Medical Radionuclide Innovation Programme

UK Regulatory Study

EA, ONR, HSE, NRW, SEPA & NIEA (2026)

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Executive summary

This report should be read with the following context:

This study was written by the regulators as part of DESNZ's Medical Radionuclide Innovation Programme (MRIP) which concluded in March 2025. It is specifically focussed on medical radioisotopes and is separate to the Nuclear Regulatory Review 2025 and subsequent government response which was published in March 2026.

The Nuclear Regulatory Review 2025, the output of the independent Nuclear Regulatory Taskforce commissioned by the Prime Minster, provided an independent review of the UK's regulatory system for both civil and defence nuclear. The government's response to the regulatory review committed to implementing all its 47 recommendations and work is ongoing towards this.

Although separate, and written prior to the regulatory review being launched, this report is aligned with the principles behind the government response to the regulatory review. It provides recommendations to examine regulatory processes in the UK, specifically in relation to medical radioisotopes, but which are relevant to the broader recommendations outlined in the regulatory review.

This report aims to develop an understanding of the roles and requirements of key radiological and civil nuclear safety regulatory bodies within the radiopharmaceutical supply chain and determine how new, innovative production methods would be regulated. The report includes how the regulators interlink, how the regulatory requirements change depending on the origin of the radionuclide and summarises any challenges faced.

The UK government provided a series of questions to UK regulators likely to have a function within the supply chain of innovative radiopharmaceuticals that consider the following:

- roles and requirements of key regulatory bodies within the radionuclide supply chain
- graded regulatory approach
- regulatory challenges

Responses to this question set and the guidance document 'How we regulate radiological and civil nuclear safety in the UK' (adapted to be relevant to the questions asked and to medical radionuclide production) form the basis of this report.

The report clearly sets out the relationships and interfaces between the different regulatory bodies, as well as how we currently work together and how requests for new radionuclide production technologies are currently managed. We also briefly highlight how the newly developed early engagement process for nuclear licensable activities (developed for new power reactor build) could be used for novel nuclear licensable medical radionuclide production facilities.

Across all regulators, the responsibility for radiological and nuclear safety, and for meeting regulatory requirements, rests with those who create the radiation risks. Consequently, organisational development and operator competence are likely to need consideration as well as the regulatory requirements associated with the physical elements of the facility (such as the design, construction, operation and decommissioning).

Environmental regulators

The relevant UK environmental regulator (Environment Agency, Natural Resources Wales, Northern Ireland Environment Agency or Scottish Environment Protection Agency) would regulate radioactive substances activities associated with the production and use of medical radionuclides, dependent on where in the UK the activity was carried on. The regulatory remit of the relevant environmental regulator would vary depending on whether the activity was carried out on a nuclear licensed site or not. Unless exempt from radioactive substances regulation or carried on under general binding rules, the radioactive substances activity would likely require an environmental permit or authorisation.

For environmental regulation, this report has only considered radioactive substances activities, but non-radiological environmental protection regulation is also likely to need consideration, as well as considerations under the planning regime. This is particularly important for larger and more complex facilities, with more significant non-radiological environmental impacts.

Health and safety regulators

The relevant UK Health and Safety regulator (HSE in Great Britain or HSENI in Northern Ireland) regulates the occupational and public safety aspects of the production and use of medical radionuclides, not including patient safety, when this work is not undertaken on a nuclear licensed site. The addition of radioactive substances to pharmaceuticals and the administration to patients of the radiopharmaceuticals produced will require consent. Additionally, some sites are likely to require consent for discharge of significant quantities of radioactive substances.

Office for Nuclear Regulation

The UK nuclear regulator for safety, security, safeguards and transport, Office for Nuclear Regulation (ONR), would regulate the production of certain medical radioisotopes if undertaken on a nuclear licensed site in Great Britain. A nuclear site licence is required if that site is to be used for the installation or operation of prescribed kinds of installations (including installations designed or adapted for the storage of bulk quantities of radioactive matter). ONR also regulates the transport of (Class 7 dangerous goods) by road, rail and inland waterways radioactive material within Great Britain under The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009. More information on proposed installations is required for ONR to determine whether a nuclear site licence is required.

Conclusion

During this project the regulators assessed three different radionuclide production scenarios:

- particle accelerators
- research reactors; and
- harvesting of legacy waste

While the regulators conclude the current regulatory framework is suitable, there are two aspects that will require deeper consideration. Firstly, the interface between the vires of different regulators, particularly ONR and HSE/HSENI on whether a nuclear site licence is required: a licence would incur significant additional cost and regulatory burden to the operator. Secondly, how novel technologies interact with the Radiation (Emergency Preparedness and Public Information) Regulations, 2019: sites with potential to cause a radiation emergency and their local authorities have duties to prepare emergency plans and make information available to the public; this would introduce financial and regulatory burden and could delay a site becoming operational.

On the basis of the information provided, the regulators have not identified any significant challenges that would prevent most of the scenarios presented being brought to market. One exception may be the use of Th-228/Pb-212 generators due to the anticipated quantity of Th-228 exceeding the REPPIR threshold for hazard evaluation and potentially requiring emergency plans and public information; this could constitute duties on hospitals, local authorities and the regulators.

The regulators are able to support the development of the scenarios and technologies presented and welcome early engagement. This report contains a number of recommendations which may assist the development of proposals for new medical radionuclide production facilities and for the use of novel medical radionuclides, a number of these have been included below.

Recommendations

Government

Recommendations for **HMG**:

- The regulators recommend further work to explore the interface between the vires of ONR, HSE and the environmental regulators. This work should explore the interpretation of nuclear matter, excepted matter, isotopes and the requirement for licensing. An example of where regulators could provide guidance is the designation of target materials for accelerator production of radiopharmaceuticals; whether they are nuclear matter and excepted matter will determine which regulator has vires recognising there may be issues determining the origin of some target materials.

  Recommendations 2 and 3 of the regulatory review government response outline plans to rethink how the regulators interact and make decisions by implementing a lead regulator model in the first instance, followed by a collective decision making body. The above recommendation in the MRIP report is similar but is specific to medical radionuclides. It therefore aligns with the principles outlined in the regulatory review government response.

- As the proposals develop, the regulators recommend that HMG explore how the proposed radiopharmaceutical generator technology will interact with REPPIR (which is dependent on their design and proposed clinical use). These regulations impose duties where quantities of radioactive substances used exceed specified thresholds and there is potential for an accident resulting in significant radiation exposure of the public. Based on the specific proposed scenario, it is possible that hospitals, the Local Authorities within which they are located and the relevant regulator(s) will bear duties due to REPPIR. However, it should be noted this depends on the distribution model that is adopted for new technologies, which are still early in development.

  Recommendation 34 of the regulatory review government response outlines plans to amend REPPIR to ensure planning zones for Gigawatt scale reactors, SMRs and AMRs are proportionate. The above recommendation in the MRIP report is specific to novel radiopharmaceutical technology and how they interact with REPPIR thresholds but is aligned with the principles outlined in the regulatory review government response.

Developers

Recommendations for **developers** of innovative medical radionuclide production proposals:

- The Environment Agency notes the potential for the REPPIR 2019 legislation to apply to some novel generators. For the Environment Agency, uses of radioactive substances that fall into scope of REPPIR may require a Transboundary Radiological Dose Assessment to be submitted as part of an application for an environmental permit, adding an additional level of complexity to the application. We recommend that, for developers where this is relevant, they should consider the additional time and complexity required and appropriately build into their plans.
- The Environment Agency highlights that, building on work carried out for new power reactors, international designs of medical radionuclide production facilities that have already been through domestic regulatory body assessment, may want to consider using pre-existing information as well as a gap analysis with UK-specific expectations, as part of a submission for an environmental permit.
- The Environment Agency highlights that discharges of radioactivity into the environment from centralised locations or single sites with co-located / multiple facilities and for longer-lived, novel radionuclides may require more complex radiological assessments. Under some circumstances discharges into the environment could feasibly present a challenge to dose constraints, with resultant discharge limits potentially preventing future operations taking place. For such proposals, we recommend that developers consider early screening level dose assessments, as this may help to better understand their potential impacts, could help inform the determination of the best available techniques for minimising discharges (for example the need for liquid effluent treatment), and could help indicate whether discharge limits could constrain planned production and uses of medical radionuclides.
- The Environment Agency notes that novel radionuclides may lack empirical dose assessment values in existing models and in such circumstances typically use conservative values. We recommend that early identification of this by developers and the Environment Agency would help to enable work to derive more realistic values, leading to more realistic assessments and in turn helping to remove unnecessary constraints such as overly conservative discharge limits.
- The Environment Agency highlights that full life-cycle consideration for all radioactive wastes (solid, liquid and gaseous) and spent fuel generated via any production option is an important part of a permit application and that this includes identifying disposal routes for any radioactive wastes generated. This is particularly pertinent for those options that generate wastes which currently have uncertainty around their management, for example, some novel medical radionuclides (such as radium isotopes) have known solid waste disposal constraints to existing disposal facilities. We recommend that developers of proposals where this is relevant take the necessary steps to consider early and potentially enable any required development work that will facilitate a successful permit application.

Regulatory bodies

Recommendations for key civil nuclear and radiological safety **regulatory bodies** of innovative medical radionuclide production proposals:

- ONR should lead a working group to explore the interpretation of nuclear matter, excepted matter, isotopes and the requirement for licensing. This should consider the all the proposals in more detail with engagement with technology stakeholders.
- UK Regulators should consider establishing agreements such as Memorandums of Understanding between UK Regulators and overseas regulatory bodies where these are not already in place (where international designs being considered in the UK for medical radionuclide production have already been licensed / authorised), as this may help facilitate UK assessments.
- If a research reactor option were to be pursued then UK regulatory bodies may need to consider if there is anything that needs to be brought into UK regulatory guidance from the IAEA Safety of Research Reactors Specific Safety Requirements-03 (SSR-03) document.

Introduction

This report aims to develop an understanding of the roles and requirements of key UK radiological and civil nuclear safety regulatory bodies within the radiopharmaceutical supply chain. This will include how they interlink, how the requirements change depending on the origin of the radionuclide, and summarise any challenges faced. The UK government provided a series of questions to UK regulators likely to have a function with the supply chain that considers the following:

- roles and requirements of key regulatory bodies within the radionuclide supply chain
- graded regulatory approach
- regulatory challenges

A response to this question set forms the basis of this report. A number of responses in Chapter 1 and parts of Chapter 2 are based on the guidance document 'How we regulate radiological and civil nuclear safety in the UK' but specifically in a medical radionuclide context.

A number of radionuclide production options have been reviewed at a high level by a selection of UK regulatory bodies. This aims to provide confidence in the different options from a regulatory perspective. The review will help reduce uncertainty and project risk.

