Department for Business, Energy & Industrial Strategy

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REVISED REQUIREMENTS FOR RADIOLOGICAL PROTECTION

Regulation of Public Exposures and the Justification of Practices

October 2017

REVISED REQUIREMENTS FOR RADIOLOGICAL PROTECTION

Regulation of Public Exposures and the Justification of Practices

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Any enquiries regarding this publication should be sent to us at [insert contact for department].

Introduction

Introductory text

This consultation sets out our proposals for transposition of the 2013 Euratom Basic Safety Standards Directive (2013 BSSD) in relation to public radiation exposures. This consultation is part of a series of consultations covering different areas of the Directive.

The 2013 BSSD lays down minimum standards for medical, occupational and public radiation exposures. It also lays down requirements for emergency exposure situations. These four exposure types are managed in UK legislation in a number of different regulatory regimes. The corresponding legislation is in some cases reserved to the UK parliament and in other cases is the responsibility of the Devolved Administrations for Scotland, Wales and Northern Ireland.

This consultation covers the 2013 BSSD provisions regarding:

- **Planned public exposure situations**, in relation to authorised activities involving radioactive substances, for example for power generation or healthcare;
- **Existing public exposure situations**, including the management of legacy radioactive contaminated land and exposure to naturally occurring radon gas in homes; and
- The **justification of practices involving ionising radiation**, which relates to the process for determining whether the benefits of a practice justify the potential detriment.

This document describes:

- **Current regulatory arrangements** in the UK for keeping and use of radioactive substances, the management of radioactive contaminated land and the justification of practices;
- **Proposals to amend the current regulatory arrangements** in order to ensure that the UK is compliant with the requirements 2013 BSSD;
- **Proposals to reduce unnecessary burdens on industry (“better regulation”)**
- **Amendments and additions to existing legislation necessary to deliver these proposals**

The Health and Safety Executive has consulted on occupational exposure aspects of the 2013 BSSD and the Department of Health has consulted on the medical exposure aspects. The Department for Business Energy and Industrial Strategy, jointly with the Health and Safety Executive and the Ministry of Defence, are also consulting separately on proposals for transposition of the requirements in relation to Emergency Preparedness and Response. We welcome views from all interested parties. Information on how to respond to this consultation is outlined in the ‘General information’ below.

Contents

General information

Purpose of this consultation

This consultation invites views on proposed changes to legislation by the UK Government and by the Devolved Administrations for Scotland, Wales and Northern Ireland. This consultation document is published by the Department for Business, Energy and Industrial Strategy (BEIS) on their behalf. The proposed changes are designed to implement the requirements of the 2013 BSSD.

Issued: 5th October 2017

Respond by: 15th November 2017

Enquiries to:
Nuclear Decommissioning and Radioactive Waste Policy Team,
Department for Business, Energy & Industrial Strategy,
Level 3 Victoria 1,
1 Victoria Street,
London, SW1H 0ET

Email: BSSDPublicExposures@beis.gov.uk

Territorial extent:
The UK Government has worked together with the Devolved Administrations to develop the proposals in this consultation document. Many of the proposals relate to legislation which is devolved in all parts of the UK and responsibility for making the requisite changes to legislation rests variously with the UK Government and with the Devolved Administrations. The UK Government and the Devolved Administrations will work together to analyse the responses to this consultation and also to prepare a Government response.

How to respond

Your response will be most useful if it is framed in direct response to the questions posed, though further comments and evidence are also welcome.

This consultation is being made available on the GOV.UK website and the BEIS Citizen Space website. Responses can be returned using the questionnaire on the Citizen Space website (preferable) or by email or post. In order to help us analyse responses, please provide details of your organisation/industry.

Please send your comments on the proposals in this paper and on the accompanying draft impact assessment to the following address:

Send your comments by email to: BSSDPublicExposures@beis.gov.uk

or by post to:
Alexander Hartley
Nuclear Decommissioning and Radioactive Waste Policy Team,
Department for Business, Energy & Industrial Strategy,
Level 3 Victoria 1,
1 Victoria Street,
London, SW1H 0ET

Respondents in Scotland should also send their response to:

Send your comments by email to: Charles.StewartRoper@gov.scot

or by post to:
Charles Stewart Roper
Environmental Quality Division
Scottish Government
Area 3H South
Victoria Quay
Edinburgh
EH6 6QQ

Respondents in Wales should also send their response to:

Send your comments by email to: EQR@gov.wales

or by post to:
Environment and Quality Regulation
Welsh Government
Crown Buildings
Cathays Park
Cardiff
CF10 3NQ

Respondents in Northern Ireland should also send their response to:

Send your comments by email to: wslpr@daera-ni.gov.uk

or by post to:
Janice Harris
Environmental Policy Division
DAERA
Klondyke Building
Cromac Ave
Belfast BT7 2JA

Additional copies:
You may make copies of this document without seeking permission. An electronic version can be found on the GOV.UK website or on the BEIS Citizen Space website.

Confidentiality and data protection

Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information legislation.

If you want information that you provide to be treated as confidential please say so clearly in writing when you send your response to the consultation. It would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded by us as a confidentiality request.

We will summarise all responses and place this summary on the GOV.UK website and the BEIS Citizen Space website. This summary will include a list of names of organisations that responded but not people's personal names, addresses or other contact details.

Quality assurance

This consultation has been carried out in accordance with the Government's Consultation Principles.

If you have any complaints about the consultation process (as opposed to comments about the issues which are the subject of the consultation) please address them to:

Email: enquiries@beis.gov.uk

Public sector equality duty

The Government is committed to equal treatment and equality of opportunity. The Public Sector Equality Duty (PSED) is a key lever for ensuring that public bodies take into account equality when conducting their day-to-day work in shaping policy and delivering services. Under section 149, public bodies are required to have regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations when making policy decisions.

In developing the proposals contained in this consultation, the Government has taken into account the PSED as set out in the Equality Act 2010. The Government does not consider that its proposals have an unjustifiable adverse impact on any protected groups, but would welcome your views.

Executive Summary

The 2013 Basic Safety Standards Directive (2013 BSSD) consolidates and updates existing Euratom radiation safety legislation. The new Directive takes account of developments in the recommendations and standards issued by the International Commission on Radiological Protection and the International Atomic Energy Agency. Its scope includes medical, occupational and public radiation exposures and it provides for three different types of exposure situation:

- **Existing public exposure situations**, including the management of legacy radioactive contaminated land and exposure to naturally occurring radon gas in homes;
- **Planned exposure situations**, in relation to authorised activities involving radioactive substances, for example for power generation or healthcare; and
- **Emergency exposure situations** that could arise for example following an accident.

This consultation focuses on **public radiation exposures in planned and existing exposure situations** and also includes proposals to revise the existing regulatory framework for the **justification of practices involving ionising radiation**.

The UK already has a mature and effective framework for radiological protection and for the justification of practices involving ionising radiation. In most cases the requirements of the Directive are already implemented by existing legislation, so transposition of the Directive into UK legislation can therefore be achieved largely within the framework of existing UK legislation. In most cases only minor amendments are required to UK legislation, for example to update references that are now out of date. Some articles of the 2013 BSSD require more substantial amendments or introduce new requirements that do not currently exist in UK legislation. It is these transposition measures that are the subject of this consultation.

The regulatory regimes for managing planned and existing exposures in the UK are devolved, but the UK and Devolved Governments have sought to maintain common standards as far as possible. The proposals in this consultation have therefore been prepared jointly by BEIS, the Department of Health, the Department for Communities and Local Government and the Devolved Administrations to enable the changes to be made to the respective regimes on a consistent basis.

The regulatory framework for justification of practices provides a process for determining whether, taking account of the potential benefits of the practice and the potential health detriment, the practice is justified. The regulatory bodies, such as the environment agencies, only authorise practices that are considered to be justified.

Implementation of the 2013 BSSD ensures that the UK can meet its commitment to comply with its obligations as Member State of the EU and the Euratom Treaty prior to exiting the EU. Our primary approach to transposition is to ensure that the **proposed measures continue to strengthen and streamline the UK's arrangements for radiological protection of the**

public and are as proportionate and efficient as possible. We have identified a number of opportunities to streamline and clarify existing legislation to ensure that the required standard of protection is achieved more efficiently. The environmental and economic benefits associated with these “better regulation” measures are also detailed in the draft Impact Assessment that accompanies this consultation. By further strengthening the UK’s framework for radiological protection the measures proposed will also maintain public confidence in the arrangements for enabling radioactive substances to continue to be used safely for nuclear power, healthcare and many other beneficial applications.

Our policy approach is also driven by the aim of ensuring the UK maintains its position as an international leader in radiological safety. The 2013 BSSD requirements are based largely on standards and recommendations issued by the International Atomic Energy Agency and other international bodies, which the UK supports.

The UK has benefited from more than 60 years of clean and safe nuclear-generated electricity. All of our nuclear and radiological sites and the transport of radiological material are independently regulated to ensure they are safe, secure and environmentally sound.

We look forward to receiving comments and additional evidence from consultees which we will use to inform the preparation of a final Impact Assessment and implementing legislation to bring the measures into effect.

