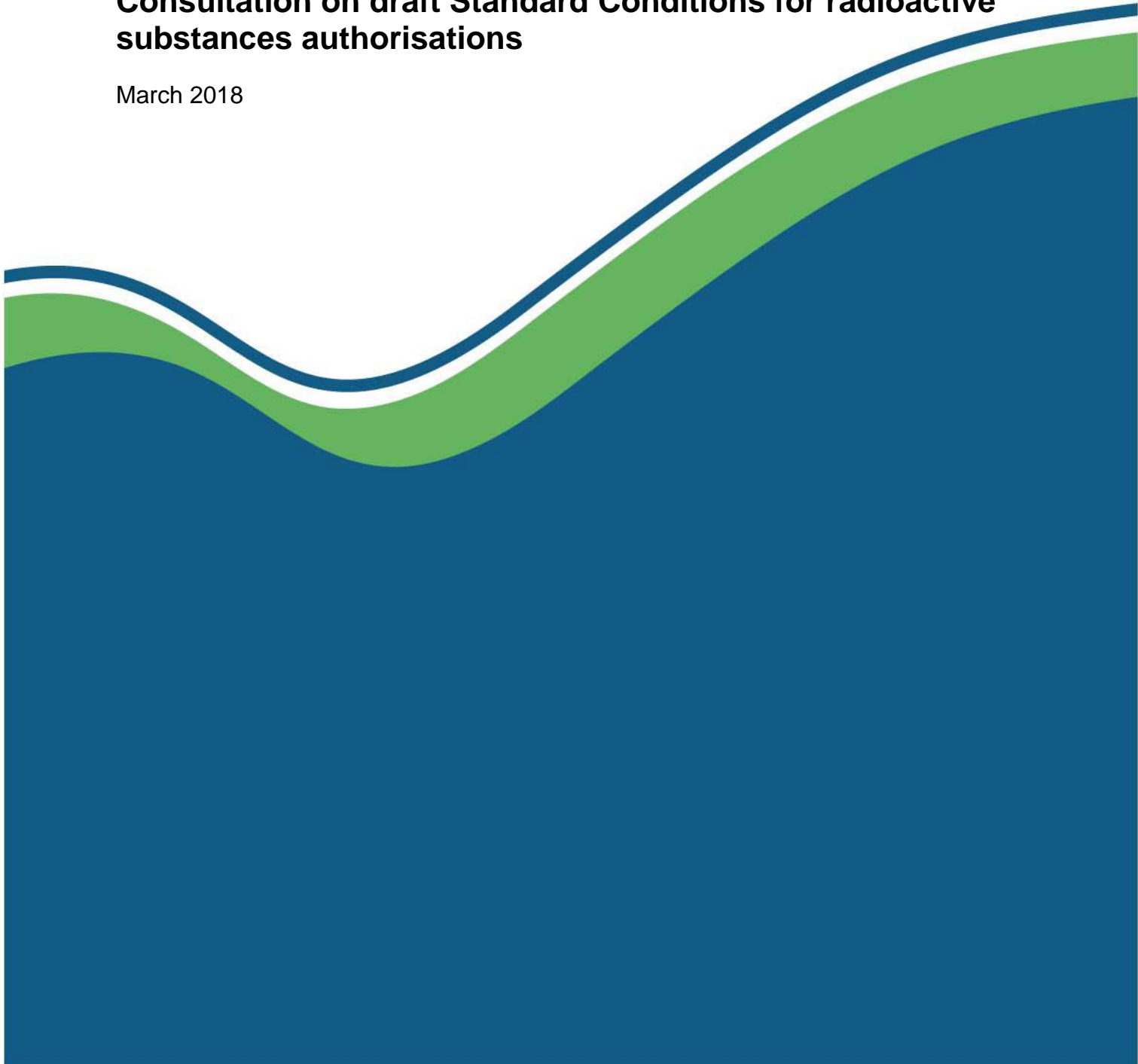


Better Environmental Regulation Programme

Environmental Authorisations (Scotland) Regulations 2018

## **Consultation on draft Standard Conditions for radioactive substances authorisations**

March 2018



## Purpose

The Scottish Government published a consultation in September 2017 on the draft Environmental Authorisations (Scotland) Regulations 2018 (EA(S)R). These regulations will replace existing radioactive substances legislation and set out the procedure for making and revising Standard Conditions.

Standard Conditions are ones that have been determined by SEPA, consulted on and published. The purpose of this document is to consult on our draft Standard Conditions for radioactive substances so that we have them ready to use in registrations and permits when the Environmental Authorisations (Scotland) Regulations 2018 come in to force.

## How to respond

You can respond to this consultation online <https://consultation.sepa.org.uk/radioactive-substances-unit/consultation-on-draft-standard-conditions-for-radi> or by sending your views and comments on the Standard Conditions to:

Angela Wright  
SEPA  
Strathallan House  
Castle Business Park  
Stirling  
FK9 4TZ

Email: [rsenquiries@sepa.org.uk](mailto:rsenquiries@sepa.org.uk)

Responses should be submitted to us by **20 June 2018**.

## Handling your response

We would like to know if you are content for your response to be made public.

If responding online, please complete the confidentiality questions where prompted. If responding by post or email, please complete and return the Respondent Information Form with your response.

If you ask for your response not to be published it will be regarded as confidential and treated accordingly.

## Executive summary

As part of the Better Environmental Regulation Programme, the Scottish Government and the Scottish Environment Protection Agency (SEPA) are working together to develop an integrated authorisation framework. The aim of the framework is to integrate the authorisation, procedural and enforcement arrangements relating to water, waste management, radioactive substances and pollution prevention and control. The integrated authorisation framework will be developed in a phased manner, starting with radioactive substances; the other regulatory regimes will be added in due course.

