

Revised Proposals for a Future Exemptions Regime Under the Radioactive Substances Act 1993 and the Environmental Permitting Regulations 2011

Engagement document

11 August 2010

1. Introduction

Background

- 1.1 In June 2009 we (the Department of Energy and Climate Change, Welsh Assembly Government, Scottish Government and Department of the Environment in Northern Ireland – collectively referred to as ‘government’ in this paper) consulted on our “Proposals for a Future Exemptions Regime Under The Radioactive Substances Act 1993 and The Environmental Permitting Regulations 2010” (the Exemption Order(EO) review). The background to the review and the engagement process we have carried out to date are set out on the Department of Energy and Climate Change website at: <http://www.decc.gov.uk/en/content/cms/consultations/exemptions/exemptions.aspx>
- 1.2 The consultation raised a number of technical issues which we have now considered. In view of the number of issues raised by consultees and the technical nature of the changes made since that consultation, we believe that our stakeholders should be given the opportunity to comment on these updated proposals. The purpose of this paper is therefore to introduce the revised draft regulations for amendments to the Radioactive Substances Act 1993 (RSA93) and the new Exemption Order together with amendments to the Environmental Permitting Regulations 2010 (referred to as the ‘exemptions framework’).
- 1.3 Since the consultation in 2009 we have made changes to the technical content of the exemptions framework, however, the principles upon which it is based remain largely unchanged. Within these draft proposals, all materials and wastes are placed into one of three categories:
 - **Outside the scope of regulation**; that is, not defined as radioactive for the purposes of regulation.
 - **Within the scope of regulation**, but **conditionally exempted** from the need for prior permitting by reason of low risk.
 - **Within the scope of regulation**, and requiring prior permitting by the environmental regulators.
- 1.4 The review that we have undertaken relates to the first two bullet points, it has not altered the arrangements for permitting the use of radioactive materials and accumulation/disposal of radioactive wastes (other than to alter what falls into or out of this latter category).

Key issues

1.5 The main issues raised during the consultation (discussed in more detail in section 2) and which we have, in the main, addressed in our revised proposals (either via draft regulations or through guidance) are summarised here:

- How to account for background radioactivity when determining whether or not radioactive substances or articles are outside the scope of regulation.
- How to provide appropriate and proportionate regulation of naturally occurring radioactive substances including replacement of the Phosphatic Substances, Rare Earths Exemption Order.
- How to provide an appropriate replacement for the Substances of Low Activity Exemption Order.
- How to appropriately remove low risk aqueous liquids and gases from the scope of regulation or alternatively exempt them.
- How to avoid re-permitting of earlier permitted waste disposals i.e. 'double regulation'.
- How to include provisions for non-aqueous liquids.
- How to adequately incorporate specific provisions for holdings of sealed sources and other items, and waste disposal of these items, as covered by the current exemptions regime.
- Consideration of applying different concentration limits for exempting 'wet sludges' (RP122 Part 2) and recycling building rubble and scrap metal (RP113 and 89).

1.6 These issues were considered by a group comprising technical experts from Government, the environmental regulators, the Health Protection Agency (HPA), and external consultants. The group sought input from industry on specific technical matters where it was deemed necessary. In addition to the responses received from the 2009 consultation we have considered and incorporated, where appropriate, other proposals from expert representations and recommendations. These consequential changes are also outlined in section 2.

Implementation of the proposals

1.7 Since the 2009 consultation, RSA93 has been repealed and migrated into the Environmental Permitting Regulations 2010 in England and Wales (except for the exemption order provisions). The outcome of these proposals will therefore be incorporated directly into the Environmental Permitting Regulations 2011 (EPR2011) in England and Wales. In Scotland and Northern Ireland, RSA93 will be amended by regulations under the European Communities Act 1972 and their new Exemption Orders will be made at the same time. More information on the implementation of the EO

review across the UK can be found in section 3. Section 4 has further detail on the completion of the migration of RSA93 into the EPR2011.

1.8 Please note registration and authorisation under RSA93 and permitting under EPR are referred to as permitting in the rest of this paper.

Guidance

1.9 To assist users to understand these proposals, the draft Government guidance is considered in section 5, with the complete draft incorporated as an appendix to this engagement paper.