Abbreviations

Abbreviation	Definition
1996 BSSD	The 1996 Basic Safety Standards Directive
2013 BSSD	The 2013 Basic Safety Standards Directive
Bq/ Becquerel	The SI derived unit of radioactivity
BSSD Regulations	Ionising Radiation (Basic Safety Standards)(Miscellaneous Provisions) Regulations
DAs	Devolved Administrations
EAs	The Environment Agencies, made up of Natural Resources Wales, Scottish Environment Protection Agency, Northern Ireland Environment Agency and the Environment Agency.
EPR 2016	Environmental Permitting (England and Wales) Regulations 2016
HASS Regulations	High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005
HSE	Health and Safety Executive
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
IRR	Ionising Radiations Regulations 1999
JoPIIR Regulations	The Justification of Practices Involving Ionising Radiation Regulations 2004

Abbreviation	Definition
LA	Local Authority
NI	Northern Ireland
NORM	Naturally Occurring Radioactive Material
NRW	Natural Resources Wales
ONR	Office for Nuclear Regulation
PHE	Public Health England
RCL	Radioactive Contaminated Land
RCL Regimes	Radioactive Contaminated Land Regimes (made up of the Environmental Protection Act (c.43.) 1990, Radioactive Contaminated Land Regulations and statutory guidance for each Devolved Administration)
REPPIR	Radiation (Emergency Preparedness and Public Information) Regulations 2001
RSA	Radioactive Substances Act 1993 (applicable in Scotland and Northern Ireland)
Sv/ Sievert	The SI derived unit of ionising radiation dose

Catalogue of consultation questions

We welcome views on any of the issues set out in this paper, particularly responses to the following questions:

Consultation Questions

1.	**High-activity sealed sources** (see 3.26 for background information) What is a reasonable interval frequency for reporting of HASS based on turnover of sources etc.? Please evidence your answer.
2.	**Clearance and exemption** (see 3.55-3.56 for background information) Do you agree with our proposals for NORM waste? If not, why?
3.	**Geothermal energy** (see 3.57-3.60 for background information) What would be the impact of making the geothermal industry subject to regulation for radioactive substances?
4.	**Legacy sites contaminated with radium** (see 3.63-3.66 for background information) Do you agree that applying the NORM industrial activities “out of scope” values to waste arising from the remediation of radium contaminated legacy sites is proportionate? If not please detail why.
5.	**Legacy sites contaminated with radium** (see 3.63-3.66 for background information) In order to capture “legacy” contaminated sites only, we propose to limit the new provision by reference to the date the contamination occurred. Do you have a view as to the appropriate date to use? Do you have any other ideas on how to define “legacy radium contamination”?
6.	**Regulatory regime for liquid wastes** (see pages 35-36 for background information) Do you agree that the definition of relevant liquid needs to be refined? Please provide specific examples of liquids that you believe should be included in this definition along with the reasoning why.

Consultation Questions

7.	**Regulatory regime for liquid wastes** (see pages 35-36 for background information) Do you agree that it is appropriate to undertake a review of the policy and scientific issues associated with the regulation of liquids containing low levels of radioactivity?
8.	**Regulatory regime for liquid wastes** (see pages 35-36 for background information) Do you have any views on the scope of this review and the factors and information it should take into account?
9.	**Potential exemption for flaring or venting of gaseous radioactive waste arising from the NORM Industrial Activity of the production of oil and gas** (see page 37 for background information) Do you agree that the introduction of such an exemption would be proportionate where flaring or venting is the only radioactive substances activity taking place in the production of oil and gas? Do you have any evidence that you believe has a bearing on the proposed introduction of such an exemption?
10.	**Reference Levels** (see 3.71-3.73 for background information) Do you think our approach to establish Reference Levels is reasonable and effective? If not, why?
11.	**Land contaminated as a result of a radiological emergency** (see 3.90-3.95 for background information) Do you have any views on the proposed approach to transposing the requirements of Articles 73, 100-102 in relation to land contaminated as a result of a radiological emergency? Please evidence your answer.
12.	**General** Are there any other impacts, positive or negative, of the proposed changes which we need to be aware of? If yes please detail in full for each situation, what the current practice is, the impact of the change and any financial information to support this. Do you think that this consultation has identified all of the opportunities and risks relevant to the transposition of the BSSD? Please specify any that you think are missing.

Part 1: Background

Part 1 of the consultation outlines the background to the Basic Safety Standards Directive (2013/59/Euratom) and the scope of this consultation.

The Basic Safety Standards Directive

1.1 The 2013 BSSD sets out standards for protection against the dangers arising from exposure to ionising radiation. It must be transposed into national legislation by 6th February 2018. BEIS is responsible for coordinating and reporting the UK transposition to the European Commission and the Member States.

1.2 The 2013 BSSD consolidates and updates existing European legislation in line with guidance and advice prepared by the International Commission on Radiological Protection (ICRP)[1] and the International Basic Safety Standards published by the International Atomic Energy Agency (IAEA).[2]

1.3 The new Directive builds on a lengthy history of European and UK work in the area of radiological protection. The first Euratom Basic Safety Standards Directive came into force in 1959 and has been revised several times. The 2013 BSSD consolidates, updates and supersedes the following:

- Basic Safety Standards Directive 96/29/Euratom (1996 BSSD)
- Medical Exposures Directive 97/43/Euratom
- Outside Workers Directive 90/641Euratom
- Control of high-activity sealed radioactive sources and orphan sources 2003/122/Euratom (HASS Directive)
- Public Information Directive 89/618/Euratom
- Radon, Commission Recommendation 90/143/Euratom

1.4 The 2013 BSSD covers different exposure types and situations. It covers planned public, medical and occupational radiation exposure situations (for example in relation to the authorised use of a radioactive substance or the accumulation or management of radioactive waste) and existing public exposure situations (for example in relation to naturally occurring radon gas or sites contaminated by historic industrial activities involving radioactive substances). The Directive also covers emergency exposure situations.

[1] http://www.icrp.org/
[2] IAEA General Safety Requirements (Part 3), *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*, 2014

The EU referendum and Euratom

1.5 On 29 March 2017 the United Kingdom Government formally notified the European Commission of its intention to withdraw from Euratom. Leaving Euratom is a result of the decision to leave the EU as they are uniquely legally joined. The UK supports Euratom and will want to see continuity of co-operation and standards.

1.6 While the UK remains a member of the EU and of Euratom, we are legally obliged to implement Directives, and respect the laws and obligations required by that membership. We will continue to implement the 2013 BSSD. This will bring us in line with revisions to the corresponding international safety requirements published by the IAEA.

1.7 The UK remains committed to the highest standards of nuclear safety and support for the industry and will continue to apply international standards on nuclear safeguards. Our aim is clear: we want to maintain our mutually successful civil nuclear co-operation with Euratom and the rest of the world.

Scope of this Consultation

1.8 The 2013 BSSD is broad in scope. Work to transpose the Directive has been taken forward by a cross-government programme board and proposals are being consulted on in a series of consultation packages. The Health and Safety Executive has consulted on occupational exposure aspects of the Directive and the Department of Health has consulted on medical aspects. The Department for Transport will consult in due course on occupational exposure of air and space crew. BEIS, jointly with the Health and Safety Executive and the Ministry of Defence, are also consulting on articles relating to Emergency Preparedness & Response.

1.9 This consultation document covers:

- **Public radiation exposures**
    - in planned exposure situations, which concern public exposures that may arise as a result of the authorised keeping and use or disposal of radioactive substances
    - in existing exposure situations, which include public exposures arising from the presence of historic contamination or past industrial practices or as a result of naturally occurring radioactivity
- **Justification**
    - The regulatory framework for enabling the determination of whether an existing or proposed practice involving ionising radiation is justified, taking into account the expected benefits and the potential detriment to health. Only practices that are justified may be authorised by the regulatory bodies, such as the environment agencies

1.10 Many of the proposals in this consultation relate to legislation which is devolved in all parts of the UK. Government worked together with the Devolved Administrations to prepare the consultation proposals in this document.

1.11 A draft Impact Assessment has also been prepared and is published alongside this document. The draft Impact Assessment identifies any likely impact on current practice as a result of the measures proposed. Only amendments that require a change to legislation have been included in this document.

1.12 Following this consultation we will be modifying RCL statutory guidance which will be prepared in light of responses received. We will then carry out a further consultation on this statutory guidance.

1.13 Relevant existing legislation is listed in Table 1.

Rationale

1.14 Where possible, we will identify “better regulation” measures, while ensuring that the UK does not go beyond the minimum requirements of the Directive, and that high standards of risk control are maintained. The UK’s preferred option when transposing a Directive, where possible, is to use a “copy-out” approach. This is where the implementing legislation adopts the same or similar wording as that of the 2013 BSSD or where it cross-refers to the relevant Directive provision. This approach to transposition follows the UK Government’s Guiding Principles for EU Legislation.

Part 2: Relevant legislation

Part 2 outlines the legislation covered in the consultation and its territorial extent.

2.1 The Directives being consolidated into the 2013 BSSD (listed in 1.7) have been implemented through various regulations administered by different government departments and, in some cases, by different UK administrations for England, Wales, Northern Ireland and Scotland.

2.2 Most of the legislative provisions needed to transpose the 2013 BSSD will consist of amendments to the following:

- Environmental Permitting (England and Wales) Regulations 2016 and equivalent legislation for Scotland and Northern Ireland. BEIS is responsible in England for legislation relating to the environmental permitting of radioactive substances and Welsh Government is responsible for this area in Wales. The Scottish Government and the Department of Agriculture, Environment & Rural Affairs are responsible for similar legislation in Scotland and Northern Ireland respectively
- Radioactive Contaminated Land (Modification of Enactments) (England) Regulations 2006 and equivalent legislation for Wales, Scotland and Northern Ireland
- Radioactive Contaminated Land statutory guidance
- The Justification of Practices Involving Ionising Radiation Regulations are UK-wide and provide the framework in which justification decisions are made. Under the Regulations all justification decisions are taken by Government, either the relevant Secretary of State or the relevant Devolved Administration

2.3 In addition, we propose to make a new statutory instrument to transpose various provisions of the 2013 BSSD that do not fit within existing regulatory frameworks. The working title for this instrument is the Ionising Radiation (Basic Safety Standards)(Miscellaneous Provisions) Regulations (referred to in this document as the BSSD Regulations).