A key part of developing the integrated authorisation framework is the introduction of new regulations, the Environmental Authorisations (Scotland) Regulations 2018 (EA(S)R), which will be made and come in to force later this year.

Under EA(S)R, we need to make Standard Conditions that will be used in permits and registrations. Standard Conditions are conditions that have been predetermined by us in advance of receiving any application. They may be specific to a certain type of regulated activity or could apply to any regulated activity. This is in contrast to bespoke conditions, which are developed on a case-by-case basis taking into account the specific information that is included in an application for a permit. Registrations can only have Standard Conditions.

The principal objective of this consultation is to seek your views on the proposed Standard Conditions for radioactive substances. Views are sought on both the technical content and the presentation including style of language used. This consultation is targeted at people that are currently regulated under the Radioactive Substances Act 1993 or who may carry out a radioactive substances activity in the future. We also welcome views from any person that has an interest in radioactive substances regulation, for example, other regulators and interested members of the public.

As part of implementing EA(S)R, we have taken the opportunity to review certain aspects of our regulation of radioactive substances. Consequently, a number of changes are proposed that will be implemented by using Standard Conditions. We are seeking views on these changes in approach.

This consultation only applies to radioactive substances activities. No decisions have been made regarding the Standard Conditions that will apply to other regulatory regimes or how such Standard Conditions will be used. Further consultation will be undertaken when the other regulatory regimes are brought into EA(S)R which may include changes to the radioactive substances Standard Conditions.

## Contents

Purpose .....	2
How to respond .....	2
Handling your response .....	2
Executive summary .....	3
Contents .....	4
1 Introduction .....	5
Background .....	5
Objective .....	7
Scope .....	8
Structure of this document .....	8
2 Development and proposed use of Standard Conditions for radioactive substances .....	9
How we developed the Standard Conditions for radioactive substances .....	9
Involvement with stakeholders .....	10
How we intend to use Standard Conditions .....	11
Proposed guidance .....	12
3 Proposed Standard Conditions for radioactive substances .....	13
Structure of the Standard Conditions .....	13
4 Changes in regulatory approach .....	15
Standard Conditions that replicate GBR provision .....	15
Contaminated items kept on authorised premises .....	15
Transfers of radioactive substances (Section C) .....	15
Holdings of sealed sources (section D.1) .....	18
Security requirements for sealed sources (section D.2) .....	20
Introduction of radioactive material into the environment or into organisms .....	21
Radioactive gaseous discharges outwith authorised outlets (section H.2) .....	21
Quarterly Notification Levels (QNL) .....	22
Three-yearly prospective and retrospective dose assessment for non-human species .....	22
Waste management plan (section B.9) .....	23

# 1 Introduction

## Background

- 1.1 As part of the Better Environmental Regulation Programme, the Scottish Government and Scottish Environment Protection Agency (SEPA) are working together to develop an integrated authorisation framework. The aim of the framework is to integrate, as far as possible, the authorisation, procedural and enforcement arrangements relating to water, waste management, radioactive substances and pollution prevention and control. The integrated authorisation framework will be developed in a phased manner, starting with radioactive substances: the other regulatory regimes will be added in due course.
- 1.2 It is anticipated that new regulations, The Environmental Authorisations (Scotland) Regulations 2018 (EA(S)R), will be made by 1 July 2018 and will come in to force on 1 September 2018. These regulations will replace the existing radioactive substances legislation in Scotland including:
  - the Radioactive Substances Act 1993 (RSA93);
  - the High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005 (HASS regulations); and
  - the Radioactive Substances Exemption (Scotland) Order 2011 (Exemption Order).
- 1.3 The EA(S)R provide for a graded approach to regulation and introduce four tiers of authorisation (see Figure 1). In general, more complex and risky environmental activities will require a higher tier of authorisation (e.g. a permit) whilst simple and low risk activities will be authorised under the lower tiers e.g. a general binding rule (GBR). The level of SEPA effort and scrutiny that is required in issuing an authorisation increases with the tier of authorisation.
- 1.4 The EA(S)R also provide for the use of Standard Conditions. Standard Conditions are conditions that have been predetermined by SEPA in advance of receiving any application. They may be specific to a certain type of regulated activity or could apply to any regulated activity. This is in contrast to bespoke conditions, which are developed on a case-by-case basis taking into account the specific information that is included in an application for an authorisation. Standard Conditions are the only type of condition that can be included in registrations; they can also be included in permits. Notifications and GBRs are subject to rules made by the Scottish Government.
- 1.5 If a Standard Condition is included in a registration or permit under EA(S)R its content cannot be appealed but the inclusion of that Standard Condition in the authorisations (e.g. because it is not relevant) can.

	Tier of authorisation	What does this tier cover?	What controls are in place?
Complex	<b>Permit</b>	Permits regulate activities that: <ul style="list-style-type: none"> <li>• may have environmental and community impacts; and/or</li> <li>• are non standard and/or</li> <li>• are complex and</li> <li>• need rigorous assessment.</li> </ul>	Permits place conditions on the operator to ensure the activity can take place in ways that protect the environment and human health. These may be standard conditions or bespoke conditions.
	<b>Registration</b>	Registration activities are lower risk and a simple assessment can take place to enable us to grant or refuse the application.	A set of standard conditions will apply to a particular activity and the registration will contain no bespoke conditions.
Simple	<b>Notification</b>	Low risk activities that we do not need to grant or refuse the authorisation for, but where we need to know where and when certain activities take place to understand the potential for cumulative effects or for reporting purposes.	The activity will be carried out in accordance with a set of General Binding Rules (GBRs).
	<b>General Binding Rule (GBR)</b>	Low risk activities that need to be carried out in accordance with a set of General Binding Rules.	GBRs authorise an activity automatically without any prior contact or agreement from us.

