Title: Revised requirements for radiological protection: regulation of public exposures and the justification of practices	**Impact Assessment (IA)**
	Date: 05/10/2017
IA No: BEIS017(F)-17-CNRD	**Stage:** Consultation
RPC Reference No: RPC-4100(1)-BEIS	**Source of intervention:** Euratom
Lead department or agency: BEIS	**Type of measure:** Secondary legislation
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Summary: Intervention and Options

RPC Opinion: Green

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
£55m	£55m	-£6m	In Scope	Qualifying provision

What is the problem under consideration? Why is government intervention necessary?

The Basic Safety Standards Directive (2013/59/Euratom), referred to hereafter as the BSSD, consolidates and updates existing Euratom provisions for protection against the harmful effects of ionising radiation. The BSSD establishes minimum standards for radiological protection of workers, medical patients and the public in existing exposure, planned exposure and emergency situations.This impact assessment covers the requirements of the BSSD in relation to public exposures in existing and planned exposure situations, and in relation to the justification of practices involving ionising radiation. The deadline for transposition of the BSSD is 6th February 2018.

What are the policy objectives and the intended effects?

- Maintain the UK's high standards of radiological protection of the public in existing and planned exposure situations.
- Minimise the environmental and economic cost of implementing these standards by, ensuring that they are streamlined and proportionate.
- Demonstrate UK compliance with the latest recommendations and safety standards issued by the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA) and fulfill the UK's obligations under Euratom law.
- Ensure, where possible, consistent application of BSSD requirements by BEIS and the Devolved Administrations in order to maintain a level playing field for industry.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Alternatives to regulation have been considered but were not deemed to be viable as they would not fulfil the UK's obligations under Euratom law. An approach short of regulation would not fully implement the BSSD; this would risk infraction proceedings against the UK.

Option 1 is to update existing UK legislation to ensure coverage of all additional requirements of the BSSD. This approach involves the minimum changes to legislation required to ensure compliance with BSSD requirements. The changes proposed in this option are designed to minimise regulatory burdens and cost to business whilst also maintaining the UK's high standards of radiological protection. Further cost savings are possible through the implementation of additional measures (see Option 2).

Option 2 is the preferred option, as it includes the minimum necessary changes set out in Option 1 plus additional measures to improve the regulatory framework that, while not required, will have cost savings for both the private and public sectors. These measures include streamlining the regulatory requirements for disposal of Gaseous Tritium Light Devices (GTLDs), and updating, in light of best available evidence, the limits for the quantity and concentration of radionuclides deposited in land as a result of historic radium activities. This option complies with the UK's Guiding Principles for European Legislation, and maintains or improves the UK's high standards of radiological protection while decreasing the overall burden on industry.

Will the policy be reviewed? It will be reviewed.

Does implementation go beyond minimum EU requirements?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Richard Harrington Date: 05/10/2017

Summary: Analysis & Evidence

Policy Option 1

Description: Minimum changes required to transpose the BSSD

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: £58m	**High:** £68m	**Best Estimate:** £63m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		0m	**0m**
High	Optional		0m	**0m**
Best Estimate			**0m**	**0m**

Description and scale of key monetised costs by 'main affected groups'

There are currently no additional monetised costs over and above those in the baseline/ do nothing option which may be incurred as a result of this policy option. However some costs that are currently described as non-monetised may be found to incur costs, after further stakeholder engagement and consultation.

Other key non-monetised costs by 'main affected groups'

Administrative burdens will fall on Government as a result of the requirement for the Justifying Authority to exchange information with other Member States on consumer product justification decisions and from the requirement to identify practices involving Non-Medical Imaging Equipment (NMIE) and Naturally Occurring Radioactive Material (NORM). Operators in the geothermal industry will also face costs as a result of this policy option from having to assess whether their waste arisings are above the "out of scope" values for radioactive substances.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		£6m	**£50m**
High	Optional		£7m	**£59m**
Best Estimate			£6m	**£55m**

Description and scale of key monetised benefits by 'main affected groups'

The titanium dioxide and steel industries will save £5.8m-£6.9m per year from legislative changes relating to Naturally Occurring Radioactive Materials (NORM).

Users of High Activity Sealed Sources (HASS) will save £4000-£8000 per year per permit holder from changes to activity values for defining these HASS. There will also be an additional one-off saving for HASS users of £6000-£12000 per permit holder.

Other key non-monetised benefits by 'main affected groups'

The steel, oil and gas industries will benefit from the ability to reuse and recycle NORM rather than generating NORM waste for disposal.

These industries will also benefit from lower decommissioning and site remediation costs due to the reduced need for radioactive waste management.

Impacts arising from the environmentally intensive management of NORM as radioactive waste will also be reduced.

Improvement to the financial viability of further investment in improvements for the steel manufacturing process.

Further evidence of the above benefits will be sought during consultation.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

Estimates of the amount saved as a result of changes to exemption values for NORM are based on the assumption that 600-800 tonnes of NORM waste would not come into scope of the regulations and do not include further costs associated with handling NORM.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits: £6m**	**Net: £6m**	28.5

Summary: Analysis & Evidence

Policy Option 2

Description: Minimum requirement to comply with the BSSD as well as further cost saving measures to improve the regulatory framework FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: £59m	High: £68m	Best Estimate: £64m

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		0m	**0m**
High	Optional		0m	**0m**
Best Estimate			**0m**	**0m**

Description and scale of key monetised costs by 'main affected groups'

There are currently no additional monetised costs over and above those in the baseline/ do nothing option that arise as a result of this policy option. However some costs that are currently described as non-monetised may be found to incur costs, after further stakeholder engagement and consultation.

