

**Better Environmental  
Regulation Programme**

# **Consultation on Proposals for an Integrated Authorisation Framework**

**January 2017**

## **Part 7 – Radioactive Substances**

## 7. Part 7 - Radioactive substances

7.1 This Part of the Consultation considers the regulation of (1) keeping and use of radioactive materials (2) management of radioactive waste and (3) the production of radioactive material within the integrated authorisation framework. This Part considers:

- The background to the regulation of radioactive substances by SEPA;
- How we propose to regulate radioactive substances in the integrated authorisation framework;
- The changes from current arrangements;
- Our proposals for authorisations for radioactive substances, including standard rules; and
- Our proposals for transitional arrangements.

### 7.2 Background

7.2.1 In the UK, the regulatory framework that governs the safe use and management of radioactive substances is split between various regulatory regimes. These include health and safety at work; environmental protection, nuclear safety and transport of radioactive materials. It is notable that of these regulatory regimes, environmental protection is within the devolved competence of the Scottish Government; the others relate to reserved matters and so are the responsibility of the UK Government.

7.2.2 The principal environmental protection legislation dealing with radioactive substances is the Radioactive Substances Act 1993 (“RSA 1993”). SEPA is responsible for administering RSA 1993 and ensuring that businesses using radioactive substances, and managing radioactive waste, do so in a manner that protects the environment and the public.

7.2.3 There have been many developments in radiation protection and associated international standards and requirements since RSA 1993 (which is largely unchanged since the Radioactive Substances Act 1960) came into force. In particular, these are: regularly reviewed safety standards, requirements on the safe management of radioactive waste and requirements on the safe keeping of sealed sources, each described below:

- **Regularly reviewed safety standards** – The recommendations of the International Commission on Radiation Protection (ICRP) which are codified into Safety Standards by the International Atomic Energy Agency (IAEA) and the European Union. The most recent ICRP recommendations have been incorporated into the latest version of the European Basic Safety Standards Directive (BSSD 13) which Member States must transpose into national law by 6 February 2018.
- **Requirements on the safe management of radioactive waste** – The UK is a signatory to the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. The

provisions of this convention have also been incorporated into European law in the form of the Radioactive Waste and Spent Fuel Directive.

- **Requirements on the safe keeping of radioactive sources** – The UK has committed to act in accordance with the IAEA's Code of Conduct on the safety and Security of Radioactive Sources. Similar requirements were adopted by the EC in the form of the High Activity Sealed Sources and Orphan Sources Directive which are now incorporated in BSSD 13.

7.2.4 The current legislation that we propose replacing with the integrated authorisation framework is:

- The Radioactive Substances Act 1993 (RSA 1993);
- The Radioactive Substances (Basic Safety Standards) (Scotland) Direction 2000 (BSSD);
- The High-activity Sealed Sources and Orphan Sources Regulations 2005 (HASS Regs);
- The HASS (Scotland) Directions 2005; and
- The Radioactive Substances Exemption (Scotland) Order 2011.

This consultation is not proposing any changes to:

- The Radioactive Contaminated Land (Scotland) Regulations 2007; and
- The Transfrontier Shipment of Radioactive Waste and Spent Fuel Regulations 2008.

7.2.5 The proposals in this consultation seek to retain the flexibility of the existing regulatory framework whilst at the same time making the updates and changes necessary to reflect changes to terminology and practice that have occurred over time.

### **7.3 Proposed new legislative regime**

7.3.1 The scope of the current RSA 1993 can be understood by considering three key areas. These are:

- The substances that are captured by the definitions of radioactive material and radioactive waste;
- The people and businesses that the regime applies to; and
- The activities that need to be regulated.

Anything, any person, and any activity not caught by the Act is “out of scope” and is not subject to radioactive substances regulation.

7.3.2 We have reviewed these three areas to ensure that the integrated authorisation framework satisfies the following objectives for radioactive substances activities:

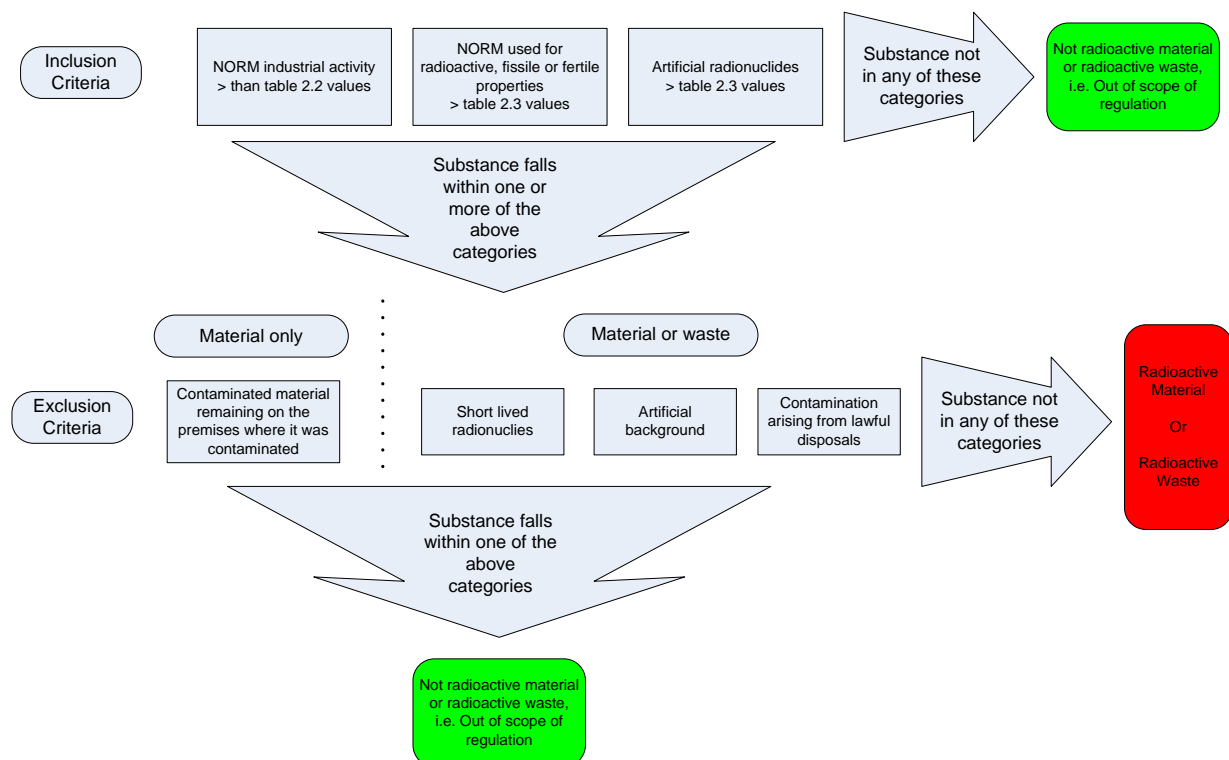
- all activities and substances that may cause harm to the environment or people can be appropriately regulated;
- relevant international obligations are implemented; e.g. the Basic Safety Standards Directive (BSSD) and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management.
- relevant government policy is implemented; and
- ensures that radioactive substances are held in a secure manner.

Each of these areas is set out in turn in this section, with proposals for change along with an explanation of what will remain the same.

### ***Definition of radioactive waste and radioactive material***

7.3.3 The definition of radioactive material and radioactive waste currently used in RSA 1993 were introduced in 2010 as part of the UK's review of Exemption Orders. The definitions set out what substances are subject to regulation under RSA 1993 and which substances are "out of scope". Further explanation of these definitions and the underpinning reasoning is available in government guidance ([https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/69357/pb13624-rsl-guidance-110914.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69357/pb13624-rsl-guidance-110914.pdf)); a summary of the definitions is given in Figure 8 below.

**Figure 8 – The current definitions of radioactive material and radioactive waste and how they combine to define the scope of the radioactive substances legislation**



Source: Guidance on the scope of and exemptions from the radioactive substances legislation in the UK. Tables referred to in this figure can be found in this document.

7.3.4 We have reviewed the definitions and consider that in general, they provide a robust framework by which substances are brought within the scope of the radioactive substances regime and which is consistent with the aims and scope of BSSD 13. There may need to be some changes to the numerical values used within the definitions to reflect the BSSD 13 requirements. Such changes are being considered on a UK-wide basis and will be consulted on separately.

7.3.5 During our review we identified some changes that we consider will simplify and improve the overall functioning of the radioactive substances regulatory regime; these are described below.

***Contaminated materials remaining on the premises whilst contaminated***

7.3.6 The current definition of radioactive material excludes from regulatory control any radioactively contaminated materials not contaminated with the intention of using its radioactive, fissile or fertile properties so long as the material remains on the premises where it was contaminated. If that material were to become waste, or were it to be moved off the premises, it would fall within regulatory controls.

7.3.7 We believe that the reason for the exclusion is that it was considered impractical to require a registration under RSA 1993 for the keeping and use

as “radioactive material” for all the different materials and equipment that may become contaminated through the registered use of other radioactive materials (i.e. it is excluded for administrative rather than technical reasons). However, this means SEPA is unable to ensure the safe keeping of these radioactive materials and that the appropriate steps are being taken to minimise radioactive waste.

7.3.8 We consider this to be an unsatisfactory situation and propose to remove this exclusion from the radioactive materials definition. As a consequence new conditions, or standard rules, will be required in an authorisation that allow such contaminated materials to be kept and used and will place proportionate controls on such materials. This proposal will simplify the legislation and maintain high standards of environmental and public protection.