This report is based on the involvement of the Environment Agency, the Health and Safety Executive (HSE) and the Office for Nuclear Regulation (ONR) through all stages of the project, which were comprised of three workshops (one for each radionuclide production scenario), assessments of each production scenario, development of this report and the presentation of findings to DESNZ. The Medicines and Healthcare products Regulatory Agency (MHRA) were involved in the project workshops. Natural Resources Wales (NRW), the Northern Ireland Environment Agency (NIEA) and the Scottish Environment Protection Agency (SEPA) participated by reviewing and commenting on the draft report. Key UK radiological and civil nuclear safety regulators and some of their main functions relevant to medical radionuclides are shown in table 1. This report has considered radiological and civil nuclear safety regulation but does not consider other regulations nor regulatory bodies that may be relevant to medical radionuclide production options, such as the planning regime. Environmental regulation outside of Radioactive Substances Activities has not been considered (such as Waste Framework Directive waste, water discharge activities etc). For the Health and Safety Executive and the Health and Safety Executive Northern Ireland, only regulation of radiological risks has been considered.

Table 1

Regulatory body	Key radiological and civil nuclear safety functions relevant to medical radionuclides
Environment Agency (EA)	Regulation of activities involving radioactive substances in England for the protection of people and the environment.
Health and Safety Executive (HSE)	The Health and Safety Executive (HSE) is Great Britain's regulator for workplace health and safety. This includes but is not limited to exposure to ionising radiations resulting from work activity, other than work on nuclear licensed sites.
The Medicines and Healthcare products Regulatory Agency (MHRA)	The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK.
Northern Ireland Environment Agency (NIEA)	Regulation of activities involving radioactive substances in Northern Ireland for the protection of people and the environment. Regulation of radioactive transport by road in Northern Ireland.
Natural Resources Wales (NRW)	Regulation of activities involving radioactive substances in Wales for the protection of people and the environment.
Office for Nuclear Regulation (ONR)	The ONR regulates safety on nuclear licensed sites in Great Britain. Facilities and activities located on nuclear licensed sites include: • Nuclear power stations • Nuclear fuel cycle facilities • Decommissioning of nuclear facilities. In addition, ONR regulates: • Transport of civil radioactive materials by road, rail and inland waterway in Great Britain • Nuclear security • Nuclear Safeguards • Suppliers of products and services primarily intended for GB (England, Scotland and Wales) nuclear sites and authorised defence sites.

Regulatory body	Key radiological and civil nuclear safety functions relevant to medical radionuclides
Scottish Environment Protection Agency (SEPA)	Regulation of activities involving radioactive substances in Scotland for the protection of people and the environment.
Health and Safety Executive Northern Ireland (HSENI)	The Health and Safety Executive Northern Ireland (HSENI) is the lead body responsible for the promotion and enforcement of health and safety at work standards in Northern Ireland. This includes but is not limited to exposure to ionising radiations resulting from work activity, other than work on nuclear licensed sites.

Devolution of environmental regulation

Environmental regulation is a devolved matter in the UK. This means that there are different environmental regulators in England, Scotland, Wales and Northern Ireland (NI). Radioactive substances are regulated by the Environment Agency in England, the Scottish Environment Protection Agency (SEPA) in Scotland, Natural Resources Wales (NRW) in Wales and the Northern Ireland Environment Agency (NIEA) in NI. Collectively we refer to these agencies as the ‘environmental regulators’. Different regulations apply in different parts of the UK, but they all have the same purpose: to protect people and the environment from the harmful effects of radioactive substances.

As the Environment Agency has been involved in all stages of the project, all sections of this report contain responses from the Environment Agency. SEPA have contributed during their review by outlining their role in Chapter 1 in the response to Question 1, 3 and 4. Similarly, NRW have outlined their role in Chapter 1 and have also indicated throughout the rest of the report aspects relevant to their regulation in Wales.

Chapter 1: Regulator roles and requirements

What is the role of each regulator in the medical radionuclide supply chain?

Relevant regulatory functions of the regulatory bodies in this study are described in the introduction, with further specifics given for each regulator below. A key aspect to consider for the production of medical radionuclides is whether the production activity requires a nuclear site licence (with nuclear safety and security then regulated by ONR) or whether it would not require a licence and HSE/HSENI having a role. In either case the relevant environmental regulator would have a role, with some significant differences in their regulatory responsibilities dependent on whether the activity is on a licensed site or not.

Environmental Regulators (EA, NIEA, NRW and SEPA)

The environmental regulators regulate planned uses of radioactive substances and radioactive contaminated land left from past practices outside any nuclear site licence boundary. Planned uses of radioactive substances occur when an operator intends to keep and use radioactive substances or accumulate and/or dispose of radioactive waste from a practice which is justified under the Justification of Practices Involving Ionising Radiation Regulations 2004 (as amended) (JoPIIRR). Using ionising radiation for medical diagnosis or for treatment purposes are both Justified Practices, as is production of radioisotopes using nuclear reactors and accelerators, and production of radioactive products including radiopharmaceuticals. The scopes of different justified practices are detailed here: ‘The Justification of Practices Involving Ionising Radiation Regulations 2004: guidance on their application and administration’.

Decisions on justification are taken by the Justifying Authority. This is the devolved administrations for devolved subject areas, and the appropriate Secretary of State in relation to subject areas which have not been devolved.

The environmental regulators are not Justifying Authorities and therefore do not make decisions on whether a practice is justified or not, however they are statutory consultees on such decisions and will not issue an authorisation or permit for an activity that is not justified.

The regulations for the planned use of radioactive substances are:

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

If an operator wants to work with radioactive substances in a planned use, they need to be authorised under the relevant regulations to do so. This will involve making an application to the relevant environmental regulator who will assess the application and decide if the operator should be allowed to undertake that activity. If the regulator decides that the operator can undertake that activity, they will grant an authorisation or permit that will apply limits and conditions on the operator. It should be noted that for Nuclear Site Licensees, the keeping and use of radioactive material (including security of radioactive sources) and accumulation of radioactive waste is regulated by the ONR. For tenant organisations operating on a Nuclear Licensed Site, keeping and use of radioactive material is regulated by the relevant environmental regulator. In Scotland the management of radioactive waste on a Nuclear Licensed Site is regulated by SEPA in addition to ONR.

There are some lower risk activities using radioactive substances that an operator can perform without needing permission from the relevant environmental regulator, for example the use of small quantities of radioactive substances for medical and veterinary uses. These activities are exempt from requiring authorisation or a permit, however the operator must still comply with the exemption requirements set out in legislation. Guidance on the scope of and exemptions from radioactive substances legislation in England, Wales and NI can be found here: 'Radioactive substances legislation: scope and exemptions'. In Scotland some lower risk activities can be carried on under EASR18 general binding rules without requiring an authorisation from SEPA.

There are additional regulations covering transboundary movements of radioactive materials and waste. Prospective operators should consider whether these will apply to their proposed activities.

- The Shipments of Radioactive Substances (EU Exit) Regulations 2019 applies to shipments of sealed sources to the UK from EU Member States. The relevant environmental regulator is the competent authority for shipments to non-nuclear sites, whilst ONR is the competent authority for shipments to Nuclear Licensed Sites
- The Transfrontier Shipment of Radioactive Waste and Spent Fuel (EU Exit) Regulations 2019 cover the import and export of radioactive waste. The Environmental Regulators are the Competent Authority

Export of certain High Activity Sealed Sources is controlled by the Export Control Joint Unit through the Export of Radioactive Sources (Control) Order 2006.

For regulation of nuclear radioactive substances activities in Wales, NRW are supported by the Environment Agency under a Service Level Agreement, which includes support towards permitting, compliance, enforcement and environmental monitoring. NRW remains the responsible regulator and decision-maker. For Radioactive Substances Activities outside of nuclear sites, NRW regulates independently.

Environment Agency and Natural Resources Wales

In England and Wales, if an activity does not meet the criteria to be exempt from permitting, the operator must apply for an Environmental Permit in order to carry out work with radioactive substances. For the current supply of medical radionuclides in England and Wales, environmental permits are issued for different activities along the supply chain, including the initial production of the radionuclide (e.g. in a cyclotron); in radiopharmacies where a radiopharmaceutical is synthesised from a medical radionuclide; and hospitals where the radiopharmaceutical is administered in patients for diagnostic or therapeutic purposes.

Typical Environmental Permits issued to hospitals may include the keeping and use of radioactive material and the accumulation and disposal of radioactive waste. This includes both transfers of solid waste to other permitted disposal sites such as incinerators and discharges of aqueous waste, such as patient excreta, via sewage treatment plants to watercourses.

Scottish Environment Protection Agency

Similarly in Scotland, if an activity does not meet the criteria to be out of scope of regulation, then an authorisation under EASR2018 is required in order to carry on a radioactive substances activity.

Authorisations granted to hospitals are for the management of radioactive substances. This includes holdings of radioactive substances, transfers of waste to other permitted disposal sites such as incinerators as well as discharges of aqueous waste, such as patient excreta, via sewage treatment plants to watercourses.

Health and Safety Regulators (HSE and HSENI)

The Health and Safety regulators regulate work activities which use radioactive substances (natural and artificial) or electrical equipment emitting ionising radiation or work which occurs in places where radon gas concentrations are elevated. The work with radioactive substances includes the production, processing, handling, disposal use, storage or holding of radioactive substances.

Employers wishing to work with radioactive substances, electrical equipment emitting ionising radiation or work in a radon atmosphere must first notify, register or obtain consent from the relevant health and safety regulator; some exemptions from this are detailed in Schedule 1 of both IRR17 and IRR(NI)17. The health and safety regulators assess all consent applications for compliance with the regulations before granting consent. Employers are required to keep exposure to ionising radiations as low as reasonably practicable and below specified dose limits. Under REPPIR, where there is potential for a radiation accident to result in significant exposure to members of the public (exceeding 1 mSv per year), site operators and their local authorities must prepare detailed emergency plans and make information available to the public on action to take if those accidents occur.

The Health and Safety regulators would regulate the production of medical radionuclides as long as this was not undertaken on a nuclear licenced site and any radioactive substances involved were not nuclear matter or bulk quantities (see question 7 in chapter 2). Neither HSE nor NSENI regulate the transport of radioactive materials; this is done by ONR in Great Britain (GB) and NIEA in Northern Ireland.

The Health and Safety regulators are not Justifying Authorities for JOPIIRR and therefore do not make decisions on whether a practice is justified or not, however HSE and HSENI are statutory consultees on such decisions and neither regulator will issue a registration or consent to carry out a work activity that is not justified.

The relevant regulations are:

- The Ionising Radiations Regulations, 2017 (IRR17) for Great Britain
- The Ionising Radiations Regulations (Northern Ireland), 2017 (IRR(NI)17) for Northern Ireland
- The Radiation (Emergency Preparedness and Public Information) Regulations, 2019 (REPPIR19) for Great Britain
- The Radiation (Emergency Preparedness and Public Information) Regulations (Northern Ireland), 2019 (REPPIR(NI)19) for Northern Ireland

Office for Nuclear Regulation

ONR is the UK's independent nuclear regulator for safety, security and safeguards. Our mission is to protect society by securing safe nuclear operations.

It delivers five statutory purposes to ensure safe nuclear operations now and in the long term. These are:

- nuclear safety
- nuclear site health and safety
- nuclear security
- nuclear safeguards; and
- safety of transport of nuclear and radioactive materials

ONR has the legal authority to regulate nuclear safety, nuclear security and conventional health and safety at the 36 licensed nuclear sites in GB. This includes the existing fleet of operating reactors, fuel cycle facilities, waste management and decommissioning sites, as well as licensed and, in part[1], authorised defence sites, together with the regulation of the design and construction of new nuclear facilities, including the supply chain.