Figure 1. Illustration of the four tiers of authorisation provided for by the EA(S)R

- 1.6 The EA(S)R details the process that must be followed for SEPA to make Standard Conditions. This process includes consulting people that we consider appropriate before we make Standard Conditions and publishing the Standard Conditions once they have been made. If any Standard Condition requires changing in the future, we must consult those affected by the change, notify them of the change and publish the changed conditions for a period of time before they become effective.
- 1.7 Our draft public participation statement describes the consultation process in relation to Standard Conditions (Figure 2). This consultation is step 2 of that process.

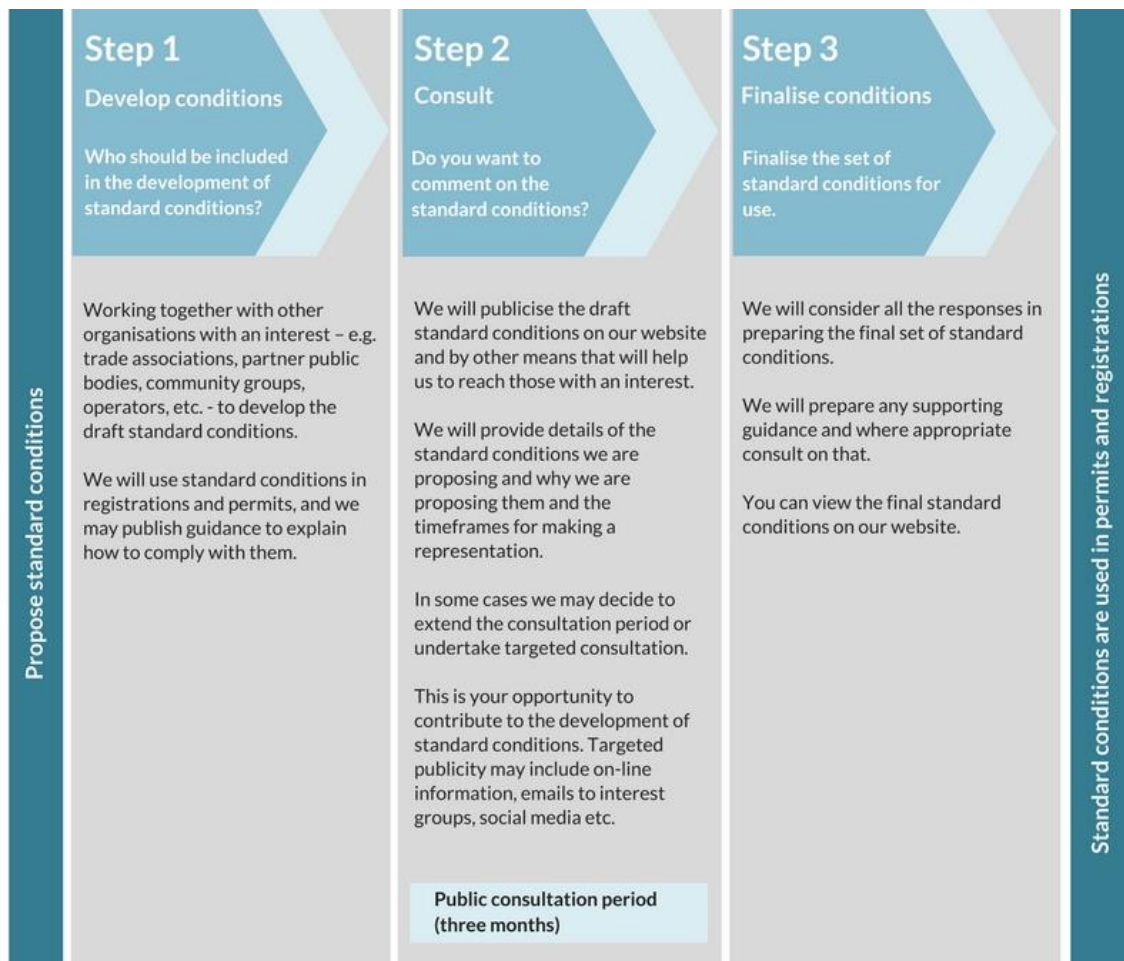


Figure 2. Illustration of consultation process for Standard Conditions

## Objective

- 1.8 The principal objective of this consultation is to seek views on the proposed Standard Conditions for radioactive substances. Views are sought on both the technical content and the presentation including style of language used. This consultation is targeted at people that currently regulated under RSA93 or who may carry out a radioactive substances activity in the future. Views are also welcome from any person that has an interest in radioactive substances regulation, for example, other regulators and interested members of the public.
- 1.9 It is also an objective of this consultation to seek views on how we intend to use the Standard Conditions.
- 1.10 As part of implementing the EA(S)R, we have taken the opportunity to review certain aspects of our regulation of radioactive substances. Consequently, a number of changes are proposed that will be implemented by using Standard Conditions. We are seeking views on these changes in approach.

## Scope

- 1.11 This consultation only applies to radioactive substances activities. No decisions have been made regarding the Standard Conditions that will apply to other regulatory regimes or how such Standard Conditions will be used. Further consultation will be undertaken when the other regimes are brought into EA(S)R which may include changes to the radioactive substances Standard Conditions.

## Structure of this document

- 1.12 This document contains four sections and three appendices. Section 1 is this introduction. Section 2 explains how we have developed the proposed Standard Conditions and how we intend to use them in radioactive substances authorisations. Section 3 provides more detail about the structure of the Standard Conditions and Section 4 highlights changes in regulatory approach that we intend to implement through Standard Conditions. The proposed Standard Conditions are included in Appendix 1. Appendix 2 includes example permits to illustrate how we plan to refer to Standard Conditions and Appendix 3 includes draft guidance.