**Question 39 – Do you agree that it is appropriate to have controls on radioactively contaminated materials whilst they remain on the premises where they were contaminated?**

**Question 40 – Do you foresee any practical implications of the proposal to have controls on radioactively contaminated materials whilst they remain on the premises where they were contaminated?**

### ***NORM materials***

7.3.9 Many substances can contain naturally occurring radionuclides; these substances are often known as Naturally Occurring Radioactive Material (NORM). NORM is brought within the scope of RSA 1993 if it is associated with a named industrial activity and the concentrations of the natural radionuclides exceed specified levels. There are two classes of NORM industrial activities, Type 1 and Type 2:

- Type 1 industrial activities include those where natural radionuclides (uranium and thorium) are deliberately added to products for their non-radioactive properties. These substances fall within the definition of radioactive material and, once they become waste, radioactive waste; and
- Type 2 industrial activities are activities where the presence of NORM is incidental and is avoided if possible. Only wastes associated with these activities fall within the scope of the legislation. NORM containing materials, such as feedstock ores and any resultant product are not included in the definition of radioactive material and are therefore out-of-scope.

7.3.10 The exclusion of Type 2 NORM materials from being radioactive material avoids the need for potentially regulating finished products that may contain radioactivity above the specified concentration values. However, we are not aware of any such products, and should any exist, we consider that it would

be more appropriate to consider materials on case-by-case basis to decide if exclusion or exemption from regulation is the optimum regulatory approach.

7.3.11 The drawback of the current approach is that it offers no control of feedstock materials, intermediate products or contaminated items that are not themselves waste. Poor control of these can cause contamination and they may become wastes. This appears to be contradictory to the reasoning underpinning the regulation of radioactive materials, which is to control waste generation at source. It is also the case that the distinction between radioactive waste and material is not always clear, as it can depend on the intent of the owner.

7.3.12 With the above considerations in mind we propose removing the differentiation between Type 1 and Type 2 NORM industrial activities and simply refer to "NORM industrial activities". Such an approach would be easier to understand and ensure a high level of environmental and public protection; it would also facilitate closer working with the Health and Safety Executive (HSE), who do not differentiate between waste and material under the Ionising Radiations Regulations.

7.3.13 This means that any substance, material or waste, would be subject to regulatory controls if it contains radionuclides above the specified levels (the NORM out-of-scope values). We consider that the industrial sector likely to be the most impacted by this change is the oil and gas industry due to their use of materials that are contaminated with NORM. However, the practical implications should be limited as current practice is to treat such materials as radioactive and the proposal to have a single authorisation covering all activities involved in the lifecycle of a radioactive substance, will eliminate the need to have multiple licenses.

**Question 41 – Do you agree that all substances associated with NORM industrial activities should be subject to control under the integrated authorisation framework, where they exceed the out-of-scope values, irrespective of whether or not they are classed as radioactive material or waste?**

**Question 42 - Do you foresee any significant implications of this proposed change, e.g. are there any finished products (consumer products or construction materials) that would become classified as radioactive material?**

### ***Exclusion of the public***

7.3.14 We propose that the integrated authorisation framework does not apply to the public in the same way that RSA 1993 does not currently apply. The prohibitions in RSA 1993 regarding the keeping and use of radioactive materials and the accumulation and disposal of radioactive waste only apply to "undertakings".

7.3.15 The concept of “undertaking” is used in RSA 1993 to avoid licensing the “trifling” or “trivial” quantities of radioactivity in domestic premises. As part of developing the integrated authorisation framework it is sensible to consider if it remains appropriate for the public to continue to be excluded.

7.3.16 We have considered the circumstances under which members of the public may carry out radioactive substances environmental activities and whether any of these mean that the public should be included within the scope of the integrated authorisation framework and we propose the public continues to be excluded. The reasoning behind this is:

- The majority of radioactive substances in public possession are consumer products which represent a trivial risk and are controlled by other regulations which prevent consumer products being placed on the market (if the risk is not trivial);
- It would be disproportionate, and very difficult, to apply controls to the public for the very few cases where the public have possession of radioactive sources which are not consumer products (e.g. owning historical artefacts containing radioactive material). Not only would inclusion of the public impose a disproportionate burden it would deliver little practical benefit as alternative mechanisms are available to provide support to the public on a case-by-case basis; and
- The approach is consistent with the scope of BSSD 13.

**Question 43 – Do you agree that we should continue to exclude the public from the scope of the radioactive substances regulatory regime?**

### ***Proposed radioactive substances regulated activities***

7.3.17 To implement the integrated authorisation framework, we need to decide which radioactive substances activities should be regulated activities. Only activities that are specified as regulated activities will be subject to authorisation. We have reviewed those activities currently captured by RSA 1993 and we also want to ensure that the regulated activities take into account the full lifecycle of a radioactive substance.