2.4 The table below identifies the legislation relevant to this consultation

Table 1

Legislation Name	Information about Legislation	Extent
The Justification of Practices Involving Ionising Radiation Regulations 2004[3]	These Regulations create the framework for making justification decisions on types/classes of practice involving exposure to ionising radiation, including the designation of Justifying Authorities	England, Wales, Scotland and Northern Ireland
The Environmental Protection Act 1990	This Act provides for a system of pollution control for the disposal of wastes to land, water and air. It covers a wide range of subjects, including contaminated land and radioactive contaminated land.	England, Wales and Scotland
The Radioactive Substances Act 1993	This Act is concerned with the control of radioactive material and disposal of radioactive waste, with the purpose of protecting human health and the environment from radioactive pollution.	Scotland[4] and Northern Ireland
The Regulatory Reform (Scotland) Act 2014	This Act provides for Regulations to be made for a new integrated authorisation framework for radioactive substances, water environment, waste and industrial pollution control.	Scotland
The Environmental Permitting (England and Wales) Regulations 2016[5]	These Regulations provide a consolidated system of environmental permitting, including the regulation of radioactive substances activities and high-activity sealed sources (HASS).	England and Wales

[3] A marked-up draft of the proposed changes to these regulations will be published on the consultation webpage [https://beisgovuk.citizenspace.com/civil-nuclear-resilience/bssd-public-exposures]

[4] The Scottish Government is currently consulting on proposals for regulations under the Regulatory Reform (Scotland) Act that will replace the radioactive substances regime under RSA with a single authorisation framework. For more information see [http://www.gov.scot/Publications/2017/01/5439]

[5] A marked-up draft version of the proposed changes to these regulations will be published on the consultation webpage [https://beisgovuk.citizenspace.com/civil-nuclear-resilience/bssd-public-exposures]

Legislation Name	Information about Legislation	Extent
The Radioactive Substances (Basic Safety Standards) Regulations (Northern Ireland) 2003	These Regulations place duties on the Chief Inspector with regard to the disposal of radioactive waste and amend the Radioactive Substances Act to provide exemptions from authorisation for clocks and watches.	Northern Ireland
The Radioactive Contaminated Land (Modification of Enactments) (England) Regulations 2006: No 1379	These Regulations modify the existing contaminated land regime contained in Part 2A of the Environmental Protection Act 1990, so it can also be applied in relation to harm attributable to radioactivity.	England
The Radioactive Contaminated Land Regulations (Northern Ireland) 2006	These Regulations modify the existing contaminated land regime contained in Part 2A of the Environmental Protection Act 1990, so it can also be applied in relation to harm attributable to radioactivity.	Northern Ireland
The Radioactive Contaminated Land (Scotland) Regulations 2007	These Regulations modify the existing contaminated land regime contained in Part 2A of the Environmental Protection Act 1990, so it can also be applied in relation to harm attributable to radioactivity.	Scotland
The Radioactive Contaminated Land (Modification of Enactments) (Wales) Regulations 2006	These Regulations modify the existing contaminated land regime contained in Part 2A of the Environmental Protection Act 1990, so it can also be applied in relation to harm attributable to radioactivity.	Wales
The High-activity Sealed Radioactive Sources and Orphan Sources Regulations 2005	The purpose of these Regulations is to prevent the exposure of workers and members of the public from inadequate control of high-activity sealed sources (HASS), and to ensure the provision of	Northern Ireland and Scotland

Legislation Name	Information about Legislation	Extent
	adequate security measures.	
The Radioactive Substances (Fees and Charges) Scheme (Northern Ireland) 2012	This Scheme prescribes fees and charges under section 43 of the Radioactive Substances Act 1993.	Northern Ireland
The Radioactive Substances Exemption (Northern Ireland) Order 2011	This Order provides for a system of exemptions from authorisation under the Radioactive Substances Act.	Northern Ireland
The Radioactive Substances Exemption (Scotland) Order 2011	This Order provides for a system of exemptions from authorisation under the Radioactive Substances Act 1993.	Scotland
The Radioactive Substances (Basic Safety Standards)(Scotland) Direction 2000	This Direction requires the Scottish Environment Protection Agency to exercise its regulatory powers under the RSA to transpose the 1996 BSSD.	Scotland
The HASS (Scotland) Directions 2005	These Directions require the Scottish Environment Protection Agency to carry out specified functions in relation to transposition of the HASS Directive	Scotland

Part 3: Proposals for transposition

Part 3 outlines the changes introduced by the 2013 BSSD and details the proposals for transposition.

3.1 The UK has a mature existing framework for radiological protection and the justification of practices involving ionising radiation. As a result existing UK legislation is, in most cases, already fully compliant with the requirements of the 2013 BSSD. Changes proposed to transpose the 2013 BSSD are therefore incremental, working within the existing framework of regulatory regimes for different exposure groups and types. The following areas are those where we have identified a need for change:

- Dose constraints and dose limits
- Orphan sources & high-activity sealed sources
- Clearance and exemption
- Reference levels for public exposure
- Contaminated land and existing exposures
- Public exposure to radon
- Justification of practices involving ionising radiation
- Building materials

Dose constraints and dose limits

3.2 This section covers Articles 12, 13 and 66 of the 2013 BSSD. Radiation dose limits and dose constraints are not a new concept to radiological protection and many of the requirements of these articles are already covered by existing legislation in the UK.

3.3 A dose limit is the total radiation dose to an individual that should not be exceeded[6]. The UK currently uses a limit for effective dose[7] of 1 millisievert (mSv) a year for all authorised practices (man-made sources excluding medical exposures). This compares with an average UK radiation dose (data for 2010) of about 2.7 mSv per year from all sources including natural, man-made, and medical exposures.

3.4 A dose constraint is the maximum dose to an individual that might arise from a particular source[8] . Dose constraints are part of the system of radiological protection and are set at a lower level than dose limits to recognise that members of the public may be exposed to more than one source of radiation. The UK has set two types of dose constraint in legislation for public exposure. The annual dose constraint is

[6] Article 4, paragraph 23, of the 2013 BSSD
[7] Article 4 paragraph 25 of the 2013 BSSD
[8] Article 4 paragraph 22 of the 2013 BSSD

currently set at 0.3 mSv for radioactive discharges from a single source and 0.5 mSv for radioactive discharges from a single site. These constraints provide for an upper limit on optimisation of exposure from individual facilities. Dose constraints are intended to ensure that total exposure from all authorised practices is kept below the public dose limit.

Dose limits for public exposure (Article 12, 2013 BSSD)

3.5 The requirements of Article 12 to set dose limits for equivalent[9] and effective doses for members of the public are already transposed in UK legislation. However, the new Article 12 removes a relaxation that had been included in the 1996 BSSD.

3.6 Specifically, the 2013 BSSD has removed the provision that, in special circumstances, a higher effective dose may be authorised in a single year, provided that the average over 5 consecutive years does not exceed 1 mSv per year.

3.7 The removal of this provision will not impact on UK practice as UK legislation did not make provision for these types of special circumstances. Article 12 will be transposed in England and Wales by updating the existing references in the EPR 2016, the RSA and the HASS Regulations and this update will be reflected in new Scottish regulations.

Estimation of the effective and equivalent dose (Article 13, 2013 BSSD)

3.8 Article 13 requires the use of "the appropriate standard values and relationships" in the estimation of effective and equivalent doses. The 2013 BSSD recommends, in its preamble, the use of dose coefficients published in ICRP Publication 119, or more recent updates based upon the underlying values laid down in ICRP Publication 103.

3.9 Additionally, for external radiation, Article 13 requires the use of the operational quantities defined in Section 2.3 ICRP Publication 116.

3.10 The use of the ICRP publication values in estimating effective and equivalent doses, although new, does not represent a significant change from current practice. We intend to transpose this change by amending EPR 2016 to require the regulator to observe the requirements of Article 13 when estimating effective and equivalent dose. This update will be reflected in the RSA, the HASS Regulations and Scottish regulations.

Estimation of doses to members of the public (Article 66, 2013 BSSD)

3.11 Article 66 requires Member States to make arrangements for the estimation of doses to the public, from authorised practices, and to identify and specify practices where an assessment is required. The Article also imposes requirements as to the means of collecting the information, the types of estimates and the records kept.

3.12 The Environment Agency has the necessary arrangements in place already. We intend to update the existing reference in EPR 2016; this will require the regulators to have regard to Article 66 when exercising their functions when estimating public doses. Corresponding updates to legislation will be made for Northern Ireland and Scotland.

[9] Article 4 paragraph 33 of the 2013 BSSD

Orphan sources and high-activity sealed sources

3.13 This section covers Articles 89 and 94 and parts of Annex III and Article 4 of the 2013 BSSD. These Articles consolidate and update the requirements of the 2003 HASS Directive.

Definition of orphan sources (Article 4, 2013 BSSD)

3.14 Article 4 of the 2013 BSSD consolidates all the definitions used in the Directive. Some definitions have changed and will require an update to definitions in UK legislation.

3.15 The definition of an orphan source has changed and now includes unsealed sources. In UK legislation orphan source applies only to sealed sources. The 2013 BSSD definition is: “a radioactive source which is neither exempted nor under regulatory control, e.g. because it has never been under regulatory control or because it has been abandoned, lost, misplaced, stolen or otherwise transferred without proper authorisation.”

3.16 The definition of an orphan source will be updated in the EPR 2016, the RSA and the HASS Regulations and this update will be reflected in new Scottish regulations.

Recovery, management, control and disposal of orphan sources (Article 94, 2013 BSSD)

3.17 Article 94 places requirements on Member States for the recovery, management, control and disposal of orphan sources. This Article broadly replicates Article 9.4 of the HASS Directive.

3.18 The main changes are:

- (94.1) the requirement is now to “control” as well as to “recover” orphan sources; and
- (94.2) a requirement has been added “to ensure that campaigns are organised, as appropriate, to recover orphan sources left behind from past practices”

3.19 The addition of the requirement to “control” orphan sources will not affect any administrative arrangements. We propose to amend EPR 2016, the RSA and the HASS Regulations to include reference to “control”. This update will be reflected in new Scottish regulations.

3.20 Source recovery campaigns have taken place in the past but there is no requirement for this in current legislation. Therefore Article 94.2 will be transposed by taking a copy out approach into the BSSD Regulations, placing this duty on the responsible Minister to ensure that arrangements are made, as appropriate, to recover orphan sources left behind from past practices. Government will continue to rely on the EAs to advise when campaigns need to be organised.

Activity values for defining high-activity sealed sources (D-values) (Annex III, 2013 BSSD)

3.21 Current UK legislation uses a threshold for each radionuclide in a source, above which defines a High Activity Sealed Source (HASS), and a much lower threshold below which defines the point where a source ceases to be a HASS. This follows the approach in the 1996 BSSD which defined HASS based on their activity at the time of manufacture. HASS sources could take many tens of years to decay to the point where the HASS requirements cease to apply.