Other key non-monetised costs by 'main affected groups'

The need for industry to familiarise themselves with the new regulation may lead to additional costs. Given that the purpose of the new regulation is to increase flexibility rather than adding regulatory requirements, we expect these costs to be nominal. Further evidence on these costs will be sought through the consultation.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		£6m	**£51m**
High	Optional		£7m	**£60m**
Best Estimate			£7m	**£56m**

Description and scale of key monetised benefits by 'main affected groups'

Further benefits should be realised beyond those described in option 1, with Government (MoD) as the main beneficiaries, from exempting Gaseous Tritium Light Devices from radioactive waste management. Total saving for the Government amounts to £100k per year, through a reduction in waste disposal costs.

Other key non-monetised benefits by 'main affected groups'

Land owners / developers may benefit from changes to the limits that determine whether land contaminated from historic radium activity are regarded as radioactive material. These changes may reduce the cost of developing former industrial sites where such activities took place. We are, as of yet, unable to monetise this impact.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

Additional to the risks described in policy option 1, the assumptions relating to Gaseous Tritium Light Devices are based on information from MoD on their best estimate of their current holdings of GTLDs, which may vary slightly year on year.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: 28.5m
Costs: 0m	Benefits6m	Net:6m	

Contents

Problem under consideration and rationale for intervention

1. The purpose of this public consultation is to enable BEIS and the Devolved Administrations to make the necessary changes to their respective legislative frameworks by the implementation deadline of February 2018.

1.1 Euratom and the Basic Safety Standards Directive

2. The Basic Safety Standard Directive (BSSD) was adopted on 5 December 2013, and the deadline for Euratom Member States to transpose the requirements into national legislation is 6 February 2018. The BSSD consolidates and replaces five existing radiation safety Directives and a Commission Recommendation. It also updates the provisions of those directives in light of the latest recommendations from the International Commission on Radiological Protection (ICRP) and standards issued by the International Atomic Energy Agency (IAEA) (see Annex II for further information on Euratom and the BSSD).
3. BEIS is the lead government department for coordinating the transposition of BSSD into UK law and for reporting on the UK transposition arrangements to the European Commission and Euratom Member States. Responsibility for implementing different aspects of the BSSD is shared by several UK Government Departments and by the Devolved Administrations in areas where legislation is devolved.
4. The BSSD lays down requirements for the justification of practices that involve ionising radiation. The concept of justification was developed by international consensus through the International Commission on Radiological Protection, and requires that practices are subject to an evidence-based process. This is to ensure that the benefits of any practice that may give rise to human exposures outweigh the potential human health detriment. Practices that are found to be justified may be carried out subject to relevant regulatory requirements.
5. The BSSD also lays down minimum radiological protection standards for the different human exposure groups. Three distinct radiation exposure groups are identified for the purpose of developing regulatory requirements:
    - **members of the public**;
    - **workers**, including those who work directly with radiation, but also workers who may be exposed indirectly in the course of their occupation; and
    - **medical patients.**

6. The BSSD contains concepts and requirements that apply to the regulation of all of the above exposure types, and also provisions which are specific to one or other exposure group. The BSSD further identifies three distinct radiation exposure situations:

   - **Emergency exposure situations** arising as a result of an accidental exposure;
   - **Planned exposure situations** arising in relation to the authorised use of radioactive substances and other activities which potentially give rise to public, occupational or medical exposures; and
   - **Existing exposure situations** arising either in connection with residual contamination from past industrial practices (for example former radium paint manufacturing sites) or accidents, or naturally occurring radioactivity (for example radon into buildings). This also includes prolonged exposure following emergencies.

1.1.1 Changes introduced by the BSSD

7. The UK has a mature existing framework for radiological protection and for the justification of practices involving ionising radiation. The Government supported the consolidation of existing Euratom legislation in this area into a single consolidated Directive which reflects recent developments in the underpinning radiation protection standards and recommendations issued by the ICRP and the IAEA. In most cases, existing UK legislation is already fully compliant with the revised requirements of the BSSD and therefore the changes proposed to transpose the BSSD are incremental, working within the existing framework of regulatory regimes for different exposure groups and types.

1.2 Scope of this impact assessment

8. This scope of this impact assessment is limited to public radiation exposures in planned and existing exposure situations, and the system for regulatory justification of practices involving ionising radiation. Consultation exercises on proposals for transposition of aspects of the BSSD relating to occupational exposures, medical exposures, and arrangements for emergency preparedness and response are being conducted separately with their own impact assessments

1.3 Public exposures in planned and existing exposure situations

9. In existing legislation, public radiation exposures in planned and existing exposure situations are regulated primarily through environmental protection legislation, for which BEIS Ministers and their ministerial counterparts in Scotland, Wales and Northern Ireland are responsible. Public exposures are currently controlled primarily through the radioactive substances regulations[1] [2] and Radioactive Contaminated Land (RCL)[3] regime (contained within Part 2A of the Environmental Protection Act 1990) which are substantially similar across the UK. The radioactive substances regulations encompass regulations for England and Wales, Schedule 23 Environmental Permitting Regulations 2016 (consolidated), and corresponding legislation for Scotland and Northern Ireland. The proposals presented below, which relate to radioactive substances regulations, will impact on those whose operations involve the keeping and use of radioactive substances, and the accumulation and/or disposal of radioactive waste. This includes hospitals, universities and other industrial and research sites, oil and gas installations, and nuclear sites.