2. The Proposals

- 2.1 This section sets out the modified proposals and shows how we have addressed the key issues identified during the consultation. This document should be read in conjunction with the draft regulations and guidance.
- 2.2 In 2009, we consulted on an exemptions framework where all substances and articles containing radionuclides were classed as radioactive material or radioactive waste unless they were specifically outside the scope of regulation. In general, this approach was supported by consultees. However, when those proposals were updated to take account of amendments following the consultation, the legal drafting proved to be extremely complex. Therefore, in order to simplify the drafting and make the legislation easier to understand, it was decided that it was more appropriate to reverse the 2009 approach. As a result, in our updated exemptions framework, unless substances and articles are specifically brought into the scope of regulation, they are not radioactive. This is similar to the approach in the current legislation. It should be stressed that this change in drafting does not affect the underlying philosophy regarding what substances and articles are in and outside the scope of regulation.

Material and waste that is within the scope of regulation

- 2.3 The Regulations in Appendices 1-3 (for England and Wales, Scotland and Northern Ireland respectively) set out the proposals which determine what material and waste is within the scope and what falls outside the scope of regulation. These need to be read in conjunction with the draft Government guidance at Appendix 4.
- 2.4 The following paragraphs explain how some of the issues raised in the consultation (highlighted in section 1) have been resolved and incorporated into the provisions of the new exemptions framework.

Accounting for background activity in determining whether radioactive material/waste is within the scope of regulation

- 2.5 Our proposals in the 2009 consultation, did not explicitly specify how background radioactivity should be considered when deciding whether or not a substance is radioactive material or radioactive waste. We have addressed this in our current draft regulations and guidance as described below.
- 2.6 We propose to allow background values to be subtracted, where appropriate, when deciding whether or not a substance is radioactive material or radioactive waste. The approach differs for artificial and naturally occurring radionuclides. The proposed regulations make special provision for artificial background to be disregarded when deciding whether or not a substance is radioactive material or radioactive waste.
- 2.7 This issue is dealt with in paragraphs 4.17-4.19 of the draft guidance.

Removing from the scope of regulation certain activities dealing with naturally occurring radioactive materials and wastes

- 2.8 There was concern from consultees about how naturally occurring radioactive material (NORM) which is not exploited for its radioactive, fertile and fissile properties would be dealt with. The new provisions have resolved this in the following way.
- 2.9 All naturally occurring radionuclides which are not listed in the tables are out of scope of regulation. The values set out in Tables 1 and 2 in the proposed Schedule 1 to RSA 93 and EPR2011 do not include primordial radionuclides such as K-40. NORM which is not used for its radioactive, fertile or fissile properties shall only be subject to control where it cannot be disregarded from a radiation protection (of the public and the environment) point of view. To facilitate this, we propose that only specified NORM industrial activities will be subject to regulation; the specified activities are listed in Table 3 to Schedule 1 of RSA93 and in EPR2011. This list is based on Euratom and IAEA documents whilst taking account of specific UK circumstances. Any industrial activity not appearing on the list will not be subject to regulation.
- 2.10 If an activity is listed and substances used in or arising from it exceed the concentrations set out in Table 1 to Schedule 1 of RSA93 and EPR2011, the substance is considered to be within scope of regulation. These values have been adopted from RP122 part 2 and are based on a dose criterion of 300 microsieverts per year. The Euratom expert committee concluded that values for regulating natural sources cannot be derived on the basis of trivial risk, or dose; it would in general not be practicable to implement a control scheme to regulate to a level of 10 microsieverts per year which in reality is a small increment to the natural background, and is below the natural variability of radiation dose from place to place. Therefore, the 300 microsieverts per year criteria was selected as it is comparable to or smaller than regional variations in total effective dose from natural background¹
- 2.11 Naturally occurring radionuclides that are being exploited for their radioactive, fissile or fertile properties are regulated as though they are artificial radionuclides. Accordingly, a 10 microsieverts per year dose criterion has been used to derive the values in Table 2 to Schedule 1 of RSA93 and EPR 2011, which can be applied to remove such material and waste from the scope of regulation. Paragraphs 2.6-2.10 of the draft guidance deal with this issue.

Providing an appropriate replacement for the Substances of Low Activity Exemption Order (SoLA)

- 2.12 In the 2009 consultation, consultees were unclear whether the numerical levels for removing substances and articles from the scope of regulation (using limits from RP122) solely applied to material, and not waste. There was concern that there was no de-minimus level for radioactive waste comparable to that provided by SoLA. All waste containing radionuclides from some form of practice or activity would therefore be considered 'radioactive' and in turn, disposals of exempted waste would be volume limited, resulting in an increase in permitted wastes. The drafting has now been

¹ It should be noted that the average natural background from all sources in the UK is of the order of 2000 microsieverts per year, rising to several times this value in certain areas of the country.

amended to remove any ambiguity and makes it clear that these levels apply to both materials and wastes.