## 2 Development and proposed use of Standard Conditions for radioactive substances

- 2.1 This part of the consultation explains how we developed the Standard Conditions and how we intend to use them.

### How we developed the Standard Conditions for radioactive substances

- 2.2 The starting point for developing the proposed Standard Conditions was the conditions used in our current RSA93 templates for registrations that allow the keeping and use of radioactive material and authorisations that allow the accumulation and disposal of radioactive waste. We started from this point because the current conditions have developed over many years and are well understood by most people. As a result, many of the requirements in the Standard Conditions are similar to those in current registrations and authorisations under RSA93, although the exact wording may differ. Significant changes are highlighted in Section 4.
- 2.3 Under EA(S)R it will no longer be necessary to issue different kinds of licence for “keeping and use” and “accumulation and disposal”. In the future, we will issue a single licence that covers the full lifecycle of a radioactive substance. Therefore, in most cases, the conditions that we currently use have been combined or re-written to apply to radioactive substances. They only refer to radioactive material or radioactive waste where this is necessary.
- 2.4 We have drafted the Standard Conditions to cover the most common activities that are undertaken. Any activities not specifically covered by the Standard Conditions will be addressed by adding bespoke conditions to permits, for example the introduction of radioactive material into the environment.
- 2.5 We have maintained the current approach used in radioactive substances regulation of writing our conditions in a goal-setting rather than prescriptive manner. This is consistent with a graded approach to regulation and allows the authorised person to put proportionate compliance arrangements in place rather than simply following a set of instructions. Accordingly, where possible we have removed prescriptive requirements that were included in our current templates. The exception to this approach is where we need to be prescriptive in order to ensure compliance with legislation or government policy.
- 2.6 Another advantage of being goal-setting rather than prescriptive is that the Standard Conditions can apply to all types of authorised activities, from nuclear sites to small laboratory uses. The arrangements put in place to ensure and demonstrate compliance should be proportionate depending on the activity being carried on. For example, everyone will be required to have a waste management plan; for a nuclear site the waste management plan is likely to be a series of detailed documents explaining the decommissioning process, the different waste streams that will be generated and how the waste will be managed, but for

someone only keeping sealed sources, the waste management plan is likely to be a short statement describing how the sources will be managed when they become waste.

- 2.7 We have attempted to write the Standard Conditions in a *plain English* style so that they are clear, concise and easy to understand whilst retaining legal enforceability. This includes removing cross references to other conditions where possible. As always, there is a balance between being concise and being able to enforce the requirement and some of the terms and language had to be retained for legal or technical reasons.
- 2.8 Some Standard Conditions have been included because EA(S)R requires us to include them in order to transpose the public exposure requirements of the *Basic Safety Standards Directive*<sup>1</sup> (BSSD). In addition to this, a great deal of other legislation, policy and guidance applies to radioactive substances, such as the *Spent Fuel and Radioactive Waste Directive*<sup>2</sup> and the standards and guidance issued by the International Atomic Energy Agency (e.g. the *International Basic Safety Standards*<sup>3</sup>). It is our job to ensure that all of this information is taken into account and that radioactive substances are controlled to the best possible standard. The Standard Conditions have been developed to ensure that the obligations placed onto the authorised person is consistent with these standards but in as concise a way as possible. Our draft guidance on the Standard Conditions provides more detail on how our conditions relate to these legal and international obligations.

### Involvement with stakeholders

- 2.9 In accordance with good practice and the draft process in our public participation statement, (see step 1 of figure 1) we have involved stakeholders in the development of the Standard Conditions. This included keeping our routine industry liaison groups, SNNILG and NILG<sup>4</sup>, up to date in developments of the better environmental regulation programme and specifically with the development of the Standard Conditions.
- 2.10 Additionally, a draft of the Standard Conditions was presented to stakeholders at the Integrated Authorisation Framework consultation workshop that we held for those interested in radioactive substances in November 2017. Following feedback from these events, during January 2018, we undertook a number of workshops with the nuclear, medical and oil and gas sectors to look at the draft Standard Conditions in detail. The feedback from these events was supportive and industry welcomed our proposed Standard Conditions. Various detailed points

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<sup>1</sup> Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation

<sup>2</sup> Council Directive 2011/70/Euratom establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste

<sup>3</sup> Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3

<sup>4</sup> Scottish Non-Nuclear Liaison Group (SNNILG) and Nuclear Industries Liaison Group (NILG)

were raised with us, which we have addressed whilst preparing the Standard Conditions and the accompanying guidance that form part of this consultation.

- 2.11 This formal consultation is step 2 in our draft public participation statement, which satisfies the legal requirements to consult on draft Standard Conditions and provides a further opportunity for any interested party to comment on the Standard Conditions.
- 2.12 The Standard Conditions that we are consulting on are set out in Appendix 1 and described in more detail in Section 3.