[1] http://www.legislation.gov.uk/uksi/2016/1154/contents/made
[2] http://www.legislation.gov.uk/ukpga/1993/12/contents
[3] https://www.gov.uk/government/publications/statutory-guidance-covering-radioactive-contaminated-land

10. Public and exposures arising from an authorised work activity using radiation or radioactive substances are regulated under the Ionising Radiation Regulations 1999. The aim of Euratom and UK legislation in this area is to control public radiation exposure via environmental pathways. Public exposures resulting from radon gas will be managed through the Radon Action Plan.

11. Technical and policy analysis has been conducted collaboratively by BEIS and the Devolved Administrations for Scotland, Wales and Northern Ireland and relevant agencies through the UK Public Exposures Working Group (PEWG), which is chaired by BEIS officials.

1.4 Justification of Practices Involving Ionising Radiation

12. Justification is currently regulated in the UK using the Justification of Practices Involving Ionising Radiation Regulations 2004[4]. The aim of Euratom and UK legislation on justification is to ensure that classes and types of practice which involve exposing the public to ionising radiation are justified before they are used for the first time. Classes and types of practice must be justified by their economic, social or other benefits in relation to the health detriment they may cause.

1.5 Rationale

13. Following the UK Government's Guiding Principles for European Legislation, BEIS and the Devolved Administrations (DAs) are consulting jointly on the public exposure elements of the BSSD. We will ensure that the UK does not go beyond the minimum requirements of the BSSD and identifies better-regulatory measures where possible, whilst ensuring that high standards of risk control for public exposure to ionising radiation are maintained. To that end the proposals were developed in close consultation with radiological protection experts at Public Health England, which advises government departments on radiation protection matters. The UK's preferred option, where possible, is to use a "copy-out" from the BSSD when transposing. "Copy-out", as the name suggests, is where the implementing legislation adopts the same or similar wording as that of the BSSD or where it cross-refers to the relevant Directive provision.

1.5.1 Economic Rationale for Intervention

14. If not managed appropriately, ionising radiation can cause considerable damage to human health and environment, incurring costs to society. Without government intervention, these costs may not be borne by the owners and users of radioactive substances, so they may not be fully incentivised to control and manage them effectively. These costs are therefore considered 'negative externalities'.

15. Whilst existing UK regulation attempts to capture and internalise these social costs, by obliging owners and users of radioactive substances to adopt safe/recommended practices when using these materials; transposition of the BSSD will further minimise the risk of government intervention resulting in failure, by bringing the UK in line with the latest international safety requirements. These new requirements also simplify areas of current UK regulation, easing the burden on industry and providing the opportunity for financial savings.

1.5.2 Wider Rationale for Intervention

16. Maintaining a strong regulatory framework will contribute to public confidence in nuclear energy and other uses of radioactive substances and radiation as it demonstrates the Government's commitment to the protection of human health and the environment. The UK wants to maintain its position as an international leader in radiological safety and security because this will facilitate the secure and sustainable growth of industry in the future. Furthermore, these changes will bring UK

[4] http://www.legislation.gov.uk/uksi/2004/1769/note/made

legislative standards for the management of radioactive substances in line with current IAEA and ICRP guidance, therefore building on the UK's high standard of regulation.

1.6 EU referendum and Euratom

17. On 29 March 2017 the United Kingdom Government formally notified the European Commission of its intention to withdraw from Euratom. The UK supports Euratom and will want to see continuity of co-operation and standards.

18. 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.

19. 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.

Policy Objectives

20. In considering the most appropriate method to transpose the requirements of the BSSD into domestic legislation, the policy objectives are to:

    - Maintain the UK's high standards of radiological protection of the public in existing and planned exposure situations.
    - Minimise the environmental and economic cost of implementing these standards, by ensuring that they are streamlined and proportionate.
    - Demonstrate UK compliance with the latest recommendations and safety standards issued by the International Commission on Radiological Protection (ICRP) and the IAEA and to fulfil the UK's obligations under Euratom law.
    - Ensure, where possible, consistent application of the BSSD requirements with Devolved Administrations in order to maintain a level playing field for industry.

21. In developing the proposals, technical and policy analysis has been conducted collaboratively by BEIS and the Devolved Administrations for Scotland, Wales and Northern Ireland, and relevant agencies through the UK Public Exposures Working Group (PEWG), which is chaired by BEIS officials.

Descriptions of Options Considered, Costs and Benefits

2. Baseline (Option 0) – 'do nothing'

22. This option results in no change to the current regulations. In this scenario the UK would be unable to demonstrate full compliance with recommendations from the International Commission on Radiological Protection (ICRP) and the requirements of the BSSD. This option could result in the risk of infraction proceedings and associated costs. The European Commission may commence

infraction proceedings against a Member State for late or incomplete transposition. This option would also fail to demonstrate compliance with international safety standards. The Euratom Basic Safety Standards are designed to be consistent with International Basic Safety Standards published by the International Atomic Energy Agency (IAEA). The 2013 Euratom and 2014 IAEA safety standards were developed on the basis of recommendations of the International Commission on Radiological Protection (ICRP Publication 103, 2007).