7.3.18 We propose that the following are included as regulated activities in the new regime:

- **Production of radioactive material**  
via the creation of radionuclides other than in a nuclear reactor or as a result of radioactive decay;



- **Keeping and use of radioactive material**  
where keeping and use includes receipt, lending, letting on hire, release to the environment, introducing radioactivity into organisms and transfer to another person; and
- **Management of radioactive waste**  
where management includes the receipt, storage, treatment, disposal and transfer to another person.

7.3.19 There are a few significant changes compared to RSA 1993. The first is that there is no intention to have a separate activity of “mobile radioactive apparatus”. This is because the integrated authorisation framework will provide flexibility as to the locations at which a regulated activity may be carried out. That means there is no longer any need to have a sub-category of radioactive material which can be authorised for use at more than one location.

7.3.20 We are also considering replacing “accumulation of radioactive waste” and “disposal of radioactive waste” with “management of radioactive waste”. This term would be applicable to all aspects including receipt, storage, treatment, disposal and transfer to another person of radioactive waste. The term will need to be defined and we are considering using the definition given in Spent Fuel and Radioactive Waste Directive (Council Directive 2011/70/EURATOM), namely: “radioactive waste management means all activities that relate to handling, pre-treatment, treatment, conditioning, storage, or disposal of radioactive waste, excluding off-site transportation.”

7.3.21 Related to the new activity of “management of radioactive waste” we propose to clarify the regulation of transfer and receipt of radioactive waste. Transfer of radioactive waste to another person is currently regulated as disposal of radioactive waste (because the definition of disposal includes removal of waste from premises). We do not consider it helpful, or clear, to include transfer of waste to other people in the same category as disposing of waste to the environment by discharge to air or water and burial in land. We therefore propose to remove this from the definition of disposal, but will continue to regulate transfer as part of radioactive waste management.

7.3.22 In terms of receipt of radioactive waste, this will also form part of radioactive waste management and any person who wants to receive radioactive waste from any person or any other premises will need to be regulated accordingly for that activity.

**Question 44 – Do you agree with the proposed radioactive substances regulated activities?**

### ***Application of the new regulatory regime to nuclear licensed sites***

7.3.23 SEPA regulates the disposal of radioactive waste on, or from, nuclear licensed sites. The keeping and use of radioactive material and the accumulation of radioactive waste on site is currently exempted from control under RSA 1993. As it is proposed that regulated activities are defined differently in the new regime there is a need to consider how they will apply on a nuclear licensed site.

7.3.24 We propose that:

- The production, keeping and use of radioactive material on a nuclear licensed site remains exempt;
- The management of radioactive waste on nuclear licensed sites would require authorisation and would **not** be exempted; and
- Consultation arrangements would continue between the Office for Nuclear Regulation (ONR) and SEPA to ensure each agency's regulatory responsibilities are taken into account in their respective licensing regimes.

7.3.25 This change would clarify the current working practice that all stages of radioactive waste management on a nuclear licensed site, from an environmental and public protection perspective, are subject to regulation by SEPA. There is no intention, or desire, to duplicate any of the functions or responsibilities of ONR or impose additional regulatory burden on nuclear licensed site operators. In practice we envisage little change to SEPA's current regulatory practice and established working arrangements with the ONR. We are currently in discussion with ONR about these proposal and the options for giving effect to them.

**Question 45 – Do you agree with the proposals for applying the new regulatory regime to nuclear licensed sites?**

### ***Application of the new regulatory regime to MOD Authorised sites***

7.3.26 The Ministry of Defence (MOD) carries out a number of activities involving radioactive substances including radioactive materials and nuclear fuels. Many of these activities occur on MOD Authorised Sites, which are regulated in a manner analogous to civilian licensed sites, with the Defence Nuclear Safety Regulator (DNSR) carrying out similar functions as a safety regulator to the ONR on civilian licensed sites. Because of this, we propose that MOD Authorised Sites should be treated by the integrated authorisation framework in a similar manner to civilian nuclear licensed sites.

7.3.27 Our intention is ultimately to incorporate MoD sites into the integrated authorisation framework so that:

- The production, keeping and use of radioactive material on an MOD Authorised Site should be exempt; and
- The management of radioactive waste on an MOD Authorised Site should require an appropriate authorisation.

However, there are outstanding technical and practical difficulties in putting this intention into the regulations, and we shall not seek to include MoD sites in the first set of integrated authorisation framework regulations for radioactive substances.”

***Where radioactive substances regulated activities will fit in the tiers of authorisation***

7.3.28 Under RSA 1993 there are essentially two tiers of authorisation:

- Registrations for the keeping and use of radioactive material and authorisations for the accumulation and disposal of radioactive waste;
- Exemptions under the Radioactive Substances Exemption (Scotland) Order 2011.

7.3.29 The majority of registrations and authorisations currently issued under RSA 1993 will become “permits” in the new integrated authorisation framework; however, some may fall into a lower tier of authorisation. Where regulated activities are proposed to fit in the new tiers of authorisation is set out in Figure 9 at the end of this part.