### How we intend to use Standard Conditions

- 2.13 Our current RSA93 registrations and authorisations contain all limits and conditions within the registration or authorisation itself. This means that if we need to include a new condition or make a change to an existing condition, we need to make a variation to each individual registration or authorisation affected by the change. Whilst we have standard templates, these templates change from time to time. Our experience shows that as the variations process can be a bureaucratic and time consuming process, changes to conditions in our standard template are often not varied into registrations and authorisations, rather the change is deferred to the next suitable opportunity, e.g. when an authorised person requests a change. In time, this has led to a situation where registrations and authorisations have different conditions or the same condition but with different numbering.
- 2.14 In future, we propose that registrations and permits will refer to published Standard Conditions, rather than including the text of the Standard Condition itself. This approach ensures the maintenance of a single set of conditions which has the following benefits:
- Everyone carrying on similar activities has the same Standard Conditions so that there is greater transparency and consistency across a sector;
  - Applicants can check the Standard Conditions they will need to meet before they apply which should help applicants in planning, financing and producing a good application;
  - We can more consistently monitor and compare compliance across a sector;
  - It is easier to produce guidance when everyone has to comply with the same conditions and all of the conditions have the same reference number.
- 2.15 This approach also makes it easier for us to make changes in the future in response to new policies, legislation and international obligations. Whilst there is a legal requirement for us to consult on any proposed changes and inform affected people, we consider that this will be administratively easier than having to make individual variations to authorisations that may not be all the same.
- 2.16 To make referring to Standard Conditions as straightforward as possible, and to facilitate future changes, we propose to refer to groups of Standard Conditions rather than every single individual condition. Despite this general approach, it would still be possible to refer to

individual Standard Condition or to dis-apply them if necessary. If any bespoke conditions (including limits) are required, these will be included in the permit.

- 2.17 The following section explains how the conditions are grouped together and Appendix 2 provides examples of how we intend permits or registrations to refer to Standard Conditions.

Question 1 – Do you foresee any problems or issues with our planned approach to refer to Standard Conditions rather than reproduce them in full in every registration and permit? If so please provide details.

### Proposed guidance

- 2.18 One of the advantages of everyone having the same Standard Conditions is that it is easier for us to produce guidance. We have written a first draft of *Guide to Standard Conditions* that, for each Standard Condition, explains why we include it and how we expect people to comply. The reasons in the *Guide to Standard Conditions* often show how directive and other international obligations are met by a specific condition. The *Guide to Standard Conditions* is included in Appendix 3 of this consultation. This guide is likely to develop over time and be a key mechanism by which we issue guidance.
- 2.19 The guidance that we have provided so far is mainly short, generic and usually aims to give further detail on what a specific condition requires and issues that would be addressed in developing compliance arrangements. In some cases, conditions that were in our previous license templates have been moved into the guidance, e.g. record keeping conditions. It may be possible for us to provide more specific guidance in the future but we will only consider this if there is an identified need.
- 2.20 As the Standard Conditions are intended to apply to all sectors it would be time consuming and difficult for us to provide guidance that is applicable to all sectors. However, the Standard Conditions do provide a good basis for specific sectors or industry groups to develop their own good practice guidance. SEPA would be happy to work with industry to review and critique such guidance to ensure that it was of a good standard.

Question 2 – Do you have any comments on our draft guidance?

### 3 Proposed Standard Conditions for radioactive substances

- 3.1 This section provides more detail about the structure and the detail of the Standard Conditions and discusses changes in regulatory approach that we propose to implement through the use of Standard Conditions. The Standard Conditions form Appendix 1 to this consultation.

#### Structure of the Standard Conditions

- 3.2 As explained earlier, we have grouped the Standard Conditions into sections. The proposed sections are:
- A. All regulated activities
  - B. All radioactive substances regulated activities
  - C. Transfers of radioactive substances
  - D. Sealed sources
  - E. High-activity sealed sources (HASS)
  - F. Mobile radioactive sources
  - G. Disposal of radioactive waste
  - H. Further conditions where bespoke limits have been authorised
  - I. Introduction of radioactive material into organisms
  - J. Environmental monitoring programme
  - K. Conditions applicable to offshore installation registrations
- 3.3 Sections A, B and C contain Standard Conditions that will apply to everyone who has a registration or permit for a radioactive substances activity under the EA(S)R. The remaining sections will only apply to certain radioactive substances activities, which should be self-explanatory from the title of the section (but will be explicitly stated in a registration or permit). The exception is Section K, environmental monitoring programme, its inclusion in permits will be decided on a case-by-case basis.
- 3.4 The conditions in Section A are grouped together because, although they have been influenced by international requirements relating the safe management of radioactive substances, they are not necessarily specific to radioactive substances. Therefore, it is possible that they could be applied to other regulated activities in the future; not just those that involve radioactive substance. However, no decision has been made regarding what Standard Conditions will apply to the other environmental regimes when they are transferred into EA(S)R and further consultation will be necessary before any Standard Condition can be applied to those activities.
- 3.5 Section B contains conditions that are specific to radioactive substances activities and will apply to all such activities.

- 3.6 Section C contains all the requirements relating to the transfer of radioactive substances. As any person holding radioactive substances may wish to transfer radioactive substances to another person, these conditions will apply to all radioactive substances activities. They are separate from section B because we consider it clearer to have all transfer requirements in one section.
- 3.7 The proposed Standard Conditions also contain three schedules. These schedules describe:
- the detail of what records need to be kept;
  - what data submissions are needed for different activities; and
  - what information needs to be provided to SEPA when informing us of an event.
- 3.8 We have grouped these specific requirements instead of spreading the detail throughout the Standard Conditions. We consider that this makes the Standard Conditions easier to understand and also provides a simple reference for the information that you may need to submit to us.

Question 3 – Do you foresee any problems in using and complying with the Standard Conditions? If so, please provide details.