[1] On authorised defence sites we regulate the Health and Safety at Work Act 1974, including Radiation (Emergency Preparedness and Public Information) Regulations 2019 and Ionising Radiation Regulations 2017.

ONR's nuclear security regulation ensures the adequacy of security arrangements for dealing with special nuclear material and special nuclear information within the civil nuclear industry and ONR also regulates the safety and security of the transport of civil nuclear and radioactive materials by road, rail and inland waterway, extending our regulation across a large number of dutyholders.

On 1 January 2021, ONR became the UK nuclear safeguards regulator for the domestic standards regime and began to operate the UK State System of Accountancy for and Control of Nuclear Materials.

ONR would regulate the production of medical radionuclides if undertaken on a nuclear licenced site. When considering any requirements for a nuclear site licence for such facilities the relevant legislation is the Nuclear Installations Act 1965 and the Nuclear Installations Regulations 1971 and the definitions therein. ONR regulates the transport of radioactive materials under the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG). Northern Ireland does not have any nuclear sites.

Case study: How is the Fluorine-18 supply chain currently regulated?

Environment Agency, Natural Resources Wales and Northern Ireland Environment Agency

For England and Wales, the production and regulation of fluorine-18 (F-18) is well established. There are a number of commercial production facilities which produce F-18 radiopharmaceuticals and deliver to hospitals around the country. The short half-life of 110 minutes means the facilities can only supply sites within a limited area. Some hospitals also have their own facilities which may supply other sites.

In England and Wales, the Environment Agency and/or NRW regulates both the facilities where F-18 is produced, and the end user hospitals where F-18 is administered.

F-18 production facilities normally comprise an 11-18 MeV cyclotron, a laboratory for the synthesis of the radiopharmaceutical, quality control (QC) laboratory, waste store, plant room containing abatement equipment and other ancillary areas. The facility requires an environmental permit due to the keeping of radioactive material, and the accumulation and disposal of radioactive waste. The primary discharge to the environment is as gaseous emissions to air via a stack. Gaseous emissions are required to be minimised by the Environmental Permit to As Low As Reasonably Achievable through the application of the best available techniques (BAT) and monitored to account for the quantity discharged. Small amounts of liquid discharges may be made to sewer. The target for F-18 production is O-18 enriched water and, following a production run, a significant quantity of water remains with contamination by tritium and activation products. This waste would normally be transferred abroad for recycling but may be discharged to the sewer under the permit. Overseas transfers of radioactive waste from England are regulated by the Environment Agency under the

Transfrontier Shipment of Radioactive Waste and Spent Fuel (EU Exit) Regulations 2019, as covered on page 14.

Additionally, parts of the F-18 production facility would be expected to become activated during operation. Activation is where a stable material that has been exposed to neutron radiation itself becomes radioactive, for example metallic parts of the cyclotron. These would be classed as radioactive waste when they are removed and cannot be re-used or at the end of the cyclotron's life. For a cyclotron, the Environmental Permit requires a decommissioning plan to be maintained to ensure the operator considers options for the final decommissioning of the facility. Hospitals administering F-18 also require an Environmental Permit to keep and use radioactive material and accumulate and dispose of radioactive waste. Typically, the primary discharge to the environment is aqueous waste (e.g. patient excreta) via the hospital foul drains, to a sewage treatment plant and ultimately to a watercourse. All disposals are required to be minimised through the application of BAT.

For all Radioactive Substance Activity Environmental Permits that permit discharges of radioactive waste to the environment, a prospective dose assessment is required as part of the application process to demonstrate that radiation dose to people and wildlife from any planned discharges do not exceed dose constraints and limits.

In Northern Ireland NIEA regulates the transport of fluorine-18 under the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010.

Health and Safety Regulators (HSE and HSENI)

The Health and Safety regulators regulate both the facilities where F-18 is produced, and the end user hospitals where F-18 is administered. F-18 production facilities require consent certificates for the operation of an accelerator (cyclotron), the addition of radioactive substances in the production of medicinal products (the radiopharmaceuticals) and potentially for discharging significant amounts of radioactive material (depending upon levels emitted). The hospitals administering F-18 require consent certificates for the deliberate administration of radioactive substances to persons and potentially for discharging significant amounts of radioactive material. Further consents, registrations or notifications may be needed depending upon the nature of any other work with ionising radiations performed by that employer.

Office for Nuclear Regulation

ONR regulates the transport of fluorine-18 under the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG) in Great Britain. Regulations governing the transport of radioactive material in the UK are based on standards developed by the International Atomic Energy Agency (IAEA). IAEA regulations are prescriptive and apply internationally to enable the safe transport of packages across international borders. The UK has implemented the requirements of IAEA Specific Safety Requirement 6 into UK law via the CDG regulations.

The regulations 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,

shipments and activities require prior competent authority approval or authorisation. Therefore, ONR issues all necessary approval or validation certificates as appropriate for civil carriage of higher hazard Class 7 (radioactive material) dangerous goods for all transport modes in all parts of Great Britan.

Compliance with the transport regulations is ensured through a programme of inspections which cover both design, shipments and activities which require prior approval as well as those that do not require pre-approval. Inspection is carried out by ONR, Civil Aviation Authority, Maritime and Coastguard Agency and NIEA depending on the mode of transport and location in the UK.

Should a medical radionuclide ever be produced which is classed as Category I/II nuclear material or Category III nuclear material, then its transportation would also be regulated by ONR under the Nuclear Industries Security Regulations 2003.

What are the high-level requirements for each regulator at each stage in the radiopharmaceutical supply chain? Where does the responsibility to meet those requirements sit?

As the ‘regulatory body’ for the UK is not one single entity, the regulatory framework is diverse and covers a broad range of legislative requirements.

The legal and regulatory framework clearly allocates responsibilities for nuclear safety, transport, security, safeguards, radiological and environmental protection. The framework ensures the effective regulatory control of facilities and activities and complies with international obligations.

For all uses of radioactive material, the safety of the public, workers, patients and the environment are a top priority.

The responsibility for radiological and nuclear safety, and for meeting regulatory requirements, rests with those who create the radiation risk. Whilst responsibility rests with those who create the radiation risk, the terms used for those responsible differs under the different legislative requirements, for:

- ONR this is the Licensee for nuclear licensed sites under the Nuclear Installations Act 1965 (NIA 1965), the employer in control of the work with ionising radiation with respect to IRR17 and the site operator for REPPIR19
- Environment Agency, NRW and SEPA it is the operator of the radioactive substances activity (the permit holder or prospective permit holder), and
- HSE and HSENI this is the employer in control of the work with ionising radiation with respect to IRR17 and IRR(NI)17 and the site operator for REPPIR19 and REPPIR(NI)19.

Environment Agency and Natural Resources Wales

The Environment Agency has published guidance on applying for a Radioactive Substances Activity (RSA) environmental permit for nuclear sites and non-nuclear sites, as well as accompanying technical guidance outlining their requirements for both nuclear and non-nuclear sites.

The Environment Agency's objective in regulating radioactive substances is to protect people and the environment from the harmful effects of ionising radiation, now and in the future. They also aim to protect and enhance the environment as a whole. They fulfil this objective by applying relevant legislation, government policy and international standards.

In an Radioactive Substances Regulations (RSR) permit application, a prospective operator would need to demonstrate how they meet the RSR Principles. For the radiopharmaceutical supply chain, key principles would include (but not be limited to):

- **Justification:** The Environment Agency will only grant a permit for a practice involving radioactive substances if it is justified
- **Optimisation:** Radiological protection must be optimised to make sure that people's exposure to ionising radiation from the disposal of radioactive waste is kept as low as reasonably achievable, taking into account environmental, social and economic factors
- **Best Available Techniques (BAT):** Operators must use BAT for the management of radioactive waste. The option identified by the optimisation process can be considered as the best available techniques (BAT). BAT is used to:
    - prevent the unnecessary creation of radioactive waste or discharges
    - minimise the quantity and activity of any radioactive waste that is created
    - minimise the impact of discharges on people and the environment

  The Environment Agency has applied this approach as a general principle to the accumulation and disposal of all radioactive wastes that the Environment Agency regulate.
- **Lifetime Planning:** Radioactive substances should be managed throughout their lifetime to make sure people and the environment are protected both now and in the future
- **Dose Limitation:** Radiation doses to the public from radioactive substances activities must be kept within statutory dose limits. The dose limit for members of the public is 1mSv/y. Permit applications are supported by prospective dose assessments based on discharges made at the annual limits proposed in the permit application. As part of our permit determination process the Environment Agency must also have regard to dose constraints, which are 0.3 mSv/y for a single source and 0.5 mSv/y for a single site

- **Protection of Wildlife:** Radioactive substances activities must not cause wildlife to be exposed to levels of ionising radiation that would have adverse consequences for ecosystems, designated conservation sites and protected species. The prospective dose assessment allows us to ensure that radioactive discharges do not affect the integrity of National Site Network habitat sites and meet our wider conservation duties.

In a permit application, the Environment Agency would also expect applicants to demonstrate their competency as an operator through an adequate description of their management and resourcing arrangements.

For Radioactive Substances Activities in Wales, NRW adopt the same expectations as outlined by the Environment Agency for England.

Health and Safety Regulators (HSE and HSENI)

The employer wishing to carry out work with ionising radiation is responsible to notify, register or obtain consent from HSE or HSENI (depending on the location of the work), before that work begins. Transitional arrangements are in place to allow employers already performing such work before October 2023 to continue. To allow employers to make these notifications, registrations and consent applications, both regulators recently introduced an application portal hosted on the HSE website called RADiation Authorisations and Notifications (RADAN). F-18 production facilities and F-18 administering hospitals will require at least one type of consent, this is the tier representing the greatest radiological risk. To apply for a RADAN consent, employers must submit a safety assessment relevant to the type of consent required along with some radiation safety documentation (local rules and contingency plans) at least three months before they intend to begin that work. The regulator will carry out a documentary review of the consent application before conducting a site inspection to verify the content of the safety assessment, assess the control measures in place to restrict exposure and ensure compliance with IRR17 or IRR(NI)17 can be sustained. Only once the relevant consent certificates have been issued can an employer begin that work with ionising radiation. The responsibilities for consent applications, radiation protection and legislative compliance all rest with the employer.

Office for Nuclear Regulation

The Nuclear Installations Act 1965 requires the licensing of sites which are to be used for the installation or operation of nuclear reactors (except reactors comprised in a means of transport) and certain other kinds of nuclear installations prescribed in the Nuclear Installations Regulations 1971.

Employers intending to work with ionising radiation on a GB nuclear site may need to register or obtain consent from ONR under the Ionising Radiation Regulations 2017 (IRR17), Where applicable, the employers must register or seek consent via ONR's graded process and application forms. In order for a consent to be granted ONR requires the submission of a suitable and sufficient Safety Assessment. The primary purpose of the submission of a Safety Assessment (SA) is to enable the employer to determine if adequate safety arrangements are in place for the practice, as defined in IRR17, and give an assurance to ONR that compliance

with IRR17 is, or will, be achieved and maintained. Certificates for registration and grant of consent will have attached conditions.