Providing appropriate levels to remove aqueous liquids from the scope of regulation

- 2.13 Consultees expressed the view that the drinking water standards were not appropriate to remove these liquids from the scope of regulation. This was because the values were derived using only the drinking water pathway for radiation dose, which was not necessarily the dominant pathway. It was also highlighted that drinking water standards are for intervention situations, and therefore not appropriate for practices, which would be the case for exemption levels. We agree with this view and have removed the drinking water standards from the proposals.
- 2.14 Further work on this aspect by the HPA has led to the development of discharge limits based on modelling which considers all pathways. However, HPA advice is to the effect that discharges at the limits need to be capped by a total volume limit. For this reason, we now believe that it is not appropriate to remove aqueous liquids from the scope of regulation altogether, but rather to employ the calculated limits as exemption levels. In this way, the total volume limit can be introduced as an exemption condition.
- 2.15 The position in relation to aqueous liquids associated with NORM industrial activities is different. We believe that such liquids should only be regulated where they cannot be disregarded from the radiation protection point of view, and have used the same criteria to remove them from regulation as for solid materials and wastes, i.e. less than 300 microsieverts per year. The HPA has developed both calculated and scaled Generalised Derived Limits (GDLs) based on the dose criterion of 300 microsieverts per year, which take into account several dose pathways (see Table 1 of Schedule 1 to RSA93 and EPR 2011).

Providing appropriate levels to remove gases from the scope of regulation

- 2.16 For the same reasons as set out above for aqueous liquids, we believe that it is appropriate to remove gases containing NORM radionuclides arising from NORM industrial activities from the scope of regulation. The HPA has also developed levels for gases containing NORM radionuclides from NORM industrial activities based on a dose criterion of 300 microsieverts per year; these are included in Table 1 of Schedule 1 to RSA93 and EPR.
- 2.17 It should also be noted, that although adventitious releases of gases remains within the scope of regulation, we propose that these are conditionally exempted.

Providing appropriate levels to remove short half-life substances from the scope of regulation

- 2.18 In the 2009 consultation there had only been the transfer of existing provisions to avoid regulating gaseous materials containing radionuclides with a half-life less than 100s. This provision has now been extended to apply to all media as there does not appear to be any feasible situation where these are likely to affect the public or environment.

Avoiding 'double regulation' of permitted waste disposals

2.19 Consultees expressed the view that any disposals which had previously been permitted should not be regulated further unless any subsequent, and originally unforeseen, natural process or human intervention (e.g. excavation and remediation) of the waste would result in significant increases in exposures to the public or the environment. We believe that there is insufficient justification to allow further regulation in cases where the resultant exposure could be deemed insignificant. When waste disposals are permitted under relevant legislation, then all reasonably foreseeable pathways for human exposure should be included in the assessment which supports the application. For instance, for a liquid discharge which results in the contamination of river sediments, which may then be dredged and removed, it is not necessary to permit the dredging at a later date; the consequences of the original discharge should have been taken into account in the initial permit. The only exception to this situation is when a process takes place which was both not envisaged in the original assessment, and which may have the effect of increasing a radiation dose.

2.20 Substances containing concentrations of radionuclides less than those set out in Table 2 of Schedule 1 of RSA93 and EPR2011 are out of scope of regulation irrespective of where the radioactivity originated. For substances containing radioactivity exceeding these concentrations as a result of disposals special provisions have been created.

2.21 Paragraphs 2.31-2.34 of the draft guidance deal with this issue.

Provision for non-aqueous liquids

2.22 The 2009 proposals did not account for any disposals of non-aqueous liquids (provisions which currently exist within SoLA for certain organic liquids containing carbon-14 and tritium); these have now been incorporated.

2.23 For such things as liquid metals (e.g. mercury) and organic liquids which may contain radionuclides, these new proposals are to the effect that the solid values in Tables 1 and 2 of Schedule 1 of RSA93 and EPR2011 can be applied in cases where the liquids are essentially treated in the same way as a solid; that is, not disposed of to water courses where the drinking water pathway to a human radiation dose may occur. These provisions also apply to concentrated mineral acids. In all other circumstances, they should be treated in the same way as aqueous liquids.