## 4 Changes in regulatory approach

### Standard Conditions that replicate GBR provision

- 4.1 Under RSA93, it is possible to have a registration to keep and use radioactive material whilst disposing of resulting waste under the Exemption Order provisions. Similarly, you can be exempt from registration for keeping and use but need an authorisation to dispose of resulting waste. EA(S)R, has been designed so that this situation should not be possible, it is intended that any specific authorisation (GBR, notification, registration or permit) should apply the full lifecycle of the radioactive substance concerned. The GBRs have been drafted with this intention in mind, therefore certain activities that are exempt under RSA93 will not be under EA(S)R. As higher tiers of authorisation should not be more restrictive than a GBR, the Standard Conditions have been drafted to replicate relevant GBR provisions, these are:
- a) Section C allows the transfer of waste sealed sources
  - b) Section G.3 Disposal in normal refuse (dustbin disposal)
  - c) Section G.4 Radioactive aqueous liquid disposals – small quantities
  - d) Section G.5 Radioactive gaseous releases- small quantities

### Contaminated items kept on authorised premises

- 4.2 The out of scope provision for contaminated items being kept on the authorised premises (provided for by 1G of RSA93) is not being carried forward into the EA(S)R. Accordingly, the keeping and use of such materials will need to be carried on in accordance with an authorisation.
- 4.3 We are not proposing any Standard Conditions that apply specifically to contaminated materials; rather contaminated items are treated the same as any other radioactive substance and compliance is required with all of the Standard Conditions that apply generally to radioactive substances, e.g. an inventory of radioactive substances should include contaminated items as well as other materials and waste.
- 4.4 We consider that this approach should allow proportionate compliance arrangements to be put in place. In many cases adequate arrangements will already be in place e.g. through compliance with Ionising Radiations Regulations.

Question 4 – Do you foresee any problems with the proposed approach to regulating contaminated items on authorised premises? If so, please provide details.

### Transfers of radioactive substances (Section C)

- 4.5 We have taken the opportunity to review the way that we regulate the transfer of radioactive substances. All of the transfer conditions are included in Section C of the Standard Conditions.

- 4.6 Our regulatory approach is to apply “duty of care requirements” to the transfer of radioactive waste in permit conditions. We do this because the “conventional waste” duty of care requirements do not apply to radioactive waste. “Duty of care requirements” do not currently apply to radioactive materials but there are special requirements for HASS sources.
- 4.7 We currently adopt a slightly different approach to the transfer of radioactive substances from nuclear and non-nuclear sites. There are some differences regarding the types of waste that may be transferred as standard and those that need to be approved on a case-by-case basis (summarised in Table 1). Also, in accordance with our policy on the transfer of low level radioactive waste (LLW) from nuclear sites<sup>5</sup>, we require that nuclear sites ensure that all transfers represent the best practicable means for that type of waste, this requirement is not currently included in non-nuclear authorisations.

Table 1. Summary of current and proposed approach to regulating the transfer of radioactive substances.

Place of transfer	Description of radioactive substance	Approach for nuclear sites	Approach for non-nuclear sites	Approach under new Standard Conditions
Anywhere	radioactive materials	Not under SEPA's control - controlled by ONR	not currently controlled other than for HASS	anyone legally entitled to receive
Transfers within the UK	Low Level Radioactive Waste (LLW)	Standard to a WPP	Standard to a WPP (Generally, non-nuclear sites do not have ILW therefore, we have not needed to make a distinction between radioactive waste types in authorisations)	anyone legally entitled to receive
	Intermediate Level Radioactive Waste (ILW)	Case by case basis description of waste and the recipient will be specified		anyone legally entitled to receive
Transfers outside the UK	radioactive waste within the scope of TFS <sup>6</sup>	Standard in accordance with TFS authorisation	Case by case	in accordance with TFS authorisation
	radioactive waste not captured by TFS within the scope of TFS (e.g. NORM)	Case by case basis description of waste and the recipient will be specified	Case by case	not standard, assessed as required on a case by case basis

- 4.8 Going forward we propose adopting the same approach for all transfers irrespective of what kind of site wants to transfer radioactive substances. This is summarised in the last column of Table 1.

<sup>5</sup> RS-POL-002, Regulation of the inter-site movement of radioactive low level waste, May 2014

<sup>6</sup> SI 2008 No. 3087 The Transfrontier Shipment of Radioactive Waste and Spent Fuel Regulations 2008



- 4.9 The main changes we propose to make are set out in the bullet points below, each one is explained in more detail in the following paragraphs:
- transfers of all radioactive substances, including radioactive material, will be subject to “duty of care requirements” (see condition C.1)
  - All persons who transfer radioactive waste will only be allowed to make such transfers if they can demonstrate that it is the best option (best practicable means) for managing that waste (See condition C.3.1)
  - ILW transfers within the UK will be allowed as standard (see conditions C.5 and C.6)
  - A consistent approach will be taken to overseas transfers of waste
- 4.10 We have decided to apply the “duty of care requirements” to radioactive material because the hazard posed by radioactive substances does not depend on its status as material or waste. Therefore, it is reasonable to expect that a person must first check that a recipient is suitable and capable of managing that radioactive material before they send it. They will also have to follow a transfer procedure (Condition C.2) which ensures that the recipient has the information necessary to manage that material safely and which confirms the safe delivery of a transferred radioactive material. Transfers of radioactive materials to and from nuclear sites are not regulated by SEPA: these will continue to be regulated by the Office for Nuclear Regulation (ONR).
- 4.11 Nuclear sites are already required to ensure that transfers of radioactive waste represent the best practicable means for the management of that type of waste, so this change will only affect the non-nuclear industry. This will not be a new requirement in practice, as this our current expectation and is checked through our routine regulatory activities. This change has not been made previously due the effort associated with varying all existing authorisation.
- 4.12 We have decided to allow intermediate level waste (ILW) transfers as standard because we consider that it will provide greater flexibility to the nuclear industry and facilitate efficient decommissioning and can be implemented without compromising our independent scrutiny and high standards of public and environmental protection. It also brings regulatory arrangements into alignment with those for LLW. We have included Standard Conditions so that ILW transfers are only allowed where they comply with the Scottish Government’s higher activity waste policy (see conditions C.5 and C.6). Our scrutiny of ILW transfers will be a matter for routine inspection rather than assessed as part of an application and reflects our experience that such transfers are usually discussed with our staff on site visits in advance of any formal application to change an authorisation. These conditions may also be applicable in some cases to the non-nuclear industry, e.g. cyclotron target foil from radiopharmaceutical generation in hospitals.