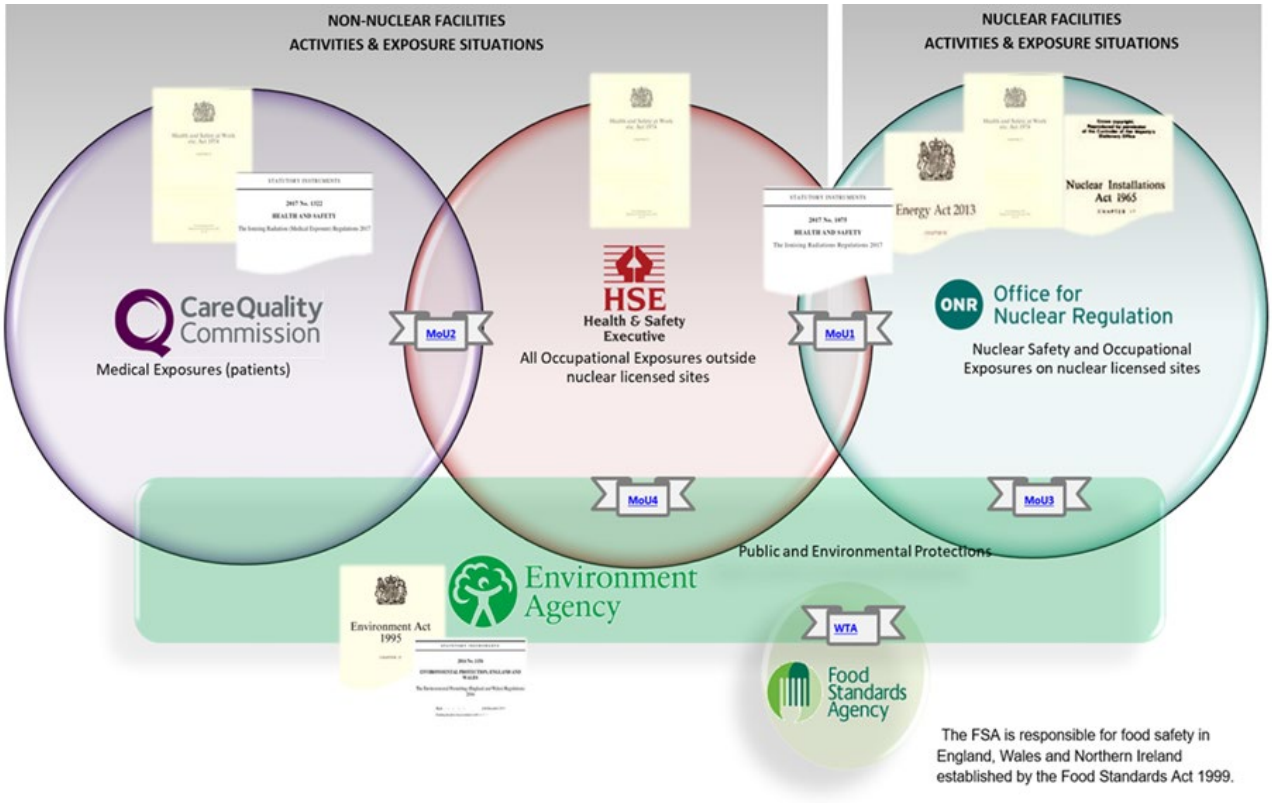
For the transport of Class 7 radioactive materials, new designs, renewal of existing approvals, validation of overseas approvals or modifications to approved designs, guidance on expectations is given in the 'Applicant's Guide' TRA-PER-GD-014.

How do the regulators currently work together?

Each regulatory body has responsibility for an area of radiological safety (excluding MHRA), however there are areas of joint interaction on some sites, where this occurs, the relevant bodies form an agreement named a Memorandum of Understanding (MoU). Other terms used by regulatory bodies to describe agreements similar to MoUs are, 'Working Together Agreements', 'Operational Agreements' and 'Agency Agreements'.

The MoU is used to ensure cooperation and collaboration between bodies for sites or situations where both have regulatory functions; however separate regulatory functions are maintained by each body, maintaining independence. The MoUs also help to achieve the common goals of the regulators to deliver effective and efficient regulation, support economic growth and maintain and improve standards of protection of people and the environment. Legal duties placed on regulators by government in this regard include the Regulators Code and the Growth Duty. For SEPA, the Scottish Regulators Strategic Code of Practice, also applies. An example MoU structure is given below in figure 1.

Figure 1. Example of MoU Structures Between Regulatory Bodies



MoU Structures Between Regulatory Bodies:

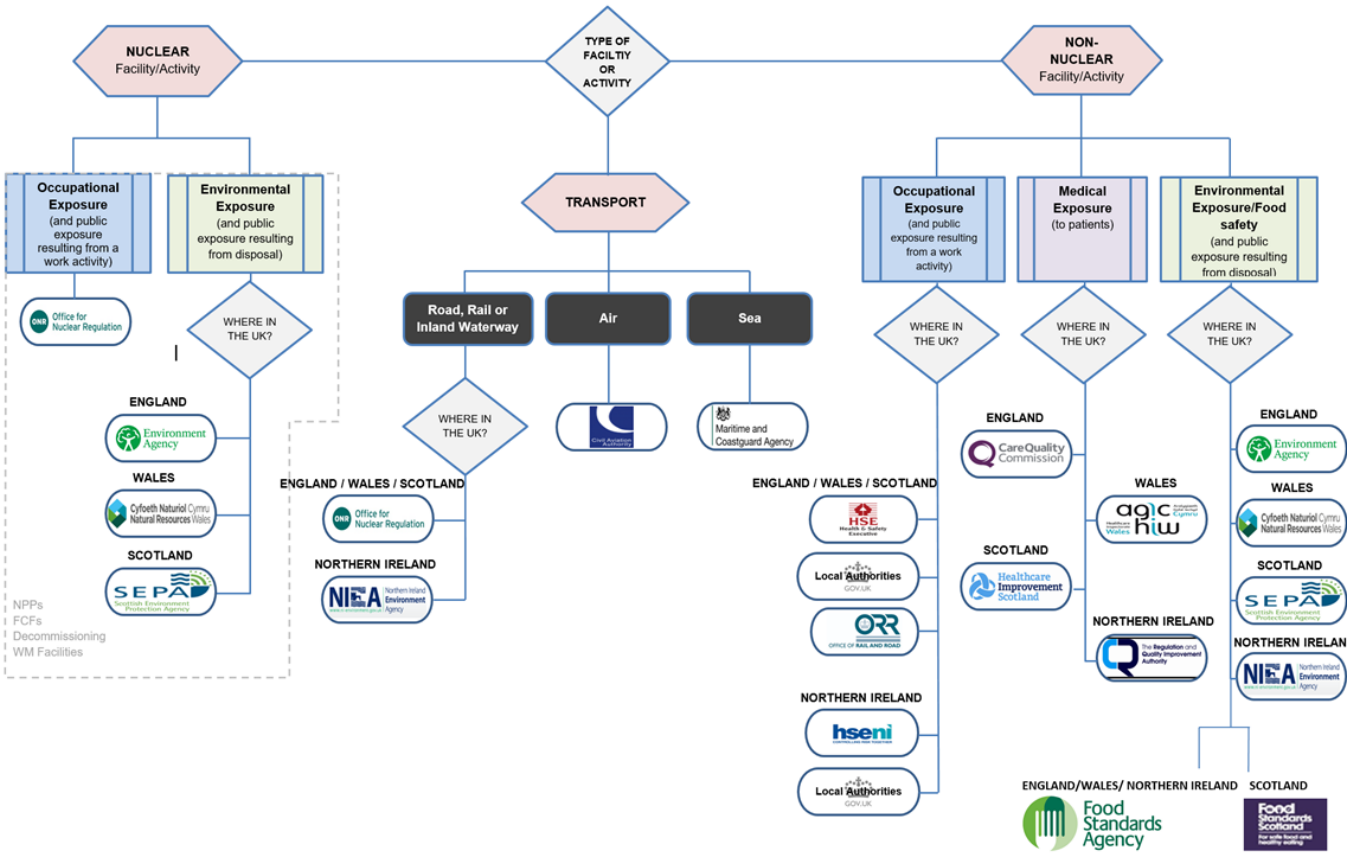
- **MoU1:** MoU enabling cooperation between HSE and ONR in regulating conventional health and safety on nuclear sites
- **MoU2:** MoU on respective responsibilities for HSE, CQC and Local Authorities when dealing with health and safety in the healthcare and adult social care sectors
- **MoU3:** MoU setting out arrangements where both ONR and EA have regulatory functions
- **MoU4:** MoU setting out the overarching agreement for liaison between HSE and EA. There is also a specific MoU between the Environment Agency and HSE on regulation of radioactive substances on non-nuclear sites

There is also an MoU enabling co-operation and support to assess, and mutual recognition, of consent certificates between HSE and HSENI.

In Scotland there are MoUs in place between SEPA/ONR and SEPA/HSE.

An overview of UK civil nuclear and radiological safety regulatory responsibilities is shown in figure 2. This highlights there are currently no areas of mutual interest between MHRA and safety or environmental regulators. Therefore, MoUs have not been required.

Figure 2. Overview of UK civil nuclear and radiological safety regulatory responsibilities



There are many examples with relevance to potential new radionuclide production facilities where UK regulatory bodies have worked effectively together in line with MoUs, including:

- ONR, Environment Agency and NRW work closely together on generic design assessment (GDA) and site-specific permitting and licensing of new nuclear power reactor designs
- ONR and the relevant environmental regulator working together on the regulation of new facilities on existing Nuclear Licensed Sites. For new facilities of mutual interest, ONR routinely consult the Environment Agency before providing consent for an operator to proceed, similarly the Environment Agency consults ONR before issuing permit variations in areas of mutual interest
- Following on from discussions at the Small Users Liaison Group, HSE and the Environment Agency have established regular liaison meetings to discuss operational issues
- The UK Health Security Agency hosted Medical Radiation Liaison Group, which brings together Care Quality Commission (CQC), Environment Agency, HSE, MHRA, NIEA, NRW, ONR, SEPA, Healthcare Improvement Scotland (HIS), the Wales Healthcare Inspectorates and the Northern Ireland's Regulation and Quality Improvement Authority (RQIA)
- In Scotland, there is also the Scottish Non-Nuclear Industry Liaison Group

Have the regulators had any feedback from the radiopharmaceutical sector on their services?

Environment Agency

Within radioactive substances regulation, the Environment Agency has previously carried out stakeholder surveys within the nuclear and non-nuclear sectors. The Environment Agency routinely engages with industry through various industry and regulatory fora, such as the Small Users Liaison Group, Nuclear Industry Liaison Group, Institute of Physics and Engineering in Medicine, Society of Radiological Protection (SRP) Medical Committee and Environment Agency area-based liaison meetings with non-nuclear users.

The Environment Agency consults on relevant guidance which can give an indication of stakeholder views, and our regulatory staff periodically visit and inspect sites that hold radioactive substances activities permits (including in the medical sector) giving further opportunity for feedback.