2.24 Paragraph 2.36 of the draft guidance deals with this issue.

Provision for contaminated items

2.25 The 2009 proposals contained a provision to unconditionally exempt contaminated materials. We have reconsidered this and now believe that it would be better to remove contaminated items from being classed as "radioactive materials", but only where they remain on the premises where they were contaminated. For example, contaminated pipe work (such as drainage plumbing or offshore tubulars), equipment or clothing would not be considered radioactive material whilst it remains in use on the premises. However, if that pipe work, equipment or clothing is removed from the premises for use elsewhere or for cleaning then it would be considered to be radioactive material. If the

items in question become waste they are radioactive waste, whether they are on or off the premises where they were contaminated.

2.26 Paragraphs 2.27–2.30 of the draft guidance deal with this issue.

Material and waste that is exempted from full regulation

2.27 The Regulations in Appendices 1, 5 and 6 (for England and Wales, Scotland and Northern Ireland respectively) set out the proposals for the exemption provisions. These need to be read in conjunction with the draft Government guidance at Appendix 4. Please note there has been a restructuring of the RSA93 Exemption Order to assist readability and usability since the 2009 consultation.

2.28 A table comparing existing exemption requirements with those proposed in the draft regulations is included in the guidance to help users see at a glance how the proposals will affect them.

2.29 The following paragraphs focus on the major issues highlighted in section 1.

Providing exemption provisions for aqueous liquids

2.30 As mentioned earlier in this paper, consultees felt that it was inappropriate to remove aqueous liquids containing radionuclides resulting from a practice from the scope of regulation without having any controls in place. For radionuclides in aqueous solution resulting from a practice, it is proposed to conditionally exempt them, rather than remove from the scope of regulation. There are two specific amendments to the 2009 consultation proposals:

- A new table containing levels for aqueous liquid waste disposal conditional exemptions (Table 4 in the Exemption Order/Table 6 in EPR2011).
- Specific aqueous liquid waste disposals intended to apply to small-scale disposals from medical establishments and laboratories have been included and revisions made to the human excreta provisions contained in Table 3 of the Exemption Order/Table 5 in EPR2011.

Providing exemption provisions for gases

2.31 As mentioned earlier, it was felt necessary to provide an exemption for incidental gaseous releases. Our current proposal is to provide for small-scale (e.g. laboratory fume hood) gaseous disposals, limited by reference to the Basic Safety Standards Directive Annex 1 values. Work is under way to see if this approach is workable.

Providing adequate replacement of the Phosphatic Substances, Rare Earths, etc Exemption Order

2.32 Some consultees did not feel that there was an adequate replacement for the Phosphatic Substances, Rare Earths, etc. Exemption Order, which has been utilised by certain industries for many years. It was felt that without an adequate replacement, the

regulatory burden would increase significantly for these industries for the disposal of higher volume NORM wastes. This has been dealt with in these proposals in two ways:

- By setting out criteria for disposals of solid NORM waste in terms of activity, based on a generic radiological impact assessment carried out by the HPA².
- By including a new provision for case-specific disposal of such wastes, based on bespoke radiological impact assessments to be carried out by the person intending to dispose (where the criteria mentioned above cannot be met).

Considering other potential new specific exemption provisions

2.33 There was a request to apply different concentration limits for exemptions when considering 'wet sludges' (RP122 Part 2) and for the recycling of building rubble and scrap metal (RP113 and RP89 respectively). We believe this to be beyond the scope of this review because of the complex nature of the current work. However, the potential incorporation of such provisions will remain open for future consideration.

Adequately incorporating specific provisions for holdings of sealed sources and other items and their disposals

2.34 The consultation responses brought to light a number of gaps, overlaps and inconsistencies in the 2009 proposals. Where appropriate, these have been incorporated into an amended Table 2 and Table 3 of the Exemption Order/Tables 4 and 5 of EPR2011 in the current proposals, but with consolidation wherever possible. Essentially, existing exemptions provisions have been transferred into the proposed new framework wherever it has been deemed acceptable based on risk considerations.

Further changes to exemptions

2.35 Exemption provisions for, and conditions relating to, the accumulation and disposal of radioactive waste have been separated into two sections, one for 'accumulation' and one for 'disposal' to allow for a clearer understanding of the appropriate conditions for each of these instances as it is not deemed appropriate to have the same conditions for both circumstances. Paragraphs 3.40-3.52 of the draft guidance deal with this issue.

2.36 The 2009 proposals attempted to use common conditions for the disposal of solid and aqueous liquid wastes but this was considered inappropriate as each media should have its own set of conditions (with an element of overlap). These have now been separated into three sets of conditions, one for solids, another for aqueous liquids and a third for NORM wastes.

