Fundamental Safety Principles
2.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 1 (Rev. 1)** – Governmental, Legal and Regulatory Framework for Safety
3.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 2** – Leadership and Management for Safety
4.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 3** – Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards
5.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 4 (Rev. 1)** – Safety Assessment for Facilities and Activities
6.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 6** – Decommissioning of Facilities
7.	**IAEA SAFETY STANDARDS SERIES No. GSR PART 7** – **Preparedness and Response for a Nuclear or Radiological Emergency**
8.	**IAEA SAFETY STANDARDS SERIES No. SSR-2/1** – Safety of Nuclear Power Plants: Design
9.	**IAEA SAFETY STANDARDS SERIES No. SSR-2/2** – Safety of Nuclear Power Plants: Commissioning and Operation
10.	**IAEA SAFETY STANDARDS SERIES No. SSR-4** – Safety of Nuclear Fuel Cycle Facilities
11.	**IAEA SAFETY STANDARDS SERIES No. SSR-5** – **Disposal of Radioactive Waste**
12.	**IAEA SAFETY STANDARDS SERIES No. SSR-6** – **Regulations for the Safe Transport of Radioactive Material**
13.	**IAEA SAFETY STANDARDS SERIES No. TS-R-1** – **Regulations for the Safe Transport of Radioactive Material**
14.	**IAEA SAFETY STANDARDS SERIES No. GSG-6** – Communication and Consultation with Interested Parties by the Regulatory Body
15.	**IAEA SAFETY STANDARDS SERIES No. GSG-12** – Organization, Management and Staffing of the Regulatory Body for Safety
16.	**IAEA SAFETY STANDARDS SERIES No. GSG-13** – Functions and Processes of the Regulatory Body for Safety
17.	**IAEA SAFETY STANDARDS SERIES No. GS-G-2.1** – Arrangements for Preparedness for a Nuclear or Radiological Emergency
18.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.1 -** Application of the Management System for Facilities and Activities
19.	**IAEA SAFETY STANDARDS SERIES No. GS-G-3.2 -** The Management System for Technical Services in Radiation Safety
20.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.3 -** Assessment of Occupational Exposure Due to External Sources of Radiation
21.	**IAEA SAFETY STANDARDS SERIES No. RS-G-1.4 -** Building Competence in Radiation Protection and the Safe Use of Radiation Sources
22.	**IAEA SAFETY STANDARDS SERIES No.** SSG-25 **-** Periodic Safety Review for Nuclear Power Plants

23. **IAEA SAFETY STANDARDS SERIES No. SSG-50 –** Operating Experience Feedback for Nuclear Installations

24. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Convention on Early Notification of a Nuclear Accident (1986) and Convention on Assistance in the Case of a Nuclear Accident or Radiological Emergency (1987), Legal Series No. 14, Vienna (1987).

25. **INTERNATIONAL ATOMIC ENERGY AGENCY** - Generic Assessment Procedures for Determining Protective Actions during a Reactor Accident, IAEA-TECDOC-955, IAEA, Vienna (1997)

26. **INTERNATIONAL ATOMIC ENERGY AGENCY -** General Safety Guide SGS-7 Occupational Radiation Protection

27. **INTERNATIONAL ATOMIC ENERGY AGENCY -** Specific Safety Guide -46 Radiation Protection and Safety in Medical uses of Ionization Radiation