Additionally, the Environment Agency uses the annual Society for Radiological Protection (SRP) conference to gain feedback from industry.

The Environment Agency liaise directly with industry where significant changes to the use, production or management of radiopharmaceuticals are identified. An example is the potential significant increase in the use of Lu-177 Prostate Specific Membrane Antigen (PSMA). In this example the Environment Agency liaised with a manufacturer of Lu-177 to understand more about the proposed use of Lu-177 PSMA and to gather information on environmental impact. As a result of this engagement the Environment Agency are now undertaking a study, partly funded by the manufacturer, to better understand the fate and behaviour of Lu-177 in the environment to support our ability to permit discharges in future. Another example would be engagement with the manufacturer of a system which filters out radionuclides from specific treatments at point of production to determine implications for permitting and the application of BAT.

No significant concerns have been raised with our regulatory services from these various radiopharmaceutical sector engagements.

Health and Safety Regulators (HSE and HSENI)

HSE and HSENI routinely engage with relevant industry sectors through the SRP, Institute of Physics and Engineering in Medicine, the British Institute of Radiology, the British Nuclear Medicine Society (BNMS), the Society of Radiographers, and the Medical Radiation Liaison Group and actively participate in a number of their committees and special interest groups. This engagement provides opportunity for prompt discussion of any emerging issues.

As the RADAN application process has only recently been introduced, there have been relatively few applications received to date for operation of an accelerator, addition to products or administration of radioactive substances to persons, so there has been very little specific feedback from the sector. However, HSE has held its own stakeholder event and participated in an SRP conference specifically about RADAN in order to gather early findings. This initial feedback has already been used to make improvements to the RADAN portal and to make some of the safety assessment templates clearer on the information and level of detail required.

To expedite the process, a number of medical employers have been issued with temporary consent to allow them to begin the work with radiation e.g. For facility commissioning purposes or for urgent medical treatment, before the thorough assessment process has been concluded and full consent granted.

Office for Nuclear Regulation

The nuclear industry comes under close public scrutiny and ONR's role as an independent regulator is open to challenge. ONR regards its reputation as one of its biggest assets and is therefore deemed as important. ONR place significant corporate and regulatory effort on maintaining high levels of engagement with those they regulate, seeking regular feedback and providing assurance that, with a suitably qualified and experienced workforce, it is effective in making evidence-based, independent, regulatory decisions that ensure the safety, security and safeguarding of the UK nuclear industry and with respect to the transport of non-nuclear radioactive material. ONR undertakes stakeholder surveys to allow for organisational

improvements, our previous report can be found here: 'ONR Annual Stakeholder Research, Report 2023'.

How are requests to regulate new radionuclide production technologies currently managed?

Requests to regulate new radionuclide production technologies are directed at the individual relevant regulators. The relevant regulators may be different in each case, depending on the proposed activity, where it is proposed to be carried out in the UK and whether the activity requires a Nuclear Site Licence.

Recently, ONR, the Environment Agency and Natural Resources Wales (NRW) have developed a process for early regulatory engagement for nuclear site licensable activities. The early engagement process is best placed to discuss novel technology, processes, designs and new organisations to help de-risk their development. It does not replace regulatory processes such as permitting and licensing.

Entry into early engagement is also dependent on the applicant entering into agreements allowing the regulators to recover costs.

There are three early engagement approaches, one-day engagement, technical workshops and preliminary design review. Each has different expectations for design and organisation maturity. Progress from one early engagement approach to a further one (e.g. from one day engagement to the preliminary design review) is not automatic nor guaranteed and will be subject to assessment of readiness by the regulators. The information provided during early engagement will inform their decision on whether the organisation is ready to progress and on what timescales. This is to ensure ONR's regulatory resource is targeted on projects that are most likely to progress and are in line with government policy. The type of factors considered are:

- the maturity of the technology and supporting analyses
- the status of the development company and the feasibility of its plans; and
- the alignment of the project with government policy

More information on the ONR, Environment Agency and NRW early regulatory engagement process, including guidance, can be found here: 'Early regulatory engagement on new nuclear projects'.

For radionuclide production technologies which do not need to be carried out on a Nuclear Licensed Site, requests would need to be directed to the individual regulators, i.e. the relevant environmental regulator and HSE or HSENI. ONR may still have a role under transport and safeguards.

Chapter 2: Graded Regulatory Approach

How do the existing requirements change should the origin of the radionuclide change?

Environment Agency and Natural Resources Wales

For the Environment Agency and NRW, the requirements differ depending on whether a Nuclear Site Licence is required or if it is not required. If no Nuclear Site Licence is required, the relevant environmental regulator would regulate the keeping and use of radioactive materials (including security of radioactive sources) as well as the accumulation and/or disposal of radioactive waste. On a Nuclear Licensed Site, the keeping and use of radioactive material (including security of radioactive sources) and accumulation of radioactive waste is regulated by the ONR with the relevant environmental regulator retaining responsibility for regulation of the disposal of radioactive waste. For tenant organisations operating on a Nuclear Licensed Site, keeping and use of radioactive material is regulated by the relevant environmental regulator.

For both nuclear and non-nuclear sites, Environment Agency and NRW regulatory effort (for example, the number of inspections carried out) depends on the complexity of the activity and hazard of the radioactive substances used. For non-nuclear sites, different categories of complexity are set out in the Environment Agency Charging Scheme and the NRW Charging Scheme. 'Higher risk' activities (such as cyclotrons) attract a higher application and annual subsistence fee which reflects the greater regulatory effort required.

Office for Nuclear Regulation and the Health and Safety Regulators

It is important to know the origin of the material in question, because it is possible that the origin of the radionuclide may determine the legislation that will be applied. For example, should the origin fall under the definition of nuclear matter (see NS-INSP-GD-004 for guidance) as defined in the Nuclear Installations Act 1965 and its supporting regulations then a nuclear site licence may be required and regulated by ONR.

Are the regulators able to (capacity and skills) take on new radionuclide production techniques?

Environment Agency and Natural Resources Wales

The Environment Agency continues to build capacity and capability in the area of Radioactive Substances Regulation (RSR) through its Strategic Workforce Planning. This includes:

- Using different Career Paths into RSR, including internships, apprenticeships, Nuclear Graduate Schemes and direct entry
- Engaging with Professional Societies, including the Society for Radiological Protection (SRP), the Royal Society for Chemistry (RSC), Nuclear Institute (NI) etc
- Horizon Scanning, of the nuclear and non-nuclear sectors. Also looking at wider emerging signals, clusters of change and wildcards and their potential impacts on RSR
- A Performance Management framework that includes Personal Development Plans to identify and address gaps in skills, knowledge and behaviours
- A training strategy based on the IAEA Competency Model, which includes requiring our staff to work towards accreditation as Radioactive Waste Compliance Advisors
- Communities of Practice in specific areas to share learning and establish Subject Matter Experts
- Participation in industry initiatives such as the National Skills Academy for Nuclear, Destination Nuclear and contributing to the Nuclear Skills Taskforce, etc

The current Environment Agency view is that regulatory demand for new radionuclide production facilities would be limited compared to reactor new build projects or regulation of existing facilities and that our current approach to Strategic Workforce Planning provides us with sufficient capacity and skills. The Environment Agency will review and be reactive to capacity and skills needs as specific proposals progress. The Environment Agency would need to consider how such capability building is funded.

In Wales, recognising that NRW are supported by the Environment Agency in the area of nuclear regulation but independent for non-nuclear Radioactive Substances Activity regulation, we maintain a proportionate capacity for regulation of radioactive substances. In response to the increasing demands from the nuclear sector, NRW has set up a new team which also supports the wider radioactive substances regime. NRW also actively participate alongside partner regulators in horizon scanning activities, in anticipation of future capacity and skills that may be required.

Health and Safety Regulators (HSE and HSENI)

It is widely acknowledged there is a national shortage of radiation protection expertise; HSE has been discussing ideas to address this with other regulators via the SRP's Heads of Profession network. The availability of specialist resource will be essential for HSE and HSENI's ability to assess new radionuclide production facilities.

HSE has been proactively recruiting for around ten years and has introduced a non-consolidated recruitment and retention allowance to assist in attraction of new staff and to retain current inspectors. HSE's current inspectors are all highly experienced, certified Radiation Protection Advisers and most are Chartered Radiation Protection Professionals; as such the skills are available to adapt to new technology and regulate new radionuclide production techniques.

A similar situation exists within HSENI and both regulators pool resources where possible.

The technologies that would be regulated by HSE/HSENI and the RADAN consent process by which they are assessed are less onerous than those requiring a nuclear licensed site. Furthermore, duty holders would require only one consent certificate per work activity regardless of the number of sites at which this work takes place, allowing the technology to be scaled-up relatively quickly. RADAN consent applications for new work are already given priority over review of existing consents. It should therefore be possible for HSE to prioritise these consent applications to minimise time between facility build and radionuclide production.

It's possible that additional resource (beyond the current vacancies) will be needed if production facilities or administering sites have potential for radiation accidents resulting in off-site consequences (under REPPIR); this has not been factored into current resource requirements.

Office for Nuclear Regulation

ONR continues to build capability through the ONR Academy to support resilience and stakeholder confidence to deliver its regulatory activity through:

- succession planning, talent management and learning opportunities to improve capability, organisational resilience, management and leadership skills
- work strategically with regulatory and support directorates to agree and implement plans to deliver the capacity and capability required to meet business needs
- develop a staff career development strategy
- provide management development and training that provides the learning, understanding, tools and techniques to build managerial capability and consistency

How do UK regulators approach the regulation of technologies which are already in operation in other trusted countries?

Environment Agency and Natural Resources Wales

The Environment Agency and NRW have established relationships and hold international exchange agreements with a number of countries to enable collaboration to protect people and the environment and support long term energy security. The Environment Agency and NRW work collaboratively with UK partner regulators to regulate new technologies including those which are already in operation internationally. The Environment Agency and NRW are enabling regulators and would work closely with the prospective operator or developer to understand the nature of the operation and regulated facility and proportionately identify the key areas of environmental risk where we would focus our scrutiny to ensure proper protection of people and the environment.

The prospective operator or developer is able to take credit for existing established good practice internationally and our assessment can be informed by information/evidence and assessment outcomes from other international regulatory processes.

The Environment Agency and NRW both welcome opportunities to work with international regulators to improve the effectiveness and efficiency of our assessments. However, the principle of sovereign decision-making must remain.

For situations where international regulatory assessments have been carried out, both the Environment Agency and NRW expect the possible future operator or developer to provide a summary and explain whether they intend to use the information that is already available to them. If the possible future operator does plan to use existing information, they should explain its scope, background, and regulatory basis.

The Environment Agency and NRW expect a prospective operator to identify any gaps or shortfalls with their technology and environment case against UK standards and expectations with respect to the information that we are expecting them to provide. The Environment Agency and NRW will provide advice to the potential future operator to help identify such gaps or shortfalls. The prospective operator must agree with us how they propose to resolve these gaps and meet our regulatory requirements and expectations.