23. The 'do nothing' option is not considered viable as it would neither deliver the policy objective nor fulfil the UK's obligations under the Euratom treaty. Option 0 has only been included in order to provide a counterfactual against which to appraise other options in accordance with Better Regulation Guidance[5]. There are no costs and benefits associated with the do nothing option. However, the issues such as infraction risk will continue without government intervention. Option 0 may also result in reputational damage. Failure to demonstrate that the UK is compliant with current Euratom radiation safety standards and the underpinning IAEA standards could result in loss of confidence in the UK regulatory framework.

3. Option 1 – Minimum changes required to transpose the BSSD

24. This option implements the BSSD in a way that does not introduce requirements which go beyond the scope of the BSSD. This is described in the UK Guiding Principles for European Legislation[6] as the 'do minimum' option.

25. This option would not result in extensive changes to existing arrangements. It maintains the UK's high standards of radiological protection and implements the BSSD in the least burdensome way. This option is achieved through revision and augmentation of existing regulatory regimes, thereby avoiding the creation of a new regulatory regime. This option complies with the UK's Guiding Principles for European Legislation while keeping burdens to a minimum.

26. For more detail with regards to changes below please refer to the consultation document. Only the amendments below have been assessed to have an impact, however we will test this during consultation.

3.1 Changes to legislation

3.1.1 "Out of scope" values for Naturally Occurring Radioactive Material (NORM)

27. Radioactive materials which occur naturally are known as Naturally Occurring Radioactive Material (NORM). Materials that contain significant quantities of NORM are required to be managed as radioactive waste. Where the amount of radioactivity is very low, materials may be deemed "out of scope" of the regulatory requirements for radioactive waste management.

28. Public Health England (PHE) has advised on certain changes in relation to NORM material and waste[7]. PHE has suggested increasing the "out of scope"[8] values for some NORM radionuclides in solid material and waste, so reducing unnecessary management of material containing NORM as radioactive waste. This change results in environmental benefits and reduced costs. The proportionate transposition of the changes to "out of scope" and exemption values for NORM will help reduce the amount of waste that needs to be managed as radioactive waste thus reducing the

[5] The Better Regulation Guidance is a guide for government officials covering all aspects of the UK Government's better regulation framework.

[6] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/185626/bis-13-774-guiding-principles-for-eu-legislation.pdf

[7] "Impact of Changes to Exemption and Clearance Values for Specific Radionuclides: Review and Industry Survey". Report produced by Public Health England's Centre for Radiation, Chemical and Environmental Hazards for Department of Energy & Climate Change.

[8] In the UK regime, the concepts of "out of scope" and "exemption" each incorporate both of the concepts used in the BSSD of exclusion and clearance.

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 be incurred by such specialised treatment and disposal.

3.1.2 Exemption values for NORM waste

29. Existing legislation allows for materials which are in scope of the legislation to be removed, subject to exemption conditions, from regulatory control in specific circumstances.

30. The BSSD allows for increased exemption values for certain types of NORM waste. PHE advises that the exemption values for NORM waste containing lead-210+ or polonium-210 could be increased resulting in environmental benefits, as described in section 3.1.1 above, and reduced costs.

3.1.3 Definition of High Activity Sealed Sources (HASS)

31. Sealed radioactive sources are subject to regulatory requirements. Sources which are High Activity Sealed Sources (HASS)[9] are subject to additional requirements in view of the increased hazard. The BSSD introduces changes to the system for determining which sources are HASS (see consultation document). As a result some sources which are currently regulated as HASS will no longer be considered to be HASS, reducing costs for some users as the sources will not be subject to the additional requirements. In other cases, sources which are currently HASS will be considered HASS following the changes will therefore be subject to the additional requirements. Analysis by the environmental agencies indicates that overall, there will be a reduction in the number of sources that are defined as HASS, therefore there is a net cost saving for the sector.

3.1.4 NORM industrial activities

32. The list of NORM industrial activities will be extended to include “geothermal energy production”. This change will extend to geothermal industry the requirement to apply for a radioactive substances permit. The impacts on the geothermal industry will depend on how much radioactive waste, if any, is produced above radioactive waste exemption levels. Further evidence will be sought through the consultation in order to assess these impacts.

3.1.5 Justification of Practices Involving Ionising Radiation

33. This section discusses the provisions contained in the BSSD that relate to the justification of practices involving ionising radiation and which and are thought to have an additional impact:

    - Article 20(3) obliges each Member State to 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;
    - Article 22(1) requires Member States to identify practices involving non-medical imaging exposure (NMIE);
    - Article 22(2)(b) requires Member States to ensure that each particular application of a generally accepted type of practice is justified;

[9] “Sealed source” means a radioactive source containing radioactive material where the structure is designed to prevent, under normal use, any dispersion of radioactive substances, excluding such a source where it is an electrodeposited source or a tritium foil source.

- Article 22(2)(e) requires Member States to ensure that circumstances warranting non-medical imaging exposures, without individual justification of each exposure, shall be subject to regular review;
- Article 22(4)(b) requires Member States to ensure that requirements for NMIE practices, including criteria for individual implementation, are established by the competent authority, in cooperation with other relevant bodies and medical scientific societies, as appropriate; and
- Article 22(4)(e) requires Member States to ensure that for NMIEs information is provided to and consent sought from the individual to be exposed (excepting cases where law enforcement authorities may proceed without consent according to national legislation).
- Article 23 requires Member States to identify practices involving naturally occurring radioactive material.