- 4.13 One perceived negative of this change could be lack of transparency; specifically, that we will no longer carry out public consultations on proposed transfers of ILW. However, we will require regular reporting of all radioactive waste transfers and these will be available to the public, both through the register requirements of EA(S)R and as a summary in our annual RIFE report<sup>7</sup>. We would also expect any such transfers from nuclear sites to be raised at local community stakeholder groups before they occur.
- 4.14 If there is a need to transfer radioactive waste overseas it will need to be allowed under both EA(S)R and under the TFS regulations. To minimise regulatory burden associated with the need to apply for two separate authorisations we are proposing to include Standard Conditions that allow transfers overseas proving that they are carried out in accordance with a TFS authorisation. Our regulatory scrutiny of such a transfer will be undertaken as part of the TFS application process.
- 4.15 There are some types of radioactive waste that fall outside the scope of the TFS regulations, e.g. NORM or a substance that we consider waste but another country does not. For these waste types, we will need to assess any proposed transfers on a case-by-case basis so that we can ensure that they are consistent with government policy on the export of radioactive waste. This is no change to the current practice.

Question 5 – Do you foresee any problems with the proposed changes to the regulation of radioactive waste transfers? If so, please provide details.

#### Holdings of sealed sources (section D.1)

- 4.16 We have reviewed the way that we limit the holding of sealed sources and propose making changes to provide more flexibility for authorised persons.
- 4.17 Our RSA93 registrations for sealed sources currently limit what sealed sources you can keep and use by specifying which radionuclides you can hold, how many you can hold, the maximum activity of individual sources and the total maximum activity of each radionuclide. If there is a need to change any of these parameters, the registered person will need to apply for a variation with an explanation of why that change is required. We assess these applications to ensure that the explanation is robust and that the person is only holding the minimum number of sources that they need. Experience has shown that these variations are rarely refused, they are largely administrative and use resource that could be better targeted elsewhere. The only circumstances in which a change in sealed source holdings makes a difference to our regulation are:

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<sup>7</sup> Radioactivity in food and the environment

- a) if the activity of an individual source is increased above the high-activity sealed source (HASS) threshold meaning that the additional requirements for HASS sources are needed (explained in para 4.18); or
- b) it causes a change in security requirements because the change in activity means that the sources fall into a different security group (explained in para 4.19-4.20).

4.18 We need to know about HASS sources including the radionuclide and activity of each source so that we can assess that adequate financial provision has been made for managing sources that are no longer needed. There will be no change in the way we authorise HASS and we will continue to include limits on radionuclides held and activity limits.

4.19 Sealed sources are categorised according to the International Atomic Energy Agency (IAEA) publication *Categorisation of Radioactive Sources* (RS-G-1.9) which assigns a category based on a combination of factors including the practice the source is used for, the radionuclide and the activity of all sources held. The categories range from 1, which is the most hazardous, to 5 which is the least hazardous.

4.20 In the United Kingdom we determine what level of security is needed for sealed sources based on the IAEA categorisation as shown in Table 2. Each security group requires different security measures that are specified in the document *Security Requirements for Sealed Radioactive Sources*. The IAEA source category can be applied to individual sources and also to the aggregate activity in all sources that a person holds. We assess which security group a collection of radioactive sources falls into based on the total activity of sealed sources that you hold.

Table 2. Relationship between IAEA Source category and UK security group

IAEA source category	Security group
1	A
2	B
3	C
4	C
5	D

4.21 The EA(S)R has general binding rules for sealed sources where the total activity means they fall within IAEA category 5. Where the individual activity of any source is less than 200 kBq activities involving them can be undertaken without contacting us providing the GBRs are followed. Activities that involve sources that have an individual activity greater than 200 kBq

but with a total activity in IAEA category 5 need to be notified to us. This means that there will be no category 5 sources that require a registration or permit. There are no special security requirements for category 5 sources over and above the standard requirements for preventing loss and theft which is already a Standard Condition and also a requirement of the Ionising Radiation Regulations 2017.

- 4.22 For sealed sources falling in categories 3 and 4 there is no difference in the security requirements needed as in both cases the security group is C. With this in mind, we propose not including limits on the radionuclides, activity and number of sources that you can hold. Providing the total activity of all sealed sources is less than IAEA category 3. Standard Condition D.1.1 imposes this requirement.
- 4.23 This change in approach means that it will no longer be necessary for people to make an application for variation every time they need to change their source holdings but it also removes the process by which we check that a person only holds the minimum sources that they need. To compensate for this, we are proposing a Standard Condition (B.8.1) that requires that holdings of radioactive material are kept to the minimum quantity necessary to carry out an activity. An authorised person would be expected to be able to demonstrate compliance with this requirement at all times, not just when making an application. We will assess compliance with this as part of routine inspection.
- 4.24 We are also proposing a new Standard Condition requiring an annual return to us of the sealed sources that are held. This will help check that holdings are within the category 3 and 4 limit and give us realistic data on what sources are actually held in Scotland.

Question 6 – Do you agree with the proposed changes to how we limit holdings of sealed sources in Categories 3 and 4?
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#### [Security requirements for sealed sources \(section D.2\)](#)

- 4.25 Our current registrations for sealed sources have security conditions whose wording is based on the requirements in the HASS (Scotland) Directions 2005. Security is assessed by Police Counter Terrorism Security Advisers (CTSA) who base their standards on the document *Security Requirements for Sealed Radioactive Sources*.
- 4.26 To ensure that the authorisation requirement is the same as the standards required by CTSA's we have introduced a Standard Condition that requires you to meet the requirements of *Security Requirements for Sealed Radioactive Sources*.
- 4.27 The Standard Condition will refer to a specific issue of this document and when it is updated we will need to make an amendment to the Standard Condition following the procedure of consultation set out in the EA(S)R. This means that you will have adequate notice of any change in security requirements.