The Environment Agency and NRW have always supported the use of submissions from overseas processes in Generic Design Assessment (GDA) of new nuclear reactors, however (in the GDA process) it is the responsibility of the requesting party to ensure that they identify and address any UK specific gaps in overseas submissions before submitting to the ONR, Environment Agency and NRW. The three regulators have recently reviewed learning from previous GDAs and are in the process of strengthening our guidance for applicants. Work is also underway with other regulators, in particular the US Nuclear Regulatory Commission (NRC) and Canadian Nuclear Safety Commission (CNSC), to enable sharing of information with a focus on designs which are being assessed in all three countries.

The Environment Agency also engages with regulators in other countries through its involvement in relevant IAEA Safety Standards Committees, either directly or through the established UK Advisory Groups to those Committees.

Health and Safety Regulators (HSE and HSENI)

HSE and HSENI use the same assessment process to determine whether an employer is in compliance with IRR17 and grant consents; a memorandum of understanding allows HSE and HSENI to recognise consents granted by each other subject to minimal additional scrutiny. However, the Health and Safety regulators do not have international agreements in place which could expedite granting of a consent certificate based on assessments made overseas. The regulators will assess consent applications based solely on the radiation protection documentation uploaded by the duty holder into the RADAN portal and the findings of an inspection. Dutyholders may reproduce relevant information from their operations overseas into their RADAN applications for review by the Health and Safety regulators.

Office for Nuclear Regulation

ONR holds international exchange agreements with a number of countries. ONR enters into international exchange agreements (also known as bilateral agreements) with other international nuclear regulators in order to share information, experience and good practice where it is believed to be mutually beneficial and in the UK's national interests. ONR does not have IEAs with every country with which it exchanges information – mutual cooperation is often achieved informally between signatories of the various international conventions. Each agreement differs, but in general covers the exchange of safety-related information concerning the regulation of siting, construction, commissioning, operation, transport of radioactive material, radioactive waste management and decommissioning of civil nuclear installations; and preparedness and management of nuclear and radiological emergencies. ONR is able to take some credit for the work of international counterparts. However, ONR must form its own view based on the UKs legal framework.

How long would it take to regulate (from application to permitting/ licensing) a new branch of the radiopharmaceutical supply chain?

Environment Agency and Natural Resources Wales

There is insufficient information available for the Environment Agency and NRW to make informed estimates on timescales. It would largely depend on whether the new activity requires a nuclear or non-nuclear Radioactive Substances Activity (RSA) EPR permit.

Where an activity takes place outside a nuclear licensed site, a non-nuclear environmental permit is required. There is a statutory determination time of four months that applies to new non-nuclear EPR applications. An application may take longer if we need to request further information from the operator or if the application is for a site designated as being of 'high public interest'. We would agree a determination period with the operator if we expect the determination to take longer, for example, if the application is particularly complex or further consultation is required.

A prospective operator is also able to access pre-application advice before making a permit application; the level of the advice required will depend on the operator and proposed activity.

There is no such statutory time limit for the determination of a new nuclear RSA environmental permit (i.e. a permit for disposal of radioactive waste from activities carried out on a Nuclear Licensed Site). The amount of time this will take, from initial approach from a prospective operator to issue of a permit, would be dependent on a number of factors, including (but not limited to):

- level of pre-application advice required
- if the activity is taking place on a site which already holds a Nuclear Site Licence, or if it is a new site where no activity involving radioactive substances has previously been carried out
- whether the type of practice is awaiting a justification decision from the relevant Justifying Authority
- quality of application
- requirement for a transboundary impact assessment
- if an independent radiological dose assessment is required
- consultation requirements

Availability of resources has the potential to impact determination timescales for both nuclear and non-nuclear site environmental permits. To mitigate this risk, we prioritise permit applications for determination and we keep resource availability under continual review, including engaging with industry to maintain an understanding of how the sector and demand might change.

Generally speaking, permitting a new nuclear medical radionuclide production activity would take longer than a new non-nuclear activity due to the likely increased complexity, increased public interest and higher potential impacts of a nuclear facility.

Health and Safety Regulators (HSE and HSENI)

HSE aims to grant 75% of consents for new work within 90 days of receiving fully completed applications. This will be dependent upon the quality of information submitted and the complexity of the work activity. An application may take longer if we need to request further information from the employer or if issues are identified during the site inspection.

Office for Nuclear Regulation

There is insufficient information available for ONR to make an informed estimates on timescales. ONRs timeline would be dependent on but not limited to:

- the hazards of the facility
- the licensing strategy
- availability of resources
- quality of submissions
- where the application is for
- government priorities

Have the regulators considered/planned for an increase in regulatory demand due to investment in new radionuclide production techniques?

Environment Agency and Natural Resources Wales

Capacity to regulate potential new radionuclide production techniques is not currently included within Environment Agency business plans. The Environment Agency expects that the resource required would be limited compared to nuclear reactor new build projects and regulation of existing facilities. Clearly this view would need to be revisited dependent on the specific proposals that come forwards.

Regulatory permissions wider than just those considered in this report would likely need consideration, especially for options that would result in the build of larger-scale facilities. This would include aspects such as the planning regime and non-radiological environmental protection (e.g. consideration of water discharge activities and Waste Framework Directive waste considerations) where other environmental permits may be required and/or where we need to respond to statutory planning consultations. The capacity of relevant Environment Agency and NRW staff outside of Radioactive Substances Regulation may also need consideration, especially given the expected demands on such staff from new nuclear build.

Additionally, for Wales, the Environment Agency delivers technical support to NRW on nuclear Radioactive Substances Activity permit determinations. This support does not extend to the assessment of non-nuclear site radioactive substances activity permits, or to other environmental permits in Wales, which are determined by Natural Resources Wales staff and whose capacity may also need to be considered.

Health and Safety Regulators (HSE and HSENI)

Capacity to regulate new radionuclide production techniques is not currently included within business plans. However, the resource required to assess new consent applications would be limited compared to ongoing work to transfer the consents of some 1600 employers onto the new RADAN system. If there were to be a significant increase in the number of (non-nuclear) sites requiring emergency plans under REPPIR, additional inspector capacity would be required.

Office for Nuclear Regulation

Demand due to radionuclide production techniques is not currently included within ONRs business plans. However, the resource required would be limited compared to reactor new build projects and regulation of existing facilities.

Chapter 3: Regulatory challenges in radionuclide supply chain

Are there any challenges associated with the current regulatory demand from the radiopharmaceutical sector?

Environment Agency

The Environment Agency has not identified any challenges with the current regulatory demand from the radiopharmaceutical sector.

Health and Safety Regulators (HSE and HSENI)

HSE and HSENI would be made aware of any significant challenges with the current regulatory demand on the radiopharmaceutical sector through our participation in various committees, such as the Medical Radiation Liaison Group and the Institute of Physics and Engineering in Medicine's Nuclear Medicine Special Interest Group. The only area in which HSE is aware of issues in recent years is the designation of radiopharmacy and nuclear medicine staff as classified radiation workers; this has caused administrative and financial burdens on NHS Trusts and there has been a shortage of doctors specialising in the assessment of fitness of classified radiation workers.

Office for Nuclear Regulation

ONR is not aware of any known challenges with the current regulation of the radiopharmaceutical sector.

Would there be any significant challenges associated with the regulation of the supply chains proposed in Annex 1 and what are the possible areas of future focus associated with these?

Environment Agency

The Environment Agency has not identified any fundamental challenges with the production scenarios discussed in this report, however, the Environment Agency has suggested a number of areas for future focus which could assist in the development and progression of proposals similar to the scenarios considered. These areas of future focus are detailed under the headings of the different production scenarios.

A common challenge to all scenarios is if the UK were to pursue a large-scale medical radionuclide production programme, this could result in centralised facilities both for production, but also potentially specialised medical settings for delivery of diagnostic and therapeutic uses. In turn this could lead to significant levels of discharge into the environment from one or a small number of places. In addition, increased availability of longer lived, novel radionuclides may result in more hospitals needing to do more complex radiological assessments. This may in turn change the balance on what represents the Best Available Techniques (BAT) for controlling discharges into the environment and necessitate consideration of techniques such as abatement technologies, which to date have seen less consideration in non-nuclear licensed site settings such as hospitals.

Depending on the production method, some medical radioisotopes can contain longer-lived contaminants which hospitals will need to consider in terms of accumulation of waste.

Consideration should be made of the disposability of wastes, including from the production processes; use of the medical radioisotope; and those that may be produced during decommissioning of the production facility.

Health and Safety Regulators (HSE and HSENI)

HSE and HSENI do not anticipate any significant challenges regulating the accelerator-produced radionuclides or separation of Y-90 from Sr-90 as listed in Annex 1.

The production routes shown for Pb-212 and Ac-225 would be regulated by ONR if the source (starting or target) materials were identified to be nuclear matter, or by HSE/HSENI otherwise. However, it is not uncommon for the heritage of materials to be unknown and so there is concern that significant effort may be required to determine the appropriate regulator.

Initial estimates for the development of generators to produce Pb-212 from Th-228 suggest the activity of source material required will be of the order of 1 GBq. The threshold of dispersible activity above which a hazard evaluation is required under REPPIR is 700 MBq for Th-228; this could lead to burden on hospitals, local authorities and the regulators. Potential manufacturers of such generators for use in the UK should therefore consider:

- Whether 1 GBq of Th-228 is clinically necessary? Would a quantity below the REPPIR threshold suffice?
- What are the possible accident scenarios with this generator type? Are they or can they be mitigated in the design?
- Would the whole amount of Th-228 be dispersible in an accident? If the amount dispersed was < 700 MBq, no further REPPIR consideration would be needed

The activity of Pb-212 produced during one elution of these generators was not provided, so no REPPIR analysis was possible for the product.

Further information or study would be required to assess the design of these generators, the potential dispersibility of the starting material and the activity of the eluted material before indicative REPPIR hazard evaluations and consequences assessments could be made. However, the duties imposed under REPPIR could clearly represent burden on any hospital using Th-228/Pb-212 generators, the Local Authorities within which they are located and the relevant regulators. Local authorities and the relevant regulators are highly likely to need additional resource to regulate the use of these generators. A more detailed consideration of REPPIR has been included on page 45 below.

Office for Nuclear Regulation

ONR is not aware of any known challenges associated with the production scenarios discussed in this report.

What challenges do the vendors face when meeting regulatory requirements?

An understanding of UK regulatory requirements should be at the forefront of a vendors engagement strategy. The goal setting nature of the UK's non-prescriptive legal framework provides a significant amount of flexibility for vendors, however this can be complex and changes of approach may be required for international stakeholders.

One area all regulators highlighted across each of the production scenarios, was the need for taking the development of operator and operator competence into consideration, particularly if a new organisation were to be established for operation of e.g. a centralised facility or a research reactor.

Environment Agency

The Environment Agency have not identified any fundamental challenges for vendors when meeting regulatory requirements.

This Regulatory Study focussed on regulation of new technologies and supply chains, but one key aspect that we suggest requires consideration by potential vendors is the siting of a new production facility. One point of discussion during the Regulatory Study workshop was the concept of a centralised production facility, that may have multiple radiopharmaceutical production activities located on it, potentially run by different operators. While each activity or facility may be under the 0.3 mSv/y single source dose constraint, operation of several facilities on the same site could potentially present a challenge to the single site dose constraint of 0.5 mSv/y. Our experience is that there are some sites where large teaching hospitals (with their own radiopharmacies) are co-located on a campus with several biomedical research facilities, and in these locations the dose constraint is challenged. This could prevent some future operations taking place, if for example operators are unable to vary their permit to increase or change their discharges.