7.3.30 The current radioactive substances exemption regime is widely accepted to be complicated and difficult to understand. The need to migrate the current exemptions into the integrated authorisation framework provides an opportunity to improve the clarity of the exemptions and make the system as easy to understand as possible.

7.3.31 Due to the complex nature of the current exemption regime this is not a straightforward task and work to develop detailed proposals is still ongoing. In addition to this we are also liaising with the HSE to explore the possibility of more closely aligning our respective regulatory frameworks as part of BSSD 13 implementation (e.g. having a single notification system). As such this consultation concerns our approach to migrating the exemptions rather than the detailed proposals.

7.3.32 Our approach is to present the replacements to the exemptions in a manner that represents the full lifecycle of a radioactive substance (i.e. the keeping and use of a material and the management of any radioactive waste arising from keeping and using it rather than having provisions relating to ‘keeping and use’, accumulation and disposal presented separately as is currently the

case). We consider this will help make the regulatory regime easier to understand. The combined exemptions are most likely to become GBRs or notifications.

7.3.33 The integrated authorisation framework will allow the creation of standard rules which can be used in registrations and permits. We propose that this ability could be used to replace some of the current exemptions, e.g. if a standard condition is developed that allows waste sealed sources to be sent to a waste permitted person (WPP) or back to supplier it could be included as a standard condition in all notifications, registrations and permits for the keeping and use of sealed sources.

7.3.34 One of the considerations that will decide which tier of authorisation a current exemption is placed in is whether a substance or source, or any waste, that is expected to be generated from its use, is suitable for disposal to the dustbin with ordinary refuse or to the sewer without specialist controls. If some form of specialist control is required then it would be authorised under a notification, registration or permit. This proposal is consistent with the primary reason for regulating the keeping and use of radioactive material *“that proper control of radioactive wastes must entail some control at source, so that users of radioactive material who, by their methods of use, are likely to create a waste disposal hazard can be checked before the hazard arises”*. Therefore, logically, if controls are required on the waste some controls must be required on material generating that waste.

7.3.35 The proposal in 7.2.32 will also contribute to minimising the possibility of such radioactive materials becoming orphan sources or of being disposed of inappropriately. The practical consequences of this proposal depend on the numerical values used to represent that something is safe to be disposed of with ordinary refuse. As an example, the current exemption allows any sealed source up to 200 kBq to be disposed of with ordinary refuse, if this value was used in the new regime it may be necessary to notify to SEPA the use of any sealed source with an activity exceeding this value.

## **7.4 Overview and comparison to current arrangements**

### ***Application***

7.4.1 The arrangements for notification will be new as this is a new tier of authorisation for the radioactive substances regime. The information required in an application for a registration or permit is likely to be similar to that currently required for an application under RSA 1993.

### ***Determination and Grant of permits***

7.4.2 Under the integrated authorisation framework it is proposed that the time for determining a registration will be 28 days and the time for determining an authorisation will remain at four months as it currently is in RSA 1993 (with the exception of nuclear licensed sites). Complex authorisation applications, such as nuclear licensed sites, are unlikely to be determined within four months.

The determination period can be extended by mutual agreement with the applicant

The integrated authorisation framework will remove the existing 28-day period between an RSA 1993 authorisation being issued and coming into force.

### ***Transfer***

7.4.3 Under RSA 1993, only authorisations for nuclear licensed sites can be transferred; whereas under the integrated authorisation framework transfer of authorisations will be allowed for all registration and permit holders.

### ***Variation***

7.4.4 Variation of permits and registrations will be allowed under the integrated authorisation framework except for changes to standard rules which will be carried out as a separate process if required.

### ***Surrender and Revocation***

7.4.5 It is proposed that if an authorised person ceases to carry on their regulated activity and no longer needs to be authorised they must surrender the authorisation. SEPA will also have powers to revoke a registration, or permit. This is different from RSA 1993, which uses only the concepts of cancellation for a registration and revocation for an authorisation. In practice, revocation in RSA 1993 can be used to cover “surrender” scenarios, where the regulated activity has ceased and the operator wishes to give up the authorisation, and “revocation” scenarios, where SEPA wants to revoke an authorisation as an enforcement tool.

7.4.6 The surrender and revocation provisions will include statutory requirements for returning sites to a satisfactory state. This explicit requirement will formalise SEPA's current requirements for revoking registrations and authorisations. Please see paragraphs 3.6.20 to 3.6.24 for further details.

### ***Enforcement powers***

7.4.7 RSA 1993 provides for enforcement and prohibition notices. These will be replaced by the enforcement powers of the new regime as described in paragraphs 3.7.3 to 3.7.17.