3.22 The 2013 BSSD introduces a change to the definition of a high-activity source by having a single threshold above which a source is HASS and below which it is not. It sets the HASS threshold, based on current activity, using D-values set out in Annex III of the 2013 BSSD. D-values are defined in the IAEA publication 'Dangerous quantities of radioactive material (D-values).

3.23 A source ceases to be HASS if it decays below the D-value, but must continue to be regulated as a sealed source.

3.24 The D-values for some radionuclides are now set at a higher activity value than the existing UK threshold for HASS. The result is that sources containing these radionuclides will no longer be defined as HASS, thereby decreasing the costs associated with the requirements for these sealed sources. For a few radionuclides the D-value is lower, and so sources containing these radionuclides will come into the HASS regime for the first time.

3.25 The change in HASS thresholds will be transposed by amending the reference to Annex III of the 2013 BSSD in EPR and the HASS Regulations, and this will be reflected in new Scottish regulations.

Record keeping by the undertaking (Article 89, 2013 BSSD)

3.26 The 2013 BSSD has removed the requirement on users for annual re-reporting of information on HASS, though there is still a requirement to provide records "at intervals to be determined by Member States." We are interested to hear views as to what would be an appropriate interval, but we think that EAs and permit holders will generally welcome this change.

Question 1

What is a reasonable interval frequency for reporting of HASS based on turnover of sources etc.?

Sources reference updates

3.27 The existing EPR 2016 and HASS regulations refer to specific articles of the HASS Directive which will require updating to refer to the equivalent revised articles in 2013 BSSD. An overview of the relevant provisions of the 2013 BSSD is set out below in Table 2 via amendments to the EPR 2016 for England and Wales (noting where appropriate the equivalent provisions of the HASS Directive). Appropriate analogous amendments will be made to legislation in Northern Ireland and Scotland to update the relevant references to the 2013 BSSD.

Table 2

Article in 2013 BSSD	Equivalent Article of HASS Directive	Relevant existing legislation coverage	Policy change and proposal
Article 85	***No equivalent provision***	*N/A*	Article 85 is a new requirement. It does not represent a policy change and its provisions are already met in practice by the regulators throughout the UK. We propose to amend the legislation to require regulators to meet the requirements of Article 85.
Article 86.1 and 86.2	***No equivalent provision***	*N/A*	Article 86.1 and 86.2 is a new requirement. It does not represent a policy change and its provisions are already met in practice by the regulators throughout the UK. We propose to amend the legislation to require regulators to meet the requirements of Article 86.
Article 86.3	***Article 4***	*Schedule 23, Part 5, section 3, para 5 (1)(b)*	Article 4 of the HASS Directive has been replaced by Article 86.3 of the 2013 BSSD. There is no practical difference between the obligations imposed by these two Articles. We propose to amend relevant references in legislation to refer to Article 86.
Article 86.4	***Article 6(d)***		Article 6(d) of the HASS Directive has been replaced by Article 86.4 of the 2013 BSSD. There is no practical difference between the obligations imposed by these two Articles. We propose to amend relevant references in legislation to refer to Article 86.
Article 87 and Article 88	***Article 3.2 and 3.3***	*Schedule 23, Part 5, section 3, para 5 (1)(a)*	Article 3.2 and 3.3 of the HASS Directive has been replaced by Article 87 and Article 88 of the 2013 BSSD. There are minor changes to the obligations imposed by Article 87(a). However the new Articles do not introduce any new obligations. We propose to amend the legislation to meet the requirements of Article 87 and Article 88.
Article 91.1 and 91.2	***Article 6 and 7***	*Schedule 23, Part 5, section 3, para 5 (1)(d)*	Articles 6 and 7 of the HASS Directive have been replaced by Article 91.1 and 91.2 of the 2013 BSSD. There is no practical difference between these Articles. We propose to amend relevant references in legislation to refer to Articles 91.
Article 90	***Article 5.3***	*Schedule 23, Part 5, section*	Articles 5.3 & 5.4 of the HASS Directive have been replaced by Article 90 of the 2013 BSSD. Article 90 does not introduce any new

Article in 2013 BSSD	Equivalent Article of HASS Directive	Relevant existing legislation coverage	Policy change and proposal
	and 5.4	*3, para 6.*	obligations. We propose to amend relevant references in legislation to refer to Article 90.
Article 104	***Article 12***	*Schedule 23 Part 5* *para 6(b)*	In relation to radioactive sources, there is already a system in place that covers Article 104 inspection requirement. However current legislation needs amending to reflect the updated provisions of 2013 BSSD. This amendment does not represent a change in legal obligations being imposed.

Broken Gaseous Tritium Light Devices

3.28 Gaseous Tritium Light Devices (GTLDs) are sealed sources containing tritium. They are convenient light sources where no power is available and are in widespread use.

3.29 These devices can sometimes break, but doses from broken GTLDs are very low for realistic scenarios and therefore there is no negative impact on radiation protection from disposing broken GTLDs to landfill.[10]

3.30 An intact GTLD up to 20 GBq is already exempt from the disposal requirements in current regulations. The effect of this is that an intact source up to 20 GBq can be disposed to landfill. However users have to dispose of broken GTLDs as radioactive waste, which can be costly, for little or no benefit from a radiation protection perspective.

3.31 As a "better regulation" measure we propose to exempt disposal of broken GTLDs up to 20 GBq so that they can be disposed of to landfill. We propose to do this by amending the EPR 2016 in relation to England and Wales. Analogous amendments will be made in Scotland and Northern Ireland.

Loss of radioactive material – international cooperation

3.32 This section deals with proposals to transpose obligations set out in Article 99.3, which concerns the arrangements for liaison with relevant international partners in relation to the loss, theft or discovery of radioactive material.

3.33 The rest of Article 99 will be covered by a separate BEIS consultation covering the other emergency exposures requirements in relation to the civil nuclear industry. See Part 1

[10] Mobbs, S., Barraclough, I., Napier, I., Carey, A., Paynter, R., and Harvey, M., 1998. A Review of the Use and Disposal of Gaseous Tritium Light Devices. Environment Agency Report.

for further details on the other consultation processes that are being carried out as part of the UK transposition of the 2013 BSSD.

Loss, theft or discovery of radioactive material (Article 99.3 2013 BSSD)

3.34 The UK already has robust arrangements in place for the regulation of materials relevant to this Article and for reporting and investigating incidents involving loss, theft or discovery as appropriate. The relevant regulatory bodies in the UK for incidents involving loss, theft and discovery of radioactive material are:

- The Office for Nuclear Regulation, which regulates nuclear sites and the transport of radioactive material
- The Health and Safety Executive, which regulates work activities involving radiation except on nuclear sites
- The EAs, which regulate the keeping and use of radioactive material, other than on nuclear sites, and radioactive waste

3.35 Article 99.3 requires Member States to, in summary, share information and cooperate with relevant international partners regarding loss, theft or discovery of radioactive material including radioactive sources. The UK already complies with these requirements. With respect to incidents that occur on civil nuclear sites or which involve the transportation of radioactive material, responsibility for relevant information sharing and cooperation with international partners is delegated to the Office for Nuclear Regulation. With respect to other incidents, where the relevant regulatory body is the HSE or one of the EAs, the relevant government department will share the information and ensure cooperation as necessary with international partners, although there are no legal obligations currently in place dealing with these arrangements.

3.36 We propose to transpose this legal requirement by creating a new duty[11] on the responsible Minister to ensure that relevant information regarding the incidents covered by Article 99.3 are shared with the appropriate countries and relevant international organisations, and to ensure cooperation as required with those parties. This approach provides flexibility for current arrangements to be retained or amended in future.

System of enforcement – inspections

3.37 This section covers Article 104 of the 2013 BSSD and details the requirements the UK's inspection system must meet. This consultation deals with inspections of radioactive substances activities to verify compliance with regulatory requirements. The EAs have an established, mature and robust system of inspection, so the changes needed to comply with the 2013 BSSD are minor and make statutory provision for practices already in place.

[11] BSSD Regulations

3.38 We propose to update EPR 2016 to reflect these specific new duties, referencing the existing provision in EPR 2016 that requires the EAs periodically to inspect regulated facilities. Analogous amendments will be made in Scotland.

Clearance and exemption

3.39 This section covers Articles 26 and 30 of the 2013 BSSD. Exemption and clearance are well established concepts in the framework of radiological protection and are part of the graded approach, which is the term used in the 2013 BSSD to describe proportionate regulation. The four tiers of regulation are: clearances/ exemptions, notification, registration and licensing. These tiers are progressively more proscriptive, in proportion to the amount of radiation and risk involved:

- Clearance levels are activity concentration values at or below which materials arising from any practice subject to notification or authorisation[12] may be released from regulatory control;
- Exemption levels are activity concentration values or total activity values at or below which a radiation source is not subject to notification or authorisation

3.40 Radioactive substances regulation in the UK requires that, unless an activity is either “out of scope” or exempt from permitting, an environmental permit is required (a permit equates to “registration” or “licensing” in 2013 BSSD terms). There is currently no “notification only” tier.

3.41 The 2013 BSSD incorporates a new set of values for the purpose of clearance and exemption of radioactive materials. These values are taken from the IAEA safety standards series RS-G 1.7[13] and are the default values for clearance and exemption. We propose to transpose these values by updating the relevant tables in UK legislation.

3.42 Like the 1996 BSSD, the 2013 BSSD provides some flexibility (set out in Articles 26 and 30) in particular circumstances for Member States to set their own exemption and clearance values provided that they are in keeping with the general exemption and clearance criteria in Annex VII. This flexibility is provided in recognition that there can be a high variability in local circumstances and the values produced by a single generic model will not always be appropriate. We propose to use this flexibility to set different values in the specific cases identified in the following paragraphs. These proposals build on our existing suite of exemption and clearance provisions.