Question 7 – Do you agree with the proposal to refer to compliance with the standards set out in the document “Security Requirements for Radioactive Sources”?

#### Introduction of radioactive material into the environment or into organisms

- 4.28 We have reviewed the way that we regulate the introduction of radioactivity into the environment or into organisms that leave the Authorised Place to ensure that full environmental impact of these activities is appropriately considered and controlled.
- 4.29 Our duties in relation to these activities is to ensure that the public and environment are protected. In this respect, we believe that the greater risk is when these organisms, whether they are human patients or animals, leave the authorised place and have the potential to interact with members of the public.
- 4.30 Under the new regulatory regime, we propose to treat these activities in a similar way to how we regulate discharges of radioactive waste. Prior to application, you will need to carry out an assessment of public exposures and you will be required to maintain that assessment as part of your permit conditions. This will be a Standard Condition for introduction into organisms (see conditions in Section I) as these are common activities, e.g. medical and veterinary uses. We have not proposed any Standard Conditions for introduction into the environment as these are rare activities that do not merit the creation of Standard Conditions. Such activities will require bespoke conditions, which in practice are likely to be very similar to those in Section I.
- 4.31 Another change is that we will require that a suitable Radioactive Waste Adviser (RWA) is appointed in relation to these activities. In practice, an RWA would likely be involved anyway as it would be unusual for there not to be a disposal authorisation associated with an unsealed registration.

Question 8 – Do you foresee any problems with the proposal to treat these activities in the same way as an authorisation for radioactive waste? If so, please provide details?

#### Radioactive gaseous discharges outwith authorised outlets (section H.2)

- 4.32 The proposed Standard Condition on small quantities of gaseous releases (section G.5), replicates the provisions of the GBRs that deals with trivial quantities of gaseous releases that are often difficult or impracticable to control. This condition is quite limited in scope and only deals with containers of radioactive substances. There are others situation that may arise which are also difficult or impracticable to control, e.g. remediation of contaminated land or the demolition of a contaminated building. Therefore, we propose to provide a more flexible approach for those situations where it is not reasonably practicable to capture all radioactive gaseous emissions as set out in Standard Condition H.2.

- 4.33 This Standard Condition will only be included in those authorisations that have bespoke gaseous discharge limits. The Standard Condition only allows discharge via a route other than an authorised outlet where it is demonstrated that capturing the gaseous emissions for disposal via an authorised gaseous outlet does not represent best practicable means (BPM). The Standard Condition also requires that the gaseous discharge must not breach the authorised limit in the authorisation.

Question 9 – Do you foresee any issues with the proposed changes to radioactive discharges outwith authorised outlets? If so, please provide details?

#### Quarterly Notification Levels (QNL)

- 4.34 We currently set QNLs in authorisations for some nuclear licensed sites. We require the site to inform us if they exceed a QNL and provide a report on how discharges continue to represent BPM.
- 4.35 QNLs were intended to act as a trigger to inform us of when discharges may be increasing and could potentially threaten the annual discharge limit; there are no environmental impact if the QNL is exceeded. Since this requirement has been in place, we have not had any reports of a QNL being exceeded. We have reviewed the rationale behind QNLs and consider that nuclear sites should be monitoring their discharges closely enough that any adverse trend is picked up long before it gets close to the QNL. Any BPM justifications should be provided as they are required and not through an artificial level in the authorisation.
- 4.36 Therefore, we propose no longer setting QNLs in any authorisations.

#### Three-yearly prospective and retrospective dose assessment for non-human species

- 4.37 Nuclear authorisations currently require the authorised person to provide a prospective and retrospective dose assessment for non-human species every three years. We have reviewed this requirement and consider that it is not necessary to require a submission of such an assessment. The impact of radioactive discharges on non-human species is assessed as part of authorisation determination. An authorisation will not be issued unless the impact is acceptable.
- 4.38 However, it is important that the impact of radioactive discharges is kept under review, as there could be various changes in circumstances that cause the impact to change. Accordingly, Standard Condition H.1 requires that an assessment of public exposures and the impact on the environment resulting from discharges is maintained. These assessments will be subject to routine inspection.

Question 10 – Do you agree with the removal of the requirement to provide three-yearly assessments of the dose to non-human species?

## Waste management plan (section B.9)

- 4.39 We have included a Standard Condition requiring all authorised persons to prepare, maintain and implement a waste management plan. This condition formalises our existing expectation that an appropriate plan exists for the management of all radioactive substances that are present or will be generated throughout the lifetime of carrying out a radioactive substances activity.
- 4.40 For nuclear sites, we recognise that you already have, or are developing, comprehensive decommissioning plans and it is not our intention to require a separate suite of documents just to satisfy this requirement.
- 4.41 For the non-nuclear sector, we recognise that you may already have arrangements in place for contamination monitoring of facilities that you are no longer using. The use of these existing arrangements along with a list of contaminated items on the site should satisfy this requirement.
- 4.42 For sealed source users, we will require you to have and maintain a plan for the disposal of the sources at the end of life. We do not envisage the plan to include detailed costs but would encourage you to at least provide an indication in order to prevent unexpected costs at the time of disposal.

Question 11 – Do you foresee any problems with the requirement to prepare, maintain and implement a waste management plan? If so, please provide details.

Question 12 – Do you have any other comments on the Standard Conditions and guidance?