## **7.5 Proposed RS permits and standard rules**

### ***Combined registrations and authorisations***

7.5.1 It has been SEPA's intention to combine registrations to keep and use unsealed radioactive material and the associated authorisation to accumulate and dispose of radioactive waste under RSA 1993 into a single licence for some time. There is nothing in RSA 1993 which prohibits issuing combined licences; however, we believe that this type of fundamental change is best

implemented as part of the other changes under the integrated authorisation framework. There are currently about 200 RSA 1993 registrations in this category that could be combined with an associated RSA 1993 authorisation.

### ***Sealed source registrations and permits***

7.5.2 Registrations under RSA 1993 for the keeping and use of sealed radioactive sources could also be combined into a single permit or registration along with registrations for unsealed radioactive material or non-nuclear authorisations for the accumulation and disposal of radioactive waste. However, due to national security restrictions, SEPA believes that separate permits or registrations for sealed sources will facilitate the administration of these types of authorisation and ensure compliance with the national security requirements. Therefore, SEPA proposes that sealed source permits and registrations will continue as stand-alone authorisations.

### ***Standard rules***

7.5.3 We are developing standard rules for use in all radioactive substances registrations and permits. Use of standard rules will ensure consistency across industry sectors involved with radioactive substances regulated activities and registrations and permits issued at different times. The use of standard rules should also increase transparency to all stakeholders with regard to SEPA's expectations as they will be published on SEPA's website.

7.5.4 We intend to provide guidance on each standard rule in the same manner as we have done in the Guidance to Permit Conditions for RSA 1993 registrations to keep and use radioactive material. SEPA will consult on the full suite of standard rules and its associated guidance prior to the transition to the new permits and registrations.

### ***Duty to display certificates***

7.5.5 Section 19 of RSA 1993 currently requires registered persons and authorisation holders to "keep posted on the premises ..." copies of certificates of the registration or authorisation issued. In some cases, registrations were posted on main notice boards that were accessible to all site personnel and visitors. The introduction of the High-activity Sealed Sources and Orphan Sources Regulations 2005 (HASS regulations) introduced a new security regime for holders of sealed radioactive sources, and at a similar time a National Security Direction was issued to SEPA by Scottish Ministers directing that information relating to sealed sources was not made available to the public.

7.5.6 The posting of documents as required by RSA 1993 does not always conform to the security requirements imposed under the HASS regulations and so we propose removing the requirements to post registration and authorisation certificates. Instead, we are proposing a requirement for the authorised person to ensure that the authorisation is made available to all persons who require it in connection with their duties.

**Question 46 – Do you foresee any problems with removing the requirement to display certificates?**

***Ability to use an off-site condition***

7.5.7 There are some circumstances when SEPA might want an authorisation holder to carry out monitoring, remediation or other works beyond their site boundary. Under RSA 1993, there is no way to ensure that other landowners allow the authorisation holder on to their site to carry out this type of activity; it has to be done under a voluntary or commercial arrangement. However, other regimes e.g. PPC 2012, do have this provision. If the other landowner will not allow the authorisation holder on to their site, SEPA currently has no powers to ensure that monitoring, remediation or other works are carried out on that site.

7.5.8 We are proposing that under the integrated authorisation framework SEPA has the ability to include an off-site condition in radioactive substances authorisations. There will be a mechanism for arbitration, appeal, consultation and compensation included in the integrated authorisation framework to support the ability to use an off-site condition.

**Question 47 – Do you agree that SEPA should have the power to impose conditions in an authorisation requiring the permit holder to carry out operations off their site?**

**7.6 Transitional arrangements**

7.6.1 Each of the existing regimes will have its own timetable for transitioning to the integrated authorisation framework. Fortunately for the radioactive substances regime, there are only a modest number of RSA 1993 registrations and authorisations (<1000) that require to be transitioned.

7.6.2 We believe that there is considerable merit in transitioning to the integrated authorisation framework as soon as possible in order to get the benefit of the consistency that standard rules and GBRs will bring.

7.6.3 In order to transition to the integrated authorisation framework in the shortest practicable timeframe we are proposing that, as far as possible, existing registrations and authorisations will automatically transfer into the appropriate tier (registration or permit). We propose to consult on standard rules that also include any new requirements from the BSSD, ahead of the Integrated Authorisation Framework coming into force so that existing registrations can transition directly into the registration tier. Any registrations that require bespoke conditions would need to transition to the permit tier. By doing this, we propose that there will be no need for the authorisation holder to make an

application for transition to the integrated authorisation framework, nor will there be a requirement for a transition fee.

- 7.6.4 With the exception of combining existing registrations for unsealed radioactive material with non-nuclear authorisations for the accumulation and disposal of radioactive waste, we do not propose combining radioactive substances authorisations with other SEPA pollution control authorisations or to produce corporate permits for those authorised persons with multiple sites in Scotland as part of this initial transition process.
- 7.6.5 If an authorised person wishes to add, delete or change an existing limit or bespoke condition at this time or to have an integrated cross-regime or corporate registration or permit, they will be required to make an application and will be liable for the appropriate application fee and go through the standard application process.