3.43 In UK radioactive substances regulations the 2013 BSSD concepts of clearance and exemption are not transposed separately but are rolled together into two different concepts, of “out of scope” and “exempt” activities. “Out of scope” describes substances which are not considered to be radioactive for the purposes of radioactive substances regulations. If an activity is in scope, it may nonetheless be exempt from the

[12] 2013 BSSD terms for registration and licencing
[13] International Atomic Energy Agency (2004). Application of the Concepts of Exclusion, Exemption and Clearance Safety Guide. Vienna, RS-G-1.7

requirement to hold a permit (see "Guidance on the Scope of and Exemptions from the Radioactive Substances Legislation in the UK[14]").

3.44 The values currently used for some of the "out of scope" and exempt provisions in UK legislation are recommended by the Commission on Radiation Protection No 122.[15]

3.45 Public Health England (PHE) was commissioned by Government to undertake a review of the potential impact to the UK from the implementation of the new 2013 BSSD values for the exemption and clearance of radioactive substances[16]. PHE has advised that adoption of the new value for certain radionuclides is not necessary for radiological protection purposes, but would be likely to result in substantial additional environmental impacts due to the excess generation and treatment of radioactive wastes. These impacts also bring with them economic costs. Proportionate transposition of the clearance and exemption provisions in the BSSD will help reduce the amount of waste that needs to be managed as radioactive waste, thus reducing the environmental impacts associated with the transport, treatment and disposal as radioactive waste in specialised permitted facilities. There will also be a reduction in the costs that would otherwise be incurred by such specialised treatment and disposal.

Carbon-14 and caesium-137

3.46 The new carbon-14 and caesium-137 values are lower than the "out of scope" values in existing UK radioactive substances regulations. PHE has advised that the adoption of the new values has little or no benefit from a radiation protection perspective when compared to the existing values, and would result in significant adverse environmental impacts associated with excess generation and treatment of radioactive wastes. The economic cost of managing this additional waste is estimated to be £2.1 billion over the long term.

3.47 We will use the flexibility in the 2013 BSSD to allow the higher "out of scope" values in existing UK radioactive substances legislation for carbon-14 and caesium-137 to continue to be used in the waste management regime. This will reduce the amount of waste that would otherwise be categorised as radioactive, so will minimise the environmental and economic impacts.

Mixing of radioactive and non-radioactive materials (Article 30.4, 2013 BSSD)

3.48 There is a new requirement for Member States to prohibit the deliberate dilution of radioactive materials for the purpose of clearing them from regulatory control. The mixing of materials that takes place in normal operations where radioactivity is not a consideration is not subject to this prohibition. The EAs may authorise, in specific circumstances, the mixing of radioactive and non-radioactive materials for the purposes of re-use or recycling. We propose to introduce a general requirement on EAs to observe the requirements of this article.

[14] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69357/pb13624-rsl-guidance-110914.pdf

[15] European Commission (2000). Practical Use of the Concepts of Clearance and Exemption - Part I. Luxembourg, Radiation Protection 122

[16] Public Health England, May 2016, "Impact of changes to exemption and clearance values for specific radionuclides: Review and Industry Survey."

3.49 UK radioactive substances regulations prohibit the dilution of waste in certain circumstances in order to be exempt, but not dilution in order to take material or waste "out of scope".

3.50 We propose to transpose this requirement by adding a new provision so that if a person has deliberately diluted a substance or article with the intention bringing it below the "out of scope" values, then it will be in scope of the regulations.

3.51 There are already specific non-dilution provisions in relation to exemptions for solid radioactive waste and aqueous radioactive waste. These provisions appear as conditions to the exemptions. However there is currently no similar provision for NORM waste. This was an oversight so a non-dilution provision will be added to the exemption for NORM waste.

NORM waste

3.52 Radioactive materials which occur naturally are known as Naturally Occurring Radioactive Material (NORM). NORM waste results from activities such as the refining of titanium dioxide and extraction of china clay, as well as the production of oil and gas. 2013 BSSD provides a default value of 1 Bq/g for such waste.

3.53 PHE has advised that, in relation to NORM waste[17], the UK Government uses the flexibilities described above to reduce any unnecessarily restrictive limits that are not required for radiological protection purposes, while adhering to the exemption and clearance criteria in the 2013 BSSD.

3.54 We therefore propose to change the current "out of scope" values for some NORM radionuclides in solid waste by increasing all of the values for NORM industrial activities that are currently set at 0.5 Bq/g to 1 Bq/g, as required by the BSSD, and leaving the remaining values unchanged.

NORM waste disposal exemption

3.55 The 2013 BSSD allows flexibility to increase EPR 2016 exemption concentration values for certain types of NORM waste containing lead-210+ or polonium-210. Relaxation of NORM waste exemption concentration values for these radionuclides could produce significant environmental benefits associated with less generation and treatment of radioactive wastes whilst still meeting the radiological protection criteria. Subsequent economic savings for the gas exploration and production sector and the steel industry are expected to be significant.

3.56 We propose to expand the definition of NORM waste by reference to a concentration of up to 100 or 200 Bq/g of lead-210+ or polonium-210 as appropriate (and to retain a value of 5 or 10 Bq g^{-1} for other NORM radionuclides as appropriate). However, the annual activity limit (Bq/yr) for lead-210+ and polonium-210 for the process of incineration will be maintained at the current value.

Question 2

Do you agree with the proposals for NORM waste? If not, why?

[17] Public Health England, May 2016, "Impact of changes to exemption and clearance values for specific radionuclides: Review and Industry Survey."

Geothermal Energy Production (Article 23, 2013 BSSD)

3.57 The 2013 BSSD specifically requires that industrial sectors involving NORM are regulated, and a list of such sectors is included in Annex VI. “Geothermal energy production” is the only NORM industrial activity listed that isn’t captured in current regulations. Therefore we propose to add ‘geothermal energy production’ to the list of NORM industrial activities in the existing regulations.

3.58 It is not known at this stage what effect this change will have on the industry, however there are likely to be financial costs associated with the disposal of this newly-designated NORM waste. As this industry in the UK is small and developing, any additional costs could be significant. Therefore we need to better understand the impact this could have on this highly innovative but still emergent low carbon technology.

3.59 By way of example, the oil and gas industry currently manages its NORM waste in two ways: it is either re-injected into the ground, as part of the “produced water” from the facility (it is not classed as waste in this case), or it is consigned to permitted waste treatment facilities.

3.60 If the waste produced from geothermal energy production is above “out of scope” levels then a permit will be required. If the industry can show that the waste produced is “out of scope” then no permit will be required.

Question 3

What would be the impact of making the geothermal industry subject to regulation for radioactive substances as above?

Monitoring of radioactive discharges (Article 67, 2013 BSSD)

3.61 Article 67 is a new requirement for the 2013 BSSD:

- Article 67.1 requires the undertaking responsible for “practices where a discharge authorisation is granted” to monitor “appropriately” or, where appropriate, evaluate the radioactive airborne or liquid discharges into the environment in normal operation and to report the results to the competent authority. The availability of the option to evaluate rather than monitor is important, as monitoring is inappropriate and disproportionate at many non-nuclear sites.
- Article 67.2 requires the undertaking responsible for a nuclear power reactor or reprocessing plant to monitor radioactive discharges and report them in accordance with standardised information.[18]

3.62 We propose amending the EPR 2016 to impose a duty on the regulator to impose conditions requiring environmental permit holders to monitor and report discharges. Appropriate amendments will be made in Scotland and Northern Ireland.

Remediation of legacy sites contaminated with radium that was used for its radioactive properties.

3.63 Across the UK there are a number of sites that are contaminated with radium as a result of historic activities. Those activities include radium luminising, the management of luminesced items (e.g. aircraft breaking yards) and the manufacture of radioactive

[18] http://ec.europa.eu/energy/sites/ener/files/documents/2004_2_en.pdf

sources containing radium. These historic activities were either not subject to any regulation or subject to lesser standards than would be required today.

3.64 The current “out of scope” value in UK legislation for radium-226 which has been processed for its radioactive properties, as is the case in the historic activities mentioned above, is 0.01 Bq/g. This value is very low and is less than natural background levels of radium-226 typically found in the UK.

3.65 The low “out of scope” value may result in a perceived need to remove radioactivity from contaminated sites to below natural background levels. Any soil and other materials removed from such land that has radioactivity concentration of radium-226 above the “out of scope” value must then be managed and regulated as radioactive waste despite its negligible environmental and public health impact.

3.66 Changes to the regulatory regime for historic radium contamination are not required to implement the 2013 BSSD. However, we consider that the current “out of scope” value for radium-226 is creating a disproportionate burden on those who remediate land that has historically been contaminated with radium. Therefore, as a “better regulation” measure, we propose to apply the NORM industrial activities out-of-scope values to Ra-226 and any associated progeny present in amounts not exceeding those which could be present through the decay of Ra-226. We propose to define such sites carefully to ensure that the provision does not apply to any undertaking that is currently using or processing any natural radionuclide for its radioactive, fissile or fertile properties.

Question 4

Do you agree that applying the NORM industrial activities “out of scope” values to waste arising from the remediation of radium contaminated legacy sites is proportionate? If not please detail why.

Question 5

In order to capture “legacy” contaminated sites only, we propose to limit the new provision by reference to the date the contamination occurred. Do you have a view as to the appropriate date to use? Do you have any other ideas on how to define “legacy radium contamination”?

Regulatory regime for liquid wastes

Changes to the regulatory regime for liquid waste are not required to implement the 2013 BSSD. However, industry has suggested that “better regulation” changes could be made in relation to liquid waste that is, or may be, contaminated with very low levels of radioactivity. Such liquid wastes typically include waste derived from rainwater, groundwater, grey-water etc.

The radioactive substances regulations class the majority of aqueous liquids containing artificial radionuclides as radioactive material or radioactive waste. Unlike solids, no “out of scope” values are provided for such liquids so they are subject to regulation even at very low radionuclide concentrations. For non-aqueous liquids and certain aqueous liquids that have specified hazardous properties (defined as “relevant liquids”) the solid “out of scope” values can be used. This is because they

are treated in a similar manner to solids as the non-radioactive properties of these liquids prevent them from being discharged to water. The regulatory regime includes exemptions that allow liquids with low levels of radionuclides to be discharged without a permit but these exemptions cannot be used by any person that already holds a permit in relation to liquid radioactive waste discharges as the legislation precludes it.