34. It should be noted that the changes relating to non-medical imaging exposures concern only NMIEs not using medical imaging equipment; NMIEs using medical equipment will be covered in the Ionising Radiation (Medical Exposure) Regulations 2000, which the Department of Health will be consulting on separately.

3.2 Benefits and Costs

3.2.1 Monetised benefit

Changes to "out of scope" values for Naturally Occurring Radioactive Material (NORM)

35. Option 1 results in some changes to "out of scope" values for NORM (section 3.1.1). PHE have advised that this will enable greater reuse and recycling of materials. This will reduce the need for disposal as radioactive waste resulting in benefits for the environment and reduced costs for the titanium dioxide industry[10].

36. The titanium dioxide industry produces high volumes of waste that currently fall within scope of regulation. It was reported that these wastes exceed 100,000 tonnes a year[11]. These would be regarded as "out of scope" under Option 1, producing savings of approximately £2.5 million per year in terms of disposal costs[12]. Reducing the volume of waste that needs to be managed as radioactive waste, particularly through disposal to landfill, is a key aim of government policy which is for waste to be managed with the least environmentally and economically intensive method.

Changes to exemption values for NORM waste

37. The steel industry reported to PHE that changes to exemption values for NORM waste (section 3.1.2) will make investment in Rotary Hearth Furnace (RHF) technology economically viable[13]. Analysis by the industry indicated annual disposal costs associated with the used of this technology of £3.3m-4.4m per annum under existing exemption values (Annex III). These numbers exclude transportation costs, specialised handling, packaging, etc. which will add to the overall amount. The steel industry reported that these costs outweigh the benefits associated with investment in RHF technology[14].

38. Under Option 1 the steel industry would not incur these costs. This would promote innovation and allow the industry to invest in these new technologies. One major steel company considers these

[10] "Impact of Changes to Exemption and Clearance Values for Specific Radionuclides: Review and Industry Survey". Report produced by Public Health England's Centre for Radiation, Chemical and Environmental Hazards for Department of Energy & Climate Change.
[11] Ibid.
[12] Ibid.
[13] Ibid.
[14] Information received as a result of correspondence with the steel industry.

costs to be large enough to affect the competitiveness of the company compared to other non-UK steel manufacturers.

Changes to Activity values for defining High Activity Sealed Sources (HASS)

39. Analysis undertaken by the environmental agencies (section 3.1.3) indicates that some users would be affected by changes to activity values for defining High Activity Sealed Sources (HASS). This analysis indicates that overall there will be a reduction in the number of sources that are defined as HASS. This will result in disapplication of additional controls for HASS sources held by these users. These controls involve additional costs associated with reporting, financial provision, regulatory and security requirements[15].

40. These changes to the reporting requirements amount to a saving of £4000 - £8000 per year and one off saving of £6000 - £12000[16] per permit holder.

41. HASS users that are affected by this change will no longer be required to make financial provision for waste management in the event of bankruptcy. This could result in savings of several thousand pounds each for sites affected by this change. However, the majority of sites are supplied by firms that include 'take back' provisions in the supply contract. These ensure that the source is returned to the supplier when no longer needed and thereby obviate the need for financial provision. Therefore it is likely that many HASS users do not currently incur any costs as a result of the requirement to make financial provision[17]. We cannot be more specific at this stage as we do not know how many will be impacted.

42. Regulatory costs associated with maintaining HASS permits amount to £1450 per site per annum (assuming for simplicity that no open sources/waste are held on the same site). The number of sites affected is likely to be greater than 70, but the extent to which sites are able to realise a saving depends on other sources that they hold, the security categorisation of sources that cease to be HASS and therefore what type of permit sites need after the changes take place:

    - Permit no longer required - £1450/year saving
    - Permit for low-risk sealed sources - £1150/year saving
    - Permit for sources of similar potential hazard - £200 /year saving
    - HASS permit still required – no saving

43. We have not been able to determine how many sites would fall into each category, therefore no estimate has been made of the potential savings at this stage. We will seek to monetise these benefits using evidence gained during consultation.

3.2.2 Non-monetised benefit

Changes to "out of scope" values for Naturally Occurring Radioactive Material (NORM)

44. Analysis of existing UK legislation in light of the requirements of the BSSD and the report produced by PHE[18], to inform this impact assessment, indicate that there are instances where the current values for "out of scope" of NORM waste may result in unnecessary generation of radioactive waste, which results in environmental and economic impacts.

[15] Information received as a result of correspondence with the Environment Agency.

[16] Ibid.

[17] Ibid.

[18] "Impact of Changes to Exemption and Clearance Values for Specific Radionuclides: Review and Industry Survey". Report produced by Public Health England's Centre for Radiation, Chemical and Environmental Hazards for Department of Energy & Climate Change.