The Environment Agency has also suggested a number of areas for future focus outlined below against each scenario. These could assist in the development and progression of proposals.

Health and Safety Regulators

No regulatory challenges are anticipated for the vendor for the separation of Y-90 from Sr-90. For the accelerator-produced radiopharmaceuticals, the vendor of the accelerator may need to gain consent to operate an accelerator during the commissioning phase; this will depend on whether it is their employees or those of the purchaser that generate the radiation beam and are responsible for radiation protection. For the Th-228/Pb-212 generators, the vendors may need to supply potentially commercially sensitive information on their generator design to allow the required REPPIR assessments to be undertaken.

Production Scenario 1: Electron Accelerator

Environment Agency

During this Regulatory Study, the Environment Agency has not identified any fundamental regulatory challenges with the particle accelerator technologies considered. The following areas of future focus may assist in the development and progression of proposals.

In terms of siting options, particle accelerator technology would likely not need to be on a nuclear licensed site (unless they included materials that brought them into licensing). However, during the Regulatory Study workshop a potential scenario was discussed whereby proposals may seek to develop not only a centralised national isotope facility for production, but also possibly a centralised facility for application of medical radionuclides to patients. If such a centralised radionuclide application facility were pursued, disposal (discharge) of radioactive waste would need consideration. This could perhaps be considered in a feasibility study, i.e. a screening level dose assessment, to see if the likely permitted discharge limits could constrain the operation, or potential siting locations, of such a facility.

Early screening level dose assessments may also be of particular use for medical radiopharmaceuticals that have a high dose per unit of release, including those based on alpha emitting radionuclides, such as Ra-223, Ac-225, Pb-212 and At-211, to help indicate whether a discharge limit would constrain the use of these radionuclides.

For particle accelerators, it is likely that a specific family of reasonably well-established medical radionuclides would be produced (e.g. F-18), but we highlight that there is also the potential for a pipeline of future, more novel radionuclides. For novel medical radionuclides, where there can be a lack of empirical dose assessment values (such as the environmental transfer parameters required for public and wildlife dose assessments), conservative values are typically used which can produce an unrealistic dose assessment. Consequently, there is a benefit to identifying novel radionuclides early to help enable work to make assessments more realistic. This could help to remove any unnecessary constraints (e.g. discharge limits) on the use of novel radionuclides.

It is also worth highlighting that for greater novelty options that include radionuclides such as radium isotopes, then disposability of solid wastes is likely to need early consideration, as

these could challenge the Waste Acceptance Criteria (WAC) at currently available disposal facilities. For a radium / actinium production route, the waste produced, and the activities and quantities of that waste would need to be understood, as well as their disposability requirements. Considerations around solid waste and disposability should be built into development work for innovative medical radionuclides, specifically those identified with radium isotopes.

Health and Safety Regulators

Subject to the exceptions for nuclear material and bulk quantities detailed in the ONR section immediately below, accelerator production of radiopharmaceuticals would generally be regulated by HSE or HSENI alongside the relevant environmental agency. Consideration should be given as to each stage of the production process and the locations at which that work will take place; as shown in the diagram by the potential shipping stages, there is opportunity for accelerator production to occur at one site while the synthesis to the radiopharmaceutical occurs at a second site and the administration to the patient occurs at a third site. It is possible that the regulators for the three potential sites could be different depending on which, if any, stages use nuclear material and/or bulk quantities of material. Careful planning to separate the production stages could minimise the requirements for a nuclear licensed site if nuclear material or bulk quantities are used, having a significant effect on the regulatory and financial burden for the employer.

Office for Nuclear Regulation

Radium-226 is non-fissile and is the most abundant naturally-occurring isotope of radium. However, naturally-occurring isotopes can be produced in, or made radioactive by exposure to the radiation incidental to, the process of producing or utilising certain fissile materials, in which case they may be nuclear matter.

The first question is whether it is intended to use the site for the purpose of installing or operating a kind of installation prescribed in NIR71 reg. 3(8). To answer that we need to know whether:

- the installation meets the specific description in NIR71
- the isotopes are being produced from nuclear matter that is not excepted matter
- the target material meets the definition of nuclear matter, and does not meet the definition of excepted matter

Storage of the Ra-226 target (and the stock of same held at the facility), together with the Ac-225 product, may qualify as ‘bulk quantities’. ONR bulk quantity policy[2] currently states:

> *“A site licence will be required for the installation and operation of a storage facility if it is designed or adapted to store quantities of radioactive matter at or above 100 times the REPPIR 2019 schedule 1 values.”*

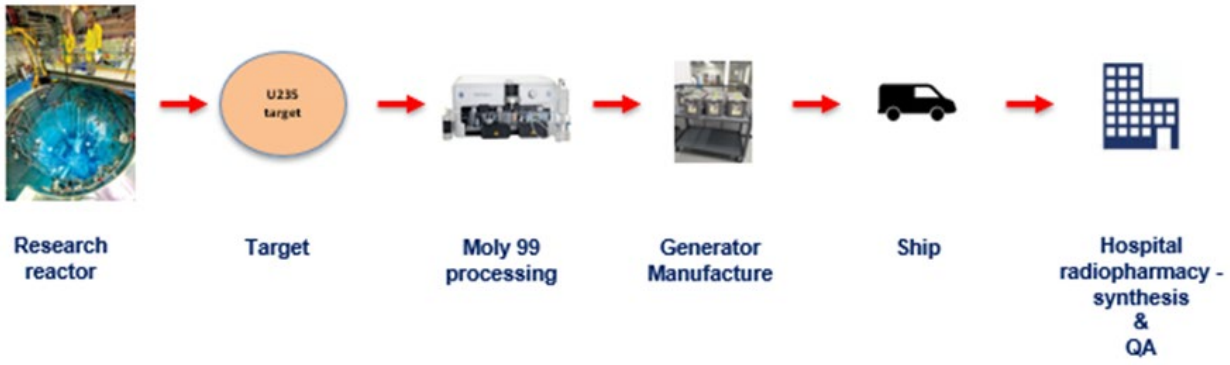
[2] ONR (2021) 'Interpretation of ‘bulk quantities’ in relation to the storage and disposal of radioactive matter'

In the event that the quantities exceed these levels[3], ONR would, in accordance with current policy, require the site to be licensed, and thus regulated by ONR. Insufficient information is provided to provide a definitive response as to whether bulk quantities might be reached. In all cases, the transport of target material to any facility, and the transport of product from any facility, would be regulated as part of ONR's activities to regulate the transport of Class 7 goods.

Safeguards may be relevant under the Nuclear Safeguards (EU Exit) Regulations 2019 if a) the qualifying nuclear material was shipped abroad AND b) depleted uranium shielding containers were used for such shipments. In this case, there may be an international reporting requirement to the IAEA.

[3] For Ra-226 a bulk quantity would be >~8g of material, for Ac-225 a bulk quantity would be >~1mg of material. These values are estimated using a threshold of 100 x 3e9 Bq from REPPIR Schedule 1, and half lives of 1600 years and 10 days respectively.

Production Scenario 2: Research Reactor, e.g. for Technetium-99m Production



Environment Agency

The Environment Agency has not identified any fundamental regulatory challenges with regards to permitting a research reactor proposal for producing medical radionuclides. The following areas of future focus may assist in the development and progression of proposals.

The IAEA produce Specific Safety Requirements (SSRs) for different types of nuclear facilities that bring the Safety Fundamentals and General Safety Requirements into a facility-specific context. UK regulatory bodies pay due regard to SSRs when developing guidance. If this option were to be pursued then we may need to consider if there is anything we need to bring into UK regulatory guidance from IAEA Safety of Research Reactors Specific Safety Requirements-03 (SSR-03) document.

During the Regulatory Study workshops, the Open Pool Australian Light water (OPAL) reactor was discussed. There is currently no MoU between the Environment Agency and ARPANSA (Australian Regulatory Body) and if an OPAL-type reactor proposal was developed, there may be a benefit with establishing one, which could help the Environment Agency to understand ARPANSA regulatory review processes.

For any international designs that have already been through domestic regulatory body assessment, this information could be used as well as a gap-analysis with UK-specific expectations.

In order to permit a new research reactor (and accompanying facilities) a prospective operator would need to demonstrate that the generation, management and disposal of radioactive wastes arising from operation of the reactor represent Best Available Techniques (BAT) in order to minimise the impact on people and wildlife. The design and manufacture of the fuel (including cladding) would be an important aspect of this as this has a direct impact on the operational wastes that require disposing of. A prospective operator would also need to

demonstrate how they intend to manage and dispose of spent fuel once it is removed from the reactor.

There is limited experience of operating a research reactor (and supporting facilities) in the UK for the purposes of isotope production. As such, development of organisational capability and competence would be needed. If this option were pursued, how the development of organisational capability (as well as design) is supported and funded may need consideration.

Environmentally-related regulatory permissions wider than just those considered in this report would likely need consideration, especially for options that would result in the build of larger-scale facilities such as a research reactor. This would include aspects such as the planning regime and non-radiological environmental protection (e.g. consideration of water discharge activities, Waste Framework Directive waste considerations). In Wales, both nuclear and non-nuclear permit applications are determined by NRW, with technical support from the Environment Agency on nuclear applications only. The capacity of Natural Resources Wales staff to respond to proposals may need to be considered.

Health and Safety Regulators

The reactor production of radionuclides is regulated by ONR. If the synthesis stage, is carried out away from the reactor site, and no nuclear matter is present, a nuclear licensed site is not necessary and it is regulated by HSE or HSENI.

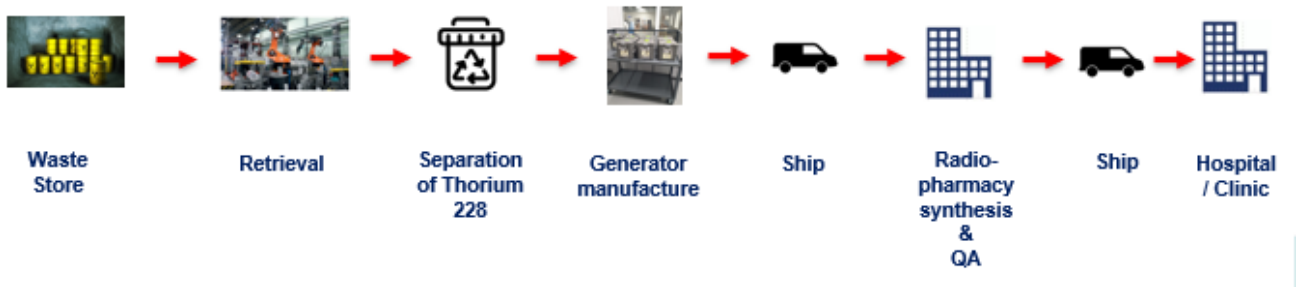
Office for Nuclear Regulation

A research reactor would be licensed by ONR in line with the Nuclear Installations Act 1965.