Suggestions put forward by industry include allowing permit holders to be able to make use of the current liquid exemption, changing the definition of “relevant liquid” to expand the types of liquid that this provision applies to and providing “out of scope” values for aqueous liquids. Government has considered these suggestions carefully and proposes the following.

The arrangements regarding who can and cannot use the liquid exemption remain appropriate. However, we propose improving our guidance to make it clearer that equivalent provisions to those in the liquid exemption can be included in permits.

Government is open to revising the definition of relevant liquids so that it applies to liquids that cannot be discharged to the rivers, sea and sewer etc. In order to take this forward, we need specific examples of liquids that cannot be discharged to the water environment but are excluded from the current definition of relevant liquid. Any supporting information including radiological impacts and cost implications for industry and for regulation would be helpful in explaining why this change is thought to be necessary.

The introduction of “out of scope” values for aqueous liquids would be a significant change to the regulatory regime. The scientific and policy issues associated with making such a change are complex and it has not been possible to fully consider all of these issues at this time. Therefore, in order to ensure that the UK’s high standards of radiological and environmental protection are maintained, it is not currently proposed to introduce “out of scope” values for aqueous liquids. Rather it is proposed that a comprehensive review of the scientific and policy issues associated with the regulatory regime for liquid waste is undertaken to determine if it is appropriate to have aqueous liquid “out of scope” values. Government would welcome any views on the scope of this review and any factors or information that need to be taken into account.

Question 6

Do you agree that the definition of relevant liquid needs to be refined? Please provide specific examples of liquids that you believe should be included in this definition along with the reasoning why.

Question 7

Do you agree that it is appropriate to undertake a review of the policy and scientific issues associated with the regulation of liquids containing low levels of radioactivity?

Question 8

Do you have any views on the scope of this review and the factors and information it should take into account?

Potential exemption for flaring or venting of gaseous radioactive waste arising from the NORM industrial activity of the production of oil and gas

The accumulation and disposal of radioactive waste from the NORM industrial activity of the production of oil and gas is permitted / authorised where appropriate by the EAs. In some cases the only radioactive substances activity taking place is the venting or flaring of trivial amounts of gaseous waste. Changes to the regulatory regime for gaseous waste are not required to implement the 2013 BSSD. However, given the negligible radiological impact of such activity we propose that a proportionate approach for these cases would be to make them subject to a conditional exemption (i.e. exemption subject to compliance with certain conditions) rather than to require specific permitting.

Question 9

Do you agree that the introduction of such an exemption would be proportionate where flaring or venting is the only radioactive substances activity taking place in the production of oil and gas? Do you have any evidence that you believe has a bearing on the proposed introduction of such an exemption?

Radiation protection experts

Radiation protection experts (Articles 68, 79 & 82, 2013 BSSD)

3.67 The 2013 BSSD sets out the requirements for radiation protection experts. Article 68 imposes an obligation on Member States to require businesses to undertake certain tasks, and to consult a radiation protection expert. Article 79 requires that recognition arrangements are in place for radiation protection experts. Article 82 lists the areas on which radiation protection experts must, where relevant, give advice.

3.68 These requirements for radiation protection experts (both Radiation Protection Advisers and Radioactive Waste Advisers) are met throughout the UK in practice, but to transpose the 2013 BSSD legislative provisions may be needed to reflect current arrangements. Therefore we propose to make any necessary changes to legislation to cover the requirements for Articles 68, 79 and 82.

Reference levels for public exposure

3.69 This section covers Article 7 of the 2013 BSSD, which introduces a new requirement to establish reference levels. For a given exposure situation, a reference level is a dose or activity concentration above which it is judged inappropriate to allow exposures to occur. Reference levels relate to the exposure of individuals from a single source (e.g. contamination of the environment). They provide a guideline, rather than an absolute limit that must not be exceeded, and so perform the role of informing optimisation

decisions about the types of protection actions that may be appropriate in different situations. They can be viewed as a tool for supporting the practical implementation of the optimisation principle and ensuring greater clarity for all relevant stakeholders.

3.70 The concept of reference levels as used in 2013 BSSD was developed by the ICRP to aid the optimisation of protection strategies in emergency and existing exposure situations. This consultation document focuses on and describes only the use of reference levels in relation to existing exposure situations. Reference levels in emergency exposure situations will be dealt with in the separate Emergency Preparedness & Response consultation and will not be discussed further here.

Reference levels (Article 7, 2013 BSSD)

3.71 The 2013 BSSD has introduced a new requirement that Member States must set reference levels for existing exposure situations. Optimisation of protection must give priority to exposures above the reference level and continue to be implemented below it. The 2013 BSSD recognises that the values chosen for reference levels will depend on the type of exposure situation. The choice of reference levels should take into account radiological protection requirements and any relevant criteria relating to wider social implications. For public exposure, guidance on setting reference levels is set out in Annex I of the 2013 BSSD. In the case of existing exposure situations involving exposure to radon, the reference levels must be set in terms of radon activity concentration in air as specified in Article 74 for members of the public.

3.72 We propose to commission PHE to produce practical guidance for Local Authorities/ decision makers on the setting and use of reference levels for existing exposure situations (where not covered by the RCL regimes).

3.73 We propose to transpose the new requirements as follows:

- For existing exposures arising from contaminated land resulting from past activities we propose to align the RCL concept of the, 3 mSv/y “harm threshold” and equivalent dose criteria with that of reference levels as required by the 2013 BSSD. In addition the RCL regimes already embed the concepts of justification and optimisation through the establishment and use of reference levels.

- For existing exposures arising from contaminated land as a result of an emergency incident which has been declared ended, we propose to take into account the 1 – 20 mSv/y range recommended in Annex 1 of the 2013 BSSD and the guidance on the standard of remediation in the RCL regimes. The process of setting a target reference level will be described in practical guidance (“the umbrella guidance”) to be produced by PHE. We propose that the duty to set reference levels for this existing exposure situation will be covered through the transposition of Article 73.1 (see paragraph 3.77 below).

- For existing exposure situations involving exposure to radon in dwellings, a reference level of 200 Bq/m^3 is already used in practice. The duty to set reference levels for this existing exposure situation is covered through the transposition of Article 74 (see paragraph 3.104 below). This will be backed up by the umbrella guidance to be produced by PHE on various aspects of the establishment and use

of reference levels for existing exposures (referencing the national UK Radon Action Plan, see paragraph 3.101 below).

- For existing exposure situations involving exposure to gamma radiation from building materials in dwellings, it is proposed to impose a new duty[19] on the responsible Minister to ensure that the reference levels are set. The 1-20 mSv/y reference level value range for existing exposures will be used in practice and this will be backed up by the umbrella guidance.

- For existing exposures resulting from commodities that are retrospectively found to incorporate, or be contaminated with, artificial or naturally occurring radionuclides, it is proposed to impose a duty[20] on the responsible Minister to ensure that the reference levels are set. The 1-20 mSv/y reference level value range for existing exposures will be used in practice and this will be backed up by the umbrella guidance.

Question 10
Are you satisfied that our approach to establish reference levels is reasonable and effective? If not, why not?

Existing exposures

3.74 This section covers Articles 73, 100, 101 and 102 of the 2013 BSSD. Existing exposures arising from indoor exposure to radon and thoron are covered in the section "Public exposure to radon" (see below). This section addresses all other existing exposure situations:

- Situation 1: existing exposures arising from land contaminated as a result of a past activity or past work activity

- Situation 2: existing exposures that arise from land contaminated as a result of a potential future emergency, after the emergency situation has been declared ended

- Situation 3: indoor public exposure to gamma radiation from building materials already incorporated into buildings or parts of buildings

- Situation 4: public exposure to commodities (excluding food, animal feeding stuffs and drinking water) that are retrospectively found to incorporate, or be contaminated with, artificial or naturally occurring radionuclides

[19] BSSD Regulations
[20] Ibid.

3.75 In the remainder of this section we summarise the requirements of each Article and then explain how we plan to meet these requirements for each situation listed above.

3.76 Following this consultation we will be modifying RCL statutory guidance which will be prepared in light of responses received. We will then carry out a further consultation on this statutory guidance.

Contaminated areas – optimised protection strategies (Article 73.1, 2013 BSSD)

3.77 Article 73.1 introduces obligations regarding the management of areas contaminated as a result of past activities or a radiological emergency - Member States' optimised protection strategies for such areas must include, where applicable:

- Objectives, including long-term goals pursued by the strategy and corresponding reference levels (as detailed above reference levels for public exposures to existing exposures should take the 2013 BSSD Annex I levels into account)
- Delineation of the affected areas and identification of the affected members of the public
- Consideration of the need for and extent of protective measures to be applied to the affected areas and members of the public
- Consideration of the need to prevent or control access to the affected areas, or to impose restrictions on living conditions in these areas
- Assessment of the exposure of different groups in the population and assessment of the means available to individuals for controlling their own exposure

Contaminated areas – establishing normal living conditions (Article 73.2, 2013 BSSD)

3.78 Article 73.2 relates primarily to the unlikely event that a future radiological emergency results in areas with long-lasting contamination. Where a Member State has decided that it is appropriate to allow habitation and a resumption of social and economic activities in such areas arrangements must be put for the ongoing control of the exposure situation. The ultimate aim is to establish living conditions that can be considered as normal. The arrangements must include the following:

- Establishment of appropriate reference levels
- Establishment of an infrastructure to support continuing self-help protective measures in the affected areas, such as information provision, advice and monitoring
- If appropriate, remediation measures
- If appropriate, delineated areas

Strategies for existing exposure situations (Article 100, 101 and 102, 2013 BSSD)

3.79 Articles 100, 101 and 102 cover strategies for managing existing exposure situations. These national strategies must ensure the appropriate management of existing

exposure situations in line with the level of risk that a given exposure situation poses and the effectiveness of protective measures available.