45. In addition to the benefits that have been monetised for this impact assessment (as described in in section 3.2.1 above), changes to "out of scope" values for NORM result in additional benefits which have not been monetised. These benefits will arise in several sectors:

    - The titanium dioxide industry reported that the change in the "out of scope" values will reduce the amount of material that would need to be removed from site during decommissioning and clean up. The savings will vary according to the characteristics of the site being remediated, but would be expected to be substantial. Other NORM industries may also realise benefits.
    - The steel industry reported that the changes will enable increased recycling. This is due to a reduction in the amount of scrap steel that is rejected on the basis of its NORM content. In turn this will reduce waste disposal volumes and therefore costs. The steel industry report that another benefit arises due to the scope for recovery of secondary materials (for example zinc) for reuse or recycling in other processes. This benefit was not directly quantified but would result in cost savings and a reduction in radioactive waste arisings.
    - The oil and gas industry reported a potential reduction in the volume of radium contaminated material under Option 1 resulting in minor savings.

    We will seek additional data through the consultation exercise in order to enable monetisation of these benefits.

Changes to exemption values for NORM waste

46. Analysis of existing UK legislation in light of the requirements of the BSSD and the report produced by PHE[19] to inform this impact assessment indicate that there are instances where the current values for "exemption" of NORM waste may result in unnecessary generation of radioactive waste, which results in economic and environmental impacts.

47. The steel industry reported that changes to exemption values for NORM waste (section 3.1.2) would have a positive impact on the steel industry. The industry produces NORM wastes containing lead-210+ and polonium-210, which currently require disposal as radioactive waste.

48. The oil and gas sector also reported potential benefits from the changes introduced under Option 1. Like the steel industry this sector also produces NORM wastes containing lead 210+ and polonium-210, which currently require disposal as radioactive waste. For the oil and gas sector the potential savings were not quantified due to lack of data; however, the unit costs of disposal of non-exempt waste are likely to be similar to those quoted for the steel industry (section 3.2.1). The potential savings are greatest for the Southern North Sea gas fields as lead-210+ and polonium-210 are the limiting radionuclides for the exemption of NORM waste in this geological region[20].

Changes to the Justification of Practices Involving Ionising Radiation

49. It is predicted that the introduction of the new justification requirements discussed above in section 3.1.5 will enhance public confidence in the safety of manufactured or imported consumer products, and improve public confidence in the use of non-medical imaging exposure equipment.

3.2.3 Monetised Cost

50. The costs associated with existing regulations (Option 0) constitute the baseline for comparison with Option 1. No additional monetised costs over and above the 'do nothing' option have been identified at this stage. Further evidence on costs will be sought through the consultation.

[19] Impact of Changes to Exemption and Clearance Values for Specific Radionuclides: Review and Industry Survey". Report produced by Public Health England's Centre for Radiation, Chemical and Environmental Hazards for Department of Energy & Climate Change.

[20] Information received from Oil & Gas UK Radiological Issues Technical Group meeting.

3.2.4 Non-Monetised Costs

Changes to NORM industrial activities

51. The changes to the list of NORM industrial activities (section 3.1.4) could result in a negative impact for the UK geothermal energy industry associated with the disposal of NORM waste, but it is not known at this stage what effect this change will have. As geothermal is a relatively small industry in the UK it may be difficult to investigate these impacts of this change. As this industry is in its infant stages, any added costs could hit the industry disproportionately hard. In order to mitigate the effect we need to better understand this highly innovative but still emergent low carbon technology. This can be better assessed during the consultation period.

Changes to the Justification of Practices Involving Ionising Radiation

52. Changes under Option 1 (set out in section 3.1.5) will impose some minor costs on the Government and industry which are difficult to quantify due to lack of available data, but which are likely to be very low. These are discussed below.

53. Article 20: With respect to consumer products, there will be a very minor additional requirement for the Justifying Authority to exchange information with other Member States on consumer product justification decisions.

54. Articles 22 (1) and 23: The Government will be required to seek to identify practices involving Non-Medical Imaging Equipment (NMIE) and Naturally Occurring Radioactive Material (NORM).

55. Article 22: There will be small additional administrative requirements (and costs) for operators of NMIE equipment:

- to secure a determination from the Justifying Authority that any new particular application of a NMIE practice falls within an existing class or type of practice;
- to set up systems either for justification of individual exposures, or for regular reviews of their NMIEs;
- and to set up a system to provide information to and seek consent from the individual to be exposed.

56. In addition, the requirement to ensure that requirements for NMIE practices, including criteria for individual implementation, are established is not expected to result in a material additional cost compared to the cost for operators of complying with self-imposed guidelines, which they already follow in practice. In addition, we think that all operators of NMIE equipment will be in, or will be acting on behalf of, the public sector (including contracted-out prisons), so the impact on private sector bodies will be minimal.

57. As mentioned earlier, further familiarisation costs are expected as a result of the transposition and will be monetised after further feedback is obtained from stakeholders.

Option 1 Summary

Impacts relative to baseline	Impact on	Monetised Amount
Changes to "out of scope" values for NORMs	Whole Industry	Savings of £2.5m per year
Changes to exemptions for NORMs	Whole Industry	Savings of £3.3m-£4.4m per year
Changes to Activity Values for Defining HASS	Industry (per permit holder)	Savings of £4000-£8000 per year
Changes to Activity Values for Defining HASS	Industry (per permit holder)	One-off saving of £6000-£12000

Policy Options relative to baseline over 10 years policy appraisal period	Total Net Present Value	Net Cost to Business per Year
Option 1	£55m	-£6m

58. The total net present value, net costs to business per year, based on the above impact summary table, are tabulated below.