**Figure 9 – Where regulated activities fit in the tiers of authorisation**

Proposed radioactive substance regulated activity	Specific sub-activity	Relevant tier under integrated authorisation framework	Reasoning/additional information
Keeping and use of radioactive material	Sealed High Activity Sealed Sources (HASS)/Sources of a Similar Level of Potential Hazard (SSLPH) (both fixed and mobile and including those used offshore)	Permit	<ul style="list-style-type: none"> <li>• No significant change from current situation.</li> <li>• Revised BSSD requires “licensing” of practices involving the use of HASS (Article 27b (d)). Also requires review of financial provision to ensure it is fit for purpose.</li> <li>• Consultation with CTSA for onshore sites.</li> <li>• Onshore premises inspected before granting (can be joint inspection with CTSA).</li> <li>• SEPA needs to assess sources to be held for both environmental protection and security purposes.</li> <li>• SEPA needs to specify individual radionuclides and total activity limits to ensure environmental protection.</li> <li>• Approximately 300 certificates affected.</li> </ul>
	Sealed category 5D (both fixed and mobile and including those used offshore)	Notification	<ul style="list-style-type: none"> <li>• No consultation with CTSA on applications.</li> <li>• Notification allows SEPA to know who is using such sources in case they appear as orphan sources in the future.</li> <li>• Assumes that if number of sources held causes category to go up to category 4, permit will be required to ensure appropriate security provisions are included.</li> <li>• Approximately 10 category 5D certificates affected.</li> </ul>

Proposed radioactive substance regulated activity	Specific sub-activity	Relevant tier under integrated authorisation framework	Reasoning/additional information
	Mobile radioactive apparatus (sealed sources) based outwith Scotland	Registration	<ul style="list-style-type: none"> <li>• Reduces administrative burden on operators undertaking cross-border work who already hold a permit elsewhere in the UK as well as with SEPA.</li> <li>• Revised BSSD requires “licensing” of practices involving the use of HASS (Article 27b (d))</li> <li>• No Scottish CTSA consultation required on applications as apparatus is kept outwith Scotland (English/Welsh/Northern Irish CTSA would be involved with the application for the site where the apparatus is normally kept).</li> <li>• SEPA does not inspect premises where apparatus is <u>normally kept</u> before granting (usually liaise with EA/NRW/NIEA at application stage to see if any issues with operator).</li> <li>• Current SEPA legal opinion is that radionuclide/activity limits in permits issued by EA/NRW/NIEA could be enforced in Scotland. If so, could refer out to limits in that permit. (No need to set authorisation-specific limits)</li> <li>• Approximately 30 certificates affected.</li> </ul>
	Unsealed sources <10 GBq of Tc-99m or 20 MBq of other radionuclides	Registration	<ul style="list-style-type: none"> <li>• If associated with a regulated activity to manage radioactive waste, SEPA’s intention is to combine the two into single permit/registration.</li> <li>• Effectively replaces current “reduced band” charging category.</li> <li>• If standalone “authorisation” required, not significantly different from current situation.</li> <li>• SEPA needs to assess justification of radionuclide(s) and activity of sources to be held.</li> </ul>

Proposed radioactive substance regulated activity	Specific sub-activity	Relevant tier under integrated authorisation framework	Reasoning/additional information
			<ul style="list-style-type: none"> <li>• Radionuclide and activity holding limits are generic and are suitable for inclusion in a standard rule.</li> <li>• No current standalone unsealed source certificates of this type.</li> </ul>
	Unsealed sources >10 GBq of Tc-99m or 20 MBq of other radionuclides	Permit	<ul style="list-style-type: none"> <li>• If associated with a regulated activity to accumulate/dispose of radioactive waste, SEPA's intention is to combine the two into single permit.</li> <li>• If standalone "authorisation" required, not significantly different from current situation.</li> <li>• SEPA needs to assess justification of radionuclide(s) and activity of sources to be held.</li> <li>• Premises inspected before granting.</li> <li>• SEPA needs to specify individual radionuclides and activity limits to ensure environmental protection.</li> <li>• Approximately 7 standalone open source certificates.</li> </ul>
Keeping and use of radioactive material	Releasing radioactive material into the environment (currently s10 open source registration)	Permit	<ul style="list-style-type: none"> <li>• No significant change from current situation (s10 open source registration).</li> <li>• Dose and ERICA assessments required (similar to radioactive waste disposal).</li> <li>• SEPA needs to specify individual radionuclide and activity limits to ensure environmental protection.</li> <li>• Approximately 3 certificates affected.</li> <li>• Usually not required to consult; however, results of ERICA assessment may require consultation with SNH.</li> </ul>