3.80 Article 100.1 introduces a new requirement: where there is indication or evidence of an existing exposure that cannot be disregarded from a radiation protection point of view, Member States must ensure that measures are taken to identify and evaluate the exposure and determine any associated public exposures arising from it. Annex XVII to the 2013 BSSD provides a list of existing exposure situations that should be taken into account.

3.81 Article 101 requires strategies to be established for the management of existing exposures in line with identified risks and the effectiveness of protective measures. Each strategy must include objectives and appropriate reference levels.

3.82 Article 102 relates to the implementation of strategies for the management of existing exposure situations. Member States must:

- Assign responsibilities for the implementation of strategies for the management of existing exposures, ensuring appropriate coordination between relevant parties in the implementation of remedial and protective measures;
- Optimise the form, scale and duration of all protective measures considered for the implementation of a strategy;
- Assess the distribution of doses that has resulted from the implementation of a strategy. Further efforts must be considered with the aim of optimising protection and reducing any exposures that are still above the reference level;
- Regularly carry out the following actions:
    - Evaluate the available remedial and protective measures for achieving the objectives and the efficiency of planned and implemented measures
    - Provide information to exposed populations on the potential health risks and on the available means for reducing their exposure
    - Provide guidance for the management of exposures at individual or local level

Land contaminated as a result of a past activity or past work activity (Situation 1)

3.83 Existing exposures arising from land contaminated as a result of a past activity or past work activity are covered by the RCL regimes: Environment Protection Act 1990, the Radioactive Contaminated Land Regulations and Radioactive Contaminated Land Statutory Guidance. The RCL regulations are listed in Table 1. These are accompanied by separate statutory guidance for each Devolved Administration (Northern Ireland will be producing statutory guidance as part of the 2013 BSSD transposition).

3.84 The different sets of statutory guidance explain the roles of the EAs and LAs in the different RCL regimes, and how the regulations should be implemented, including how it should be determined whether land is radioactive contaminated land as defined in the RCL regulations. In addition it elaborates on the remediation provisions outlined in the RCL regulations and how regulators should ensure that remediation requirements are reasonable.

3.85 We propose that the 2013 BSSD requirements in Article 73.1 are met through our RCL regimes, amended as follows:

- To transpose the requirement for reference levels we propose to align the RCL concept of the, 3 mSv/y “harm threshold” and equivalent dose criteria with that of reference levels as required by the 2013 BSSD. See the section on reference levels (paragraph 3.71) for information about the duty to establish reference levels.
- To transpose the requirement for optimisation to be inherent in the management of contaminated areas, we propose to modify the primary legislation to clarify when remediation can be considered reasonable.
- To transpose the requirements of Article 73.1(b-e) we propose to modify the definition of remediation to include the requirements listed under Article 73.1(b-e). We will also update the RCL statutory guidance. In Scotland, assessment of the exposure of different groups in the population and the means available to individuals for controlling their own exposure has already been established by the Public Health etc. (Scotland) Act 2008, so this amendment is not needed to the Scottish RCL statutory guidance.

3.86 It is unlikely that a decision would be made to allow habitation of a site designated as RCL as a result of contamination from past activities. However to transpose Article 73.2, we propose to impose a duty[21] on the Secretary of State to ensure that arrangements are in place for the on-going control of exposure to ionising radiation with the aim of establishing normal living conditions. We envisage that this duty would be triggered before habitation and other activities are allowed on land designated as RCL. In this unlikely event the duty will be implemented by issuing new statutory guidance using RCL powers.

3.87 We propose that transposition of Article 100.1 is achieved through the amended RCL regimes and corresponding statutory guidance.

3.88 We propose to transpose Articles 101 and 102 through the RCL regimes along with the amendments to be made in transposing Articles 7 and 73.1 (see paragraphs 3.71 and 3.83). In addition it is proposed that the RCL regimes are amended to include requirements to regularly evaluate the remedial and protective measures planned and implemented, provide information to exposed populations and guidance for the management of exposures at individual or local level.

3.89 For clarity and simplicity we propose to modify the text in the RCL regimes (Environment Protection Act 1990, The Radioactive Contaminated Land Regulations, Radioactive Contaminated Land Statutory Guidance) to bring it in line with the 2013 BSSD:

- We propose to remove the term “intervention” from the RCL regimes, as it is no longer used in the 2013 BSSD. We propose to rely instead on the broader term “remediation”.
- The 2013 BSSD uses the terms “protective measures” and “remedial measures” in relation to existing exposures. We propose to update the definition of remediation to specifically include these terms.

[21] BSSD Regulations

Land contaminated as a result of a radiological emergency (Situation 2)

3.90 The risk of a radiological emergency in the UK is extremely low. Nonetheless, in the event of a radiological emergency, the UK's national recovery guidance would be used to co-ordinate and manage the situation once the emergency has transitioned to the recovery phase. This guidance sets out the framework, processes and information that need to be considered in preparation for and during the recovery phase. We propose that optimised protection strategies will meet 2013 BSSD requirements through an update to the guidance and amendments to the RCL regimes.

3.91 This policy area interfaces with Article 98.3 of the 2013 BSSD which requires emergency response plans to include provision for the transition from an emergency exposure situation to an existing exposure situation. This article will be dealt with in the separate Emergency Preparedness & Response consultation and will not be discussed further here.

3.92 To transpose the requirement to ensure optimised protection strategies deal with the matters as set out in Article 73.1, we propose to impose a duty[22] on the relevant Minister.

3.93 Implementation of this new duty will be via the UK's national recovery guidance and the amended RCL regimes, which will comprise the "optimised protection strategies" for the UK.

3.94 Article 73.2 covers the unlikely event of a radiological emergency that leads to the need for decisions to be made regarding habitation of contaminated areas. We propose to impose a new duty[23] on the relevant Minister to ensure that arrangements are in place for the on-going control of exposure to ionising radiation in such areas with the aim of establishing normal living conditions. We intend that this duty will be triggered before any habitation or other activities have been allowed on such land.

3.95 We propose that the legal requirements of Articles 100.1, 101 and 102 will be covered by our transposition of Article 73.1 and the above proposed amendments to the RCL regimes.

Question 11

Do you have any views on the proposed approach to transposing the requirements of Articles 73, 100-102 in relation to land contaminated as a result of a radiological emergency? Please evidence your answer.

Indoor public exposure to gamma radiation from building materials (Situation 3)

3.96 In relation to existing indoor exposures to natural radiation sources from building materials in dwellings and other (non-workplace) buildings, it is envisaged that transposition of Article 100.1 will be achieved by imposing a new duty[24] on the relevant Minister.

3.97 In practice, there are already mechanisms in place to address the requirements of Articles 101 and 102 in relation to indoor public exposure to gamma radiation from

[22] BSSD Regulations
[23] Ibid.
[24] Ibid.

building materials incorporated into buildings or parts of buildings. To transpose Articles 101 and 102 we propose to impose new duties[25] on the relevant Minister.

Public exposure to contaminated commodities (Situation 4)

3.98 In relation to existing exposures resulting from commodities that are retrospectively found to incorporate, or be contaminated with, artificial or naturally occurring radionuclides, Article 100.1 is already covered administratively by the EAs. We propose to transpose this Article by imposing a new duty on the relevant Minister.

3.99 In practice, there are already mechanisms in place to address the requirements of Articles 101 and 102 in relation to contaminated commodities. To transpose Articles 101 and 102 we propose to impose new duties on the relevant Minister.

Public exposure to radon

3.100 This section covers Articles 7.3, 74 and 103 of the 2013 BSSD. These articles refer to radon exposure. Only public exposure to radon is considered in this consultation. Workplace exposure to radon is outside the scope of this consultation and is the responsibility of the HSE. Article 7.3 also concerns reference levels and these are discussed in the Reference levels section in paragraphs 3.69-3.71.

Radon action plan (Article 103, 2013 BSSD)

3.101 Article 103 requires the establishment of a radon action plan. Specifically, Article 103 introduces two new requirements in relation to public exposures:

- Member States must establish a national action plan that addresses the long-term risks from radon exposures in dwellings and buildings with public access for any source of radon entry, whether from soil, building materials or water. The action plan must be updated on a regular basis and must take into account the issues set out in the BSSD Annex XVIII.
- Member States must identify areas where the radon concentration (as an annual average) in a significant number of buildings is expected to exceed the relevant national reference level.

3.102 PHE has undertaken work to coordinate, with other government departments and agencies, the development of the first version of the National Radon Action Plan; there will be a separate consultation on this Action Plan. We propose to impose a duty[26] on the responsible Minister to establish a national radon action plan.

3.103 Regarding identification of areas with high radon concentrations, PHE already conduct this work in conjunction with the British Geological Survey as part of the established UK process of defining Radon Affected Areas. Although the requirement is met in practice, there is currently no legislative provision for this. We propose to impose a duty[27] on the responsible Minister.

[25] BSSD Regulations
[26] Ibid.
[27] Ibid.

Indoor exposure to radon (Article 74, 2013 BSSD)

3.104 Article 74 introduces three new requirements regarding indoor public exposure to radon:

- Member States must establish national reference levels for indoor radon concentrations. The reference levels for the annual average activity concentration in air must not be higher than 300 Bq/m^3
- As part of the national radon action plan, Member States must promote action to identify dwellings with radon concentrations (as an annual average) exceeding the national reference level and encourage, where appropriate by technical or other means, radon concentration-reducing measures in these dwellings
- Member States must ensure that local and national information is made available on indoor radon exposure and the associated health risks, on the importance of performing radon measurements and on the technical means available for reducing existing radon concentrations

3.105 The UK Action Level for radon in dwellings, set at 200 Bq/m^3, was published as formal advice from the National Radiological Protection Board in 1990 and accepted by the government at the time. It was reviewed and re-iterated in 2010 by the Health Protection Agency (now PHE). This level is beneath the upper bound of 300 Bq/m^3 required by the 2013 BSSD and so transposition of this requirement will not cause any change to current practice. We propose to transpose the requirement to establish national reference levels for indoor radon concentrations by imposing this duty[28] on the responsible Minister.

3.106 The UK already conducts work to "promote action" including:

- References to radon in house sale/purchase arrangements;
- Standing advice accessible via gov.uk and ukradon.org;
- Promotional action by firms in the radon measurement and remediation sector;
- Targeted programmes funded by central government and others; and
- Radon references in housing health and safety schemes.