Chemical processing to produce the molybdenum-99 would be licensable under the Nuclear Installations Regulations 1971. The step to generator manufacture would not fall under ONR regulation unless carried out on a licensed nuclear site. This would then be subject to the conditions of the licence. The transport of radioactive material from any facility, would be regulated by ONR under CDG Class 7.

The nuclear material would need to be accounted for and controlled pursuant to Nuclear Safeguards (EU Exit) Regulations 2019. The research reactor would be a qualifying nuclear facility pursuant to Nuclear Safeguards (EU Exit) Regulations 2019 and The Energy Act 2013. The research reactor would also be added to the list of facilities available for IAEA inspection activities pursuant to INFCIRC/951.

Production Scenario 3: Harvesting from Legacy Waste e.g. for Lead-212 Production



Environment Agency

During this Regulatory Study, the Environment Agency has not identified any fundamental regulatory challenges with extracting radionuclides from legacy radioactive waste or materials for use in the medical sector. The following areas of future focus may assist in the development and progression of proposals.

Re-working legacy radioactive wastes may result in new solid waste streams, new discharges and additional doses. In demonstrating the application of the Best Available Techniques (BAT), attendees at the Regulatory Study workshop highlighted that existing operators may be reluctant to support the re-working of their legacy wastes, given that BAT has already been demonstrated for the disposal of such wastes. It is important to note that BAT can change, as circumstances change. For example, the definition of BAT includes 'latest stage of development' and consideration of 'state of the art', as well as socio-economic factors in reaching the overall BAT option. Consequently, if a new demonstrable and economically viable approach to extract and use medical radionuclides can be made, then a BAT case may be able to be made that on balance this is the best option even if additional quantities of secondary waste are generated. If there is no clear market for the use of medical radionuclides produced from waste, then a case for large-scale conversion of wastes into new products would likely be difficult to make. However, a staged / phased approach is much more likely, which would help to build confidence and build market /off-take certainty. A respective, staged BAT case approach starting with small-scale production may help facilitate eventual larger-scale production.

During the Regulatory Study workshop, attendees asked whether there was a process for declaring that a radioactive waste still held value and was in fact a radioactive material. Work has previously been carried out both to consider how nuclear operators can make beneficial use of radioactive waste and on what a process may look like for declaring radioactive materials (such as Special Nuclear Material residues) as waste. It is suggested that Government or industry may want to consider supporting work by regulators to build on these

pre-existing pieces of work to help provide greater clarity around when a waste becomes a medical radionuclide product and how different regulatory requirements apply.

It was also noted that for some wastes there is the potential to take a stable legacy waste form and end up with less stable / less passive waste form, e.g. UO3 to uranyl nitrate. Full-lifecycle consideration for waste will be particularly important for this production option in enabling an adequate demonstration of BAT. This could include early identification of a need for R&D to support such a life-cycle consideration, for example R&D into the disposability of solid wastes, particularly if processing a waste that is currently disposable into a waste form with less certainty associated with its disposability.

The Regulatory Study workshop presentations suggested that some radionuclide generators produced from legacy waste would contain quantities of radioactive substances that would bring it into scope of the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPIR). REPPIR requires the operator and Local Authority to have plans in place to respond to a radiation emergency at the site, which must be exercised. Currently there are no hospitals in England that are subject to the REPPIR regime. The Environment Agency has a statutory role in responding to a radiation incident, and additional REPPIR sites may need increased resource and capability. Additionally, if REPPIR limits are exceeded, then a Transboundary Assessment would also need to be considered during the Environmental Permit application process, which would add additional complexity to a permit application.

Health and Safety Regulators (HSE and HSENI)

Whether the starting material is considered to be nuclear matter will decide if ONR or the health and safety regulators are responsible for regulating radiopharmaceutical production. If nuclear matter is not involved, the production of radiopharmaceuticals from legacy waste would be regulated by HSE or HSENI in conjunction with the relevant environmental agency.

For HSE/HSENI regulated work, where the activities of starting materials are beneath the radionuclide-specific thresholds listed in Schedule 1 of REPPIR, the consent application process for addition of radioactive substances to products and administration to persons is relatively straight forward. However, if the dispersible activity of the radionuclides exceeds the REPPIR threshold, additional duties under REPPIR apply as outlined below.

If a REPPIR hazard evaluation identifies any hazards which have the potential to cause a radiation emergency (1 mSv effective dose over the period of a year), a consequence report must be produced by the site operator (employer) which assesses the full range of consequences both on and off their site. The operator must write an emergency plan that details how potential radiation emergencies will be managed from on-site in order to restrict exposure. The Local Authority responsible for that site must then consider what detailed and outline planning zones are required to mitigate the consequences of a radiation emergency beyond the operator’s premises; these plans must be prepared within 8 months of the Local Authority receiving the consequences report from the operator. The Local Authority must also prepare and make information available to the general public about those emergency plans. All of the above duties must be completed before work with ionising radiation can commence and

could introduce significant delay to a site becoming operational. The hazard evaluation, consequence report and emergency plans must be reviewed and the emergency plans tested every 3 years.

These responsibilities under REPPIR clearly represent burden on any hospital using e.g. Th-228/Pb-212 generators, the Local Authorities within which they are located and the relevant regulator. Local authorities and the relevant regulators would need additional resource to support the production of emergency plans and public information, and the regulation of REPPIR sites respectively.

Office for Nuclear Regulation

Generally, waste that contains this type of fissile material would be generated and stored on a nuclear licensed site (assuming it has not already been disposed of to a disposal facility) and the storage and management of the radioactive waste on licensed sites is regulated by ONR.

The Nuclear Installations Regulations 1971 regulation 3(8) states that *"any installation designed or adapted for the carrying on of any process involved in the production from nuclear matter, not being excepted matter, of isotopes prepared for use for…medical...purposes"* is a prescribed kind of installation and thereby would require a nuclear site licence by virtue of the Nuclear Installations Act 1965 section 1. For more complex retrieval and separation processing activities may require some form of permissioning assessment by ONR to ensure these are conducted safely and securely.

UKNNL currently undertakes research into such processes as a tenant organisation on existing nuclear licensed sites.

The transport of radioactive material from any facility, would be regulated by ONR under CDG Class 7 (and by NIEA in Northern Ireland).

There is too many unknown with this scenario to expand on a possible safeguards approach. Although, safeguards would need to be considered as thorium is a qualifying nuclear material under Nuclear Safeguards Regulations 2019.

Annex 1: Nuclear Site Licensing

The UK has previously been involved in production of medical radioisotopes by GE Healthcare at their sites at Cardiff, Harwell and Amersham, sites licensed under the Nuclear Installations Act 1965.

ONR has been asked to provide advice on the circumstances under which facilities engaged in the production of radioisotopes in GB would need to be licensed under the NIA 1965.

There are a range of medical radioisotopes used in medical procedures in the UK with the overwhelmingly most used being Tc-99m (about 80%). However, there are several other key radioisotopes in use or being proposed for future use. A radioisotope production facility typically consists of a high energy particle production device and a target facility where the high energy particles bombard the target material to produce the required radioisotope.

When considering any requirements for a nuclear site licence for such facilities the relevant legislation is the Nuclear Installations Act 1965 and the Nuclear Installations Regulations 1971 and the definitions therein. Target materials can be bombarded by either neutrons, protons or electrons. These can be produced either in a fission reactor or in a suitable particle accelerator. Hence in considering the question of nuclear site licensing the source of the activation particles and the target materials need to be considered.

Particle Generation: If a fission reactor is incorporated into the facility in order to produce a high neutron flux for use in bombarding of a target then it is specifically covered by the Nuclear Installations Act 1965 and hence the site as a whole will need a nuclear site licence. Where a particle accelerator is used to produce the bombarding particles, a nuclear site licence might not be required however, consideration must also be given to the origin of the target material.

Research Reactors used in the production of Radioisotopes such as the Argentine Open Pool Australian Light Water Reactor deployed in Australia incorporate neutron tubes in the reactor vessel to allow neutrons to escape the core and be directed onto a target material. Such facilities require a nuclear site licence to be installed and operated in the UK.

Interpretation of the definition of ‘nuclear matter’ is complicated and a detailed explanation of the definition is provided in ONR’s Technical Inspection Guide (TIG) on licence condition LC4 – Restrictions on nuclear matter on the site.

Where a target material is a naturally-occurring element or produced from a natural decay chain of such elements then this is considered not to be nuclear matter other than in the case of Uranium or Plutonium themselves. Where the target material is uranium for example then this target is nuclear matter and as such a NSL would be required for such a facility. Facilities not needing a nuclear site licence would be regulated by the Health and Safety regulators. The list shown below of radionuclides of interest to the UK is not exhaustive at this stage, showing target materials and the source materials from which they are derived and the radionuclide to be generated from particle bombardment and the method of particle generation.

Radionuclide	Method of production	Source material	Target material	Initial ONR impression on licensing
Ga-68	Accelerator	-	Zn-68	Accelerators unlikely to require licensing.
As-211	Accelerator	-	Bi-209	
F-18	Accelerator	-	F-18	
Cu-64	Accelerator	-	Ni-64	
Zr-89	Accelerator	-	Y-89	
Ac-225	Accelerator	-	Th-232	
Y-90	Recovery/ purification from Sr-90	Sr-90	-	-
Pb-212	THETIS-TIGER	Th-232 or U-232	-	Dependent on history of source material.
	Natural decay	Th-228 (cannot guarantee clarity on source history)		
Ac-225	Natural decay chain	Radium-Beryllium (cannot guarantee clarity on source history)	-	Previous position that Ra-226 is not a prescribed material if not produced in a reactor. However, further legal advice would be required.

ONR recommends a working group, involving the appropriate regulators, is formed to explore the interpretation of nuclear matter and the requirement for licensing. This should consider the all the proposals above in more detail with engagement with technology stakeholders.

Glossary

ALARP:	As Low As Reasonably Practicable
BAT:	Best Available Techniques
CDG:	Carriage of Dangerous Goods
CNSC:	Canadian Nuclear Safety Commission
CQC:	Care Quality Commission
DESNZ:	Department for Energy Security and Net Zero
EU:	European Union
GB:	Great Britain
GDA:	Generic Design Assessment
IAEA:	International Atomic Energy Agency
IRR:	Ionising Radiation Regulations
HSE:	Health and Safety Executive
HSENI:	Health and Safety Executive Northen Ireland
NHS:	National Health Service
MHRA:	Medicines and Healthcare Products Regulatory Agency
MoU:	Memorandum of Understanding
mSv:	milliSievert
NI:	Nuclear Institute
NIEA:	Northen Ireland Environment Agency
NNL:	National Nuclear Laboratory
NRW:	Natural Resources Wales
ONR:	Office for Nuclear Regulation
RADAN:	RADiation Authorisations and Notifications
R&D:	Research and Development

RSA:	Radioactive Substances Activity
RSC:	Royal Society of Chemistry
RQIA:	Regulation and Quality Improvement Authority
SEPA:	Scottish Environment Protection Agency
SHINE:	Subcritical Hybrid Intense Neutron Emitter
SRP:	Society for Radiological Projection
SSR:	Specific Safety Requirements
UK:	United Kingdom
USNRC:	United States Nuclear Regulatory Commission

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