Proposed radioactive substance regulated activity	Specific sub-activity	Relevant tier under integrated authorisation framework	Reasoning/additional information
Keeping and use of radioactive material	Introducing radioactivity into organisms (currently s10 open source registration and/or authorisation)	Permit	<ul style="list-style-type: none"> <li>• Listing “introducing radioactivity into organisms” as a specific sub-activity provides clarity, especially for injections into animals (e.g. feline thyroid procedures).</li> <li>• No significant change from current situation which requires RSA93 registration and/or authorisation.</li> <li>• Dose and ERICA assessments required (similar to radioactive waste disposal).</li> <li>• SEPA needs to specify individual radionuclide and activity limits to ensure environmental protection.</li> <li>• Approximately 2 certificates affected.</li> <li>• Usually not required to consult; however, results of ERICA assessment may require statutory consultation with SNH.</li> </ul>
Production of radioactive material	Proposed new regulated activity	Permit	<ul style="list-style-type: none"> <li>• No change from current situation (usually captured as part of unsealed source registration/non-nuclear authorisation certificate pair). Not expected to capture new activities/sites.</li> <li>• Premises inspected before granting to ensure arrangements sufficient to minimise generation of radioactive waste.</li> <li>• SEPA needs to specify individual radionuclides and activity limits to ensure environmental protection.</li> <li>• Approximately 4 certificates currently affected.</li> </ul>
Radioactive waste management	Nuclear licensed sites	Permit	<ul style="list-style-type: none"> <li>• No significant change from current situation (treatment and storage of radioactive waste could now be formally captured as part of regulated activity).</li> </ul>

Proposed radioactive substance regulated activity	Specific sub-activity	Relevant tier under integrated authorisation framework	Reasoning/additional information
			<ul style="list-style-type: none"> <li>• Consultation with with ONR and FSS and notify Scottish Government on applications.</li> <li>• Custom and practice to publically consult on new authorisations (including re-authorisations) and substantial variations to existing authorisations.</li> <li>• Dose and ERICA assessments required.</li> <li>• SEPA needs to specify individual radionuclide and activity limits to ensure environmental protection</li> <li>• 6 civilian nuclear sites affected.</li> </ul>
Radioactive waste management	Land-based non-nuclear sites	Permit	<ul style="list-style-type: none"> <li>• If associated with an environmental activity to keep and use open/unsealed radioactive material, SEPA's intention is to combine the two into single permit.</li> <li>• If stand-alone "authorisation" is required, there is no significant change from the current situation.</li> <li>• Dose and ERICA assessments required.</li> <li>• SEPA needs to specify individual radionuclide and activity limits to ensure environmental protection.</li> <li>• Approximately 100 current certificates affected.</li> <li>• Usually not required to consult; however, results of ERICA assessment may require statutory? consultation with SNH.</li> </ul>
Management of radioactive waste	Transfers only of non-nuclear LLW to waste permitted	Registration	<ul style="list-style-type: none"> <li>• If associated with an environmental activity to keep and use unsealed radioactive material, SEPA's intention is to combine the two into single permit.</li> </ul>

Proposed radioactive substance regulated activity	Specific sub-activity	Relevant tier under integrated authorisation framework	Reasoning/additional information
	persons (no other disposals or disposals are exempt)		<ul style="list-style-type: none"> <li>• No consultation on applications for non-nuclear sites.</li> <li>• No dose or ERICA assessments required (no non-exempt discharges to the environment from generating site).</li> <li>• SEPA may wish to inspect premises before granting.</li> <li>• SEPA does not usually impose bespoke limits on waste storage or transfers.</li> <li>• Allows periodic data returns and notification of use of new transfer route(s) to be made to SEPA.</li> <li>• Approximately 10 certificates affected.</li> </ul>
Radioactive waste management	Offshore installations  (includes receipt of both intrafield and interfield wastes, discharge of produced water and up to 2 GBq Ra-226 & Ra-228 solid NORM waste to the marine environment as well as transfers of waste to waste permitted persons and persons outwith	Registration	<ul style="list-style-type: none"> <li>• If associated with an environmental activity to keep and use open/unsealed radioactive material, SEPA's intention is to combine the two into single permit.</li> <li>• No consultation on offshore applications.</li> <li>• SEPA does not usually inspect offshore installations before granting.</li> <li>• Radionuclide and activity limits for produced water discharges usually not included in current authorisations.</li> <li>• Radionuclide and activity limits for solid NORM waste disposals are generic and are suitable for inclusion in a standard rule.</li> <li>• SEPA does not usually impose bespoke limits on waste storage or transfers.</li> <li>• Allows periodic data returns and notification of use of new transfer route(s) to be made to SEPA. Does not affect SEPA's ability to issue "corporate authorisations" to operators with multiple installations (if so desired).</li> </ul>

Proposed radioactive substance regulated activity	Specific sub-activity	Relevant tier under integrated authorisation framework	Reasoning/additional information
	the UK)		<ul style="list-style-type: none"> <li>Approximately 90 offshore installations affected.</li> </ul>