Therefore, transposing this requirement will not cause any change to current practice. The legal requirement will be transposed by imposing this duty[29] on the responsible Minister.

3.107 Formal and scientific evidence and advice about radon and its health risks is published at gov.uk and public facing information is published through ukradon.org. There is also radon-specific information on other websites such as those of HSE, Local Authorities and other bodies. Therefore, the requirement can be transposed with no change to current practice. The legal requirement will be transposed by imposing this duty[30] on the responsible Minister.

[28] BSSD Regulations
[29] Ibid.
[30] Ibid.

Indoor exposures to radon and thoron (Article 100, 2013 BSSD)

3.108 In relation to existing indoor exposures to radon and thoron in dwellings and other (non-workplace) buildings Article 100.1 is already covered administratively by advisory measures provided by PHE. Detailed guidance for the public is available on PHE's radon website (www.ukradon.org) with detailed information and contacts for any home owner or tenant to determine whether they should test their home for radon, how to test and how to reduce high indoor radon levels. We propose to transpose Article 100.1 by imposing a new duty on the relevant Minister. This will not cause any changes in current practice.

Gamma radiation from building materials

3.109 Article 75 requires, where Member States identify building materials of concern from a radiation protection point of view, that before those materials are placed on the market appropriate safeguards are implemented.

3.110 To comply with this requirement we propose to impose a duty[31] to determine activity concentrations of "building materials of concern" (to be provided to the competent authority on request); and place a duty[32] on the responsible Minister to ensure "appropriate measures are put in place" for types of building materials liable to give gamma radiation doses exceeding 1 mSv per year.

3.111 No "building materials of concern" have been identified in the UK to date, and there is a low chance such materials will be identified in the UK in the future, but if they were identified Government would at that time develop and implement appropriate safeguard measures.

Justification of Practices Involving Ionising Radiation

3.112 The Justification of Practices Involving Ionising Radiation Regulations 2004 (the JoPIIR Regulations), implement the requirements of the 1996 BSSD in relation to the justification of classes or types of practice. We propose to amend the JoPIIR Regulations to bring them in line with the requirements of the 2013 BSSD.

3.113 The justification of individual medical exposures is (and will continue to be) dealt with separately in Department of Health legislation, specifically in the Ionising Radiation (Medical Exposures) Regulations 2000, which were consulted on in July.

3.114 The provisions relating to the justification of classes or types of practice in the 2013 BSSD are closely based on those contained in the 1996 BSSD. Some changes contained in the 2013 BSSD require minor drafting alterations to be made to the JoPIIR Regulations. These changes are not discussed further in this consultation document. Other changes that require a more material change to the Regulations are discussed below.

[31] BSSD Regulations
[32] Ibid.

3.115 The sole purpose of this consultation is to seek comments on our proposals to implement the revised obligations contained in the 2013 Directive. We are not seeking comments on broader justification policy, and will not take such comments into account when finalising the Regulations

Changes to the definition of "practice" in the BSSD

3.116 The definition of a "practice" under the 2013 BSSD has been extended to include human activities that involve exposure to radiation from natural radiation sources, even where they are not being processed for their radioactive, fissile or fertile properties. Any activities involving naturally occurring radioactive material that fall within the extended scope of "practice" will be brought within the scope of the justification regime.

3.117 This change does not affect any practice that has previously been justified in the UK (justification decisions can be found in the Justification Register[33]), nor will it require the new justification of any existing practice involving naturally occurring radioactive material that existed prior to 6th February 2018 (the transposition date), but the justification of such practices could be reviewed in accordance with the JoPIIR Regulations.

Consumer products (Article 20, 2013 BSSD)

3.118 Article 20 introduces a new requirement for undertakings intending to manufacture or import a consumer product for which the intended use is likely to be a new class or type of practice, to provide the competent authority with all relevant information, including that listed in the 2013 BSSD at Annex IV, Section A. A Member State must make a justification decision if it is provided with this information.

3.119 We propose to place a new legal requirement on the relevant undertaking to provide the required information to the Justifying Authority[34] and to make an application for a justification decision.

3.120 Member States must, when considering the justification of consumer products, take account of the considerations listed in the 2013 BSSD at Annex IV, Section B. We propose to address these new requirements by introducing a new regulation, which will ensure that the Justifying Authority takes into account those considerations in making a justification decision for the use of a consumer product.

3.121 A Member State must inform other Member States when it has been provided with information by an undertaking intending to manufacture or import a consumer product for which the intended use is likely to be a new class or type of practice, and on its justification decision and the basis for that decision. We propose to comply with this requirement by putting in place an appropriate administrative procedure.

3.122 Member States must also "prohibit the sale or the making available to the public of consumer products if their intended use is not justified or would not fulfil the criteria for exemption from notification". To address this new requirement we propose to introduce

[33] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/407582/justification_application_centre_register_updated.pdf

[34] The Justifying Authority is the Devolved Administrations for devolved subject areas, and the appropriate Secretary of State in relation to subject areas which have not been devolved.

a new regulation. This will include a cross-reference to the notification provisions contained in Schedule 1(1) to the new Ionising Radiations Regulations 2017.

Prohibition of practices (Article 21, 2013 BSSD)

3.123 The 2013 BSSD requires that practices involving the activation of material resulting in an increase in (radioactive) activity in a consumer product must be deemed not to be justified: however, the competent authority may evaluate specific types of practices within this class with regard to their justification. We propose to add a new regulation saying that all classes or types of practices involving activation in relation to a new consumer product will be classed as "new" classes or types of practice (and therefore cannot be carried out in the UK) if the class or type of practice in question has not actively been found to be justified.

3.124 Member States must prohibit practices involving the activation of material in toys or personal ornaments, resulting in an increase in activity at the time of placing the product on the market; Member States must also prohibit the import or export of such products or materials. We propose to add a new prohibition in the JoPIIR Regulations.

Justification of practices involving the deliberate exposure of humans for non-medical imaging exposure (Article 22, 2013 BSSD)

3.125 Article 22 requires Member States to ensure the identification of practices involving non-medical imaging exposure, taking into account practices identified in Annex V of the Directive. We propose to introduce a new regulation requiring Government to seek to identify such practices.

3.126 Each individual practice, as well as the relevant overall class or type of practice, must be justified. We propose to create a new regulation to require operators planning to commence a particular application of a class or type of practice involving non-medical imaging exposures to seek a determination that it is part of an existing class or type of practice that has not been found not to be justified. We consider that a "particular application" can only be determined to fall within such a class or type of practice if it has the same positive balance of benefits versus potential health detriments.

3.127 We propose creating a new regulation, which will require operators of non-medical imaging exposure equipment to implement a system of either: (i) justification of individual exposures, or (ii) regular reviews. Both approaches would involve the operator implementing arrangements to ensure exposures are justified by the economic, social or other benefits in relation to the health detriment they may cause. Where an operator chose to adopt the approach of regular reviews, the appropriate regularity of these reviews in each case would depend on the specific circumstances of the practice, including the frequency with which the exposures were conducted. The operator would also be required to provide a copy of their review report to the Justifying Authority. We propose to include further guidance on the two approaches in the Justification Guidance document.[35]

3.128 Member States must, when they have determined that a particular practice involving non-medical imaging exposure is justified, ensure that requirements for the practice, including criteria for individual implementation, are established by the competent

[35] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/432763/JoPIIRR_guidance.pdf

authority, in cooperation with other representative bodies and medical scientific societies as appropriate. We propose to transpose this requirement by creating a new regulation, which will require operators of non-medical imaging exposure equipment to hold an approval from the Justifying Authority in respect of that particular practice, which will contain the requirements a person must comply with when carrying out the particular practice.

3.129 The dose constraints for procedures not using medical radiological equipment must be significantly below the dose limit for members of the public. We propose to implement this by including a requirement, cross-referring to the relevant part of the new Ionising Radiations Regulations 2017, that dose constraints for these practices are significantly below the dose limit for the general public.

3.130 Member States must ensure that "information is provided to and consent sought from the individual to be exposed, allowing for cases where the law enforcement authorities may proceed without consent of the individual according to national legislation". We propose to transpose this requirement by creating a new regulation, including providing for the exemption for law enforcement authorities.

Identification of practices involving naturally occurring radioactive material (Article 23, 2013 BSSD)

3.131 Article 23 requires Member States to ensure the identification of classes or types of practice involving naturally occurring radioactive material, taking into account industrial sectors listed in Annex VI of the 2013 BSSD. We propose to introduce a new regulation obliging Government to seek to identify such practices.

Competent Authority to carry out tasks in accordance with the Directive (Article 76, 2013 BSSD)

3.132 In the UK, all justification decisions are currently taken by Government, either by the relevant Secretary of State or a by a Minister of the relevant Devolved Administration.

3.133 Article 76 requires Member States to designate a competent authority to carry out tasks in accordance with the Directive. This includes the making of justification decisions. The Article introduces a new requirement for Member States to ensure that, for the purpose of achieving independence from undue influence, the competent authority is functionally separate from any other body or organisation concerned with the promotion or utilisation of practices under the Directive.

3.134 This means, where a Secretary of State, or Minister of a Devolved Administration, is concerned with the promotion or utilisation of a practice in question, he may not be able to make justification decisions, and instead the function of assessing the relevant new classes or types of practice will need to be exercised by another decision-maker.

3.135 This change does not affect any justification decision that has previously been made in the UK, nor does it affect any existing practice that is currently treated as such because it was carried out prior to 6th February 2018 (the transposition date).

3.136 To comply with this new requirement we propose to provide that, in the circumstances of insufficient functional separation between the competent authority and the organisation concerned with the promotion or utilisation of the practice, another Secretary of State, or Minister of a Devolved Administration, takes the justification decision.

System of enforcement – inspections

3.137 Article 104 requires Member States to establish a system of inspection to check that only practices involving ionising radiation that are justified are being carried out. To comply with this requirement we propose to include these inspection functions in a new regulation and give Government the power to delegate the inspection and monitoring function to other bodies.