4. Option 2 – The minimum changes required to transpose the BSSD plus measures to improve the regulatory framework

59. This option includes all of the changes, costs and benefits discussed under Option 1. However Option 2 goes further than Option 1 and also includes additional measures to improve the regulatory framework. **It is only these additional measures that are discussed below**. Please refer to option 1 above for the other regulatory measures included in this option.

60. These measures are not essential in order to comply with the BSSD but making these changes will have environmental benefits and reduce costs. These additional measures are described below (section 4.1 - 4.2). This option ensures compliance with the BSSD, in line with the UK's Guiding Principles for European Legislation, and maintains or improves the UK's high standards of radiological protection, whilst reducing excess environmental and economic costs. Option 2 is therefore the preferred option.

61. As the changes in Option 2 are not associated with the transposition of the BSSD they come into the scope of the 'One-In Three-Out' rule. For all additional regulation ('in'), it is a Government target to remove ('out') three times as much regulation. It has been assessed that the proposed measures are deregulatory. As such, the preferred option would contribute towards the 'out' component of this regulatory target.

62. We do not believe that there will be any unintended consequences of these changes but this will be tested through consultation.

4.1 Measures to improve the regulatory framework

4.1.1 Broken Gaseous Tritium Light Devices (GTLDs)

63. Gaseous Tritium Light Devices (GTLDs) are used for lighting where no power is available. The Ministry of Defence (MoD) report that these devices are used extensively within the defence estate.

64. The MoD currently has approximately 27,000 broken GTLDs that require disposal. The potential radiation doses to the public from broken GTLDs are not regarded as significant for realistic exposure scenarios[21]. Advice from the regulatory bodies, based on a review of the available evidence, suggests that disposal of broken GTLDs as radioactive waste results in disproportionate economic and environmental costs.

65. The disposal of intact sources up to 20 GBq[22] to landfill is currently exempt from regulation as radioactive waste. The wording of the radioactive substances legislation, as amended in 2011, inadvertently results disallows broken GTLDs to qualify for this exemption. In Option 2 this anomaly is removed, enabling broken GTLDs to qualify for exemption from radioactive waste management requirements.

[21] 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.

[22] Bq/ becquerel is the SI derived unit of radioactivity.

4.1.2 Legacy sites contaminated with radium

66. Natural background levels of radium-226 in the UK typically exceed the current "out of scope" level of 0.01 Bq/g. This is an issue for remediation work on legacy radium contaminated sites. It is proposed to apply a higher "out of scope" value for radium-226 to such legacy sites dealing with contaminated land. This is justified as there is a need to take into account the fact that background levels of radium-226 typically exceed the current "out of scope" level. In addition, the contamination is present as a result of past practices rather than an existing regulated practice.

4.2 Benefits

4.2.1 Monetised benefit

Changes to Broken GTLDs

67. The change to enable broken GTLDs to be exempt from regulation as radioactive waste (section 4.1.1) will be of particular benefit to MoD. MoD has approximately 500,000 sources in circulation, of which they have predicted that 400,000 are GTLDs. Some 27,000 of these GTLDs are currently due for disposal. This change will mean that broken GTLDs which meet the exemption criteria can be disposed to landfill. This will reduce disposal costs and lead to an annual saving of ~£100,000 for MoD[23].

4.2.2 Non-monetised benefit

Changes to legacy sites contaminated with radium

68. The change to the "out of scope value" for legacy sites contaminated with radium (section 4.1.2) would allow sites that meet the relevant criteria to use a greater "out of scope" value than the existing value of 0.01Bq/g. Background levels of radium-226 often exceed 0.01Bq/g, so this change would help reduce costs in terms of the remediation of contaminated land from legacy radium contaminated sites. We will attempt to quantify the benefit of the revised "out of scope" value following consultation.

Option 2 Summary

Impacts relative to baseline	Impact on	Monetised Amount
Changes to "out of scope" values for NORMs	Whole Industry	Savings of £2.5m per year
Changes to exemptions for NORMs	Whole Industry	Savings of £3.3m-£4.4m per year
Changes to Activity Values for Defining HASS	Industry (per permit holder)	Savings of £4000-£8000 per year to the whole industry
Changes to Activity Values for Defining HASS	Industry (per permit holder)	One-off saving of £6000-£12000 to the whole industry
Changes to Broken GTLDs	Government	Savings of £100,000 per year

69. The total net present value, net costs to business per year, based on the above impact summary table, are tabulated below.

[23] Information received as a result of correspondence with the Ministry of Defence.

Policy Options relative to baseline over 10 years policy appraisal period	Total Net Present Value	Net Cost to Business per Year
Option 2	£56m	-£6m

Summary and preferred option with description of implementation plan

70. In Summary, both Options 1 and 2 are viable options for the UK as they both comply with the BSSD and the UKs obligations under Euratom Law, whilst maintain or improve the UK's high standards of radiological protection. Option 2 is the preferred option as it includes all the changes in Option 1 with additional measures to improve the regulatory framework that in turn will decrease the burden on the public and private sector.

71. Given that Option 1 solely demonstrates direct transposition of the BSSD it is considered as a non-qualifying regulatory provision with regards to 'Business Impact Target Status' and 'One-In Three-Out' rules. However, Option 2 includes additional exemptions to broken GTLDs and legacy radium contaminated sites, and is therefore a qualifying regulatory provision. The additional measures within Option 2 are designed to improve the regulatory framework and further reduce the burden of regulation on businesses; this is conveyed below by the relative net direct costs to business per year. These initial results are based on the evidence that has been gathered thus far and indicate that these additional regulatory measures will reduce costs, in spite of the fact that they are additional. Further evidence around the impact of these measures will be sought during consultation to further test these results and better convey the impact on business.