2.37 Conditions for 'storage in transit' of radioactive materials and radioactive wastes have been separated out from other conditions into one set specific to this practice as it is believed that the previous set of conditions were too complicated and not always appropriate for the circumstances. Paragraphs 3.58-3.61 of the draft guidance deal with this issue.

² HPA (2010). HPA-CRCE-001 - Conditional Exemption Limits for NORM Wastes.

- 2.38 The relationship between outside scope of regulation, exemption and permitting has been more clearly set out, mainly in section 4 of the draft Government guidance to assist users in understanding how the provisions work together.
- 2.39 Exemption provisions for mobile sources have been revised, and in some instances are now more restrictive than those set out in the 2009 proposals. We believe that the provisions did not provide sufficient clarity; these are, however, no more restrictive than as under the current exemptions regime. Paragraphs 3.15-3.18 of the draft guidance deal with this issue.

3. Implementation of the new exemptions regime across the UK

- 3.1 Since the 2009 consultation, RSA93 has been repealed and migrated into the Environmental Permitting Regulations 2010 in England and Wales (except for the exemption order provisions). The outcome of these proposals will therefore be incorporated directly into EPR2011 in England and Wales.
- 3.2 In Scotland and Northern Ireland, RSA93 will be amended by regulations under the European Communities Act 1972 and new Exemption Orders will be made at the same time.
- 3.3 When the new regulations come into force, we expect that a number of users of radioactive materials, or disposers of radioactive waste, will be removed from the regulatory regime, either because their activities fall outside the scope of the regulations, or the material/waste becomes exempt. There is, however, likely to be a small number of users and disposers which may, conversely, come within the regulatory regime for the first time. Transitional arrangements will be put in place through the legislation to allow a reasonable length of time (6 months) for those persons who will require a permit for the first time to make an application for such a permit and to allow those persons using an exemption to ensure that they are complying with the new conditions.

4. Migration of remaining provisions of RSA 93 into EPR 10 in England and Wales

- 4.1 The draft Regulations in Appendix 1 include proposals to migrate the remaining sections of the RSA93 into the EPR2011 in **England and Wales only**.
- 4.2 With the completion of the exemption order review it will be possible to repeal the remainder of the RSA93 in England and Wales. The only remaining section of the RSA93 which has independent substantive effect is s.40 which provides that radioactivity in materials and waste is to be disregarded for the purpose of several other regimes. This section is now replicated in the new part 7 of Schedule 23 of the EPR2011.
- 4.3 The draft Regulations also include some amendments to EPR 2010. These include:
- Addition of a definition of nuclear site licence to Schedule 23 for clarity.
 - A clarified regulation 12(3) to make clear that a person receiving waste for the purpose of disposal does not need a permit for the receipt or disposal of that waste, where the person passing the waste to them has a permit which allows both of these things.

5. Guidance supporting the exemptions regime

- 5.1 The revised exemptions framework will be supported by guidance from Government to the regulators and from the regulators to those people who are regulated. It is the aim to have consistent principles across the UK (wherever possible), although it will need to take into account differences in legal implementation throughout the UK. It is proposed that the Government guidance should be published approximately three months prior to implementation of the new regime and regulators guidance to coincide with the coming into force of the new regime.
- 5.2 Subsequent to the 2009 consultation, there has not been a significant change to the guidance template but the following refinements have been incorporated:
- The scope of regulation has been explained in more detail and reflects amendments to provisions.
 - The relationship between outside scope of regulation, exemption and permitting has been more clearly set out, with additivity of holdings clarified further.
 - There have been presentational refinements to improve the ease of use, and the main document only includes specific detail to improve the user's understanding of the proposals and philosophy behind these; additional material has been annexed or removed.
- 5.3 The draft Government guidance can be found at Appendix 4.

Appendices

Appendix 1	The Environmental Permitting (England and Wales) (Amendment) (No2) Regulations 2011 (Draft)
Appendix 2	The Radioactive Substances Act 1993 (Amendment) (Scotland) Regulations 2011 (Draft)
Appendix 3	The Radioactive Substances Act 1993 (Amendment) (Northern Ireland) Regulations 2011 (Draft)
Appendix 4	Draft Government Guidance
Appendix 5	The Radioactive Substances Exemption (Scotland) Order 2011 (Draft)
Appendix 6	The Radioactive Substances Exemption (Northern Ireland) Order 2011 (Draft)
Appendix 7	Response Form

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