Policy Options relative to baseline over 10 years policy appraisal period	Total Net Present Value	Net Cost to Business per Year
Option 1	£55m	-£6m
Option 2	£56m	-£6m

72. Our plan for transposition of the BSSD is to update existing legislation and where possible use a "copy-out" approach from the BSSD. A new statutory instrument will also be created for those requirements that do not have a natural fit in existing legislation. The changes to existing regulations have been developed to implement the minimum requirements of the BSSD. As mentioned above, the proposals were developed in close consultation with radiological protection experts at Public Health England, which advises government departments on radiation protection matters. Implementing in this way avoids the creation of a new regulatory regime, whilst ensuring high standards of risk control for public exposure to ionising radiation are maintained.

General Assumptions

73. The assessment of costs and benefits associated with changes to relevant legislation are presented in section 4. The general assumptions used to underpin the analysis in these sections are presented here.
74. It is assumed, based on our knowledge of the sector, that there is 100% compliance with existing regulations. Therefore, only additional costs that result from the proposed regulatory changes are considered in this IA.
75. As a result of amendments in this IA, changes to permits issued by the environment agencies might be required. This may result in costs to the agencies, industry, or neither, so this has not been factored in at this stage.
76. The PHE study on the Impact of Changes to Exemption and Clearance Values for Specific Radionuclides (sections 3.1.1 & 3.1.2) was based on information obtained from wide consultation with the nuclear industry and across the non-nuclear sector. This should provide confidence that industry concerns have been taken into account in identifying the significant changes in values. The changes to these values were allowed within the requirements of the BSSD therefore maintaining the UK's high standards of radiological protection whilst reducing the financial burdens on industry.
77. At this stage we believe that there are not any significant impacts that we have not taken into account. However, we will use the consultation to test whether there are any impacts and/or duty holders we have not included in this IA.
78. In places where we presently have no proven impact, we have estimated the likely impact of the change.

Risks

79. As mentioned in the costs of Option 0, there are potential risks associated with not fully transposing the BSSD:
    - Infraction proceedings
    - Fines
    - Failure to demonstrate that the UK is compliant with current Euratom radiation safety standards and the underpinning IAEA standards could result in loss of confidence in the UK regulatory framework.
80. The main risk associated with Option 1 and transposing the BSSD is related to incorrectly transposing the BSSD, partly transposing the BSSD or not transposing on time. In this scenario we are subject to the same consequences as in Option 0.
81. Option 2 includes the same risks as Option 1. However these risks are slightly increased as the extra work associated with additional measures to improve the regulatory framework could use time and resource, thereby making it more likely that we do not fully transpose the BSSD on time.
82. Although we have engaged with experts and industry to identify impacts of the changes proposed there remains a risk of unintended consequences. We will use the consultation to test further for potential unintended consequences prior to implementation of the changes.

Annex I – Abbreviations

BEIS	Department for Business Energy and Industrial Strategy
BSSD	Basic Safety Standards Directive 2013
DAs	Devolved Administrations
EPR	Environmental Permitting Regulations (England and Wales) 2016
GDP	Gross Domestic Product
GTLD	Gaseous Tritium Light Device
HASS	High Activity Sealed Source
IA	Impact Assessment
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
JOPIIR	The Justification of Practices Involving Ionising Radiation Regulations 2004
MoD	Ministry of Defence
NMIE	Non-Medical Imaging Exposure
NORM	Naturally Occurring Radioactive Material
PEWG	Public Exposures Working Group
PHE	Public Health England
RCL	Radioactive Contaminated Land
RPC	Regulatory Policy Committee
RSA	Radioactive Substances Act 1993
RWA	Radioactive Waste Advisors
SI	Statutory Instrument

Annex II - Euratom and the Basic Safety Standards Directive Continued

83. The five Directives[24] and one Recommendation[25] that have been consolidated into the BSSD are:
    - Basic Safety Standards, Directive 96/29/Euratom (BSSD96)
    - Medical Exposures, Directive 97/43/Euratom
    - Outside Workers, Directive 90/641/Euratom (OW)
    - Control of high activity sealed radioactive sources and orphan sources2003/122/Euratom (HASS)
    - Public Information Directive 89/618/Euratom
    - Radon, Commission Recommendation 90/143/Euratom
84. The Directives and the recommendation being consolidated are currently implemented in the UK through a range of legislation, which fall under the jurisdiction of a number of different government departments and overall coordination of the BSSD transposition falls to BEIS. This impact assessment only covers implementation of the BSSD in relation to public exposure to radiation and justification.

[24] http://www.ensreg.eu/nuclear-safety-regulation/eu-instruments/Basic-Safety-Standards-Directive

[25] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31990H0143

Annex III – Impact of Changes to exemption values for NORM waste

Cost of Disposal (per tonne) (2015)	
Base level cost of disposal (per tonne)	£1,000
Disposal cost of radioactive material (per tonne)	£4,500
Total disposal cost (per tonne)	£5,500
Total disposal costs per year (2015)	£3.3M - £4.4M