EXPLANATORY MEMORANDUM TO

THE SHIPMENT OF RADIOACTIVE SUBSTANCES (EU EXIT) REGULATIONS 2019

2019 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department for Business, Energy and Industrial Strategy and is laid before Parliament by Act.

2. Purpose of the instrument

2.1 This instrument corrects deficiencies in the operation of retained EU law within Euratom Regulation 1493/93 (the "Regulation") on the shipment of radioactive substances between EU Member States. The Regulation requires that shipments of radioactive sources between Member States are controlled and documented. On exit day, the Regulation will automatically become retained EU law through the European Union (Withdrawal) Act 2018 (the "EUWA") but will be inoperable. This instrument revokes the Regulation and replaces it with similar provisions so that the retained deficiencies are fixed, and the Regulation can continue to operate as it does now insofar as possible.

Explanations

What did any relevant EU law do before exit day?

2.2 The Regulation requires that shipments of radioactive sources between Member States are controlled and documented. The Regulation covers both "sealed" and "unsealed" radioactive sources. Sealed sources are radioactive material encapsulated in another material, usually metal, to prevent exposure. Unsealed sources are often test vials and powders, which tend to be lower activity and are safe to be unsealed.

2.3 The Regulation has two key aspects. The first of these, the requirement to obtain a prior written declaration, only extends to sealed sources. Under this requirement, before any shipment of sealed sources can take place, source holders are required to obtain a prior written declaration from the consignee of the source (the source receiver) to demonstrate that the consignee complies with national requirements for their safe storage, use and disposal. These declarations are stamped by the relevant competent authority (in the UK, the relevant environment agency). They can last up to three years and often cover more than one shipment.

2.4 The second key aspect of the Regulation requires source holders to submit a quarterly return detailing all the shipments made during the preceding quarter to the competent authority in the destination Member State. This part of the Regulation extends to both sealed and unsealed sources.

Why is it being changed?

2.5 The UK is leaving the Euratom Treaty on the same date as it is leaving the EU. On exit day, the Regulation will automatically become retained EU law through the EUWA but will be inoperable since it only applies to "shipments between Member States." In this event, the obligation for source holders and consignees to obtain prior

written declarations and submit quarterly returns falls away in practice as the retained law would not apply to shipments to/from the UK when it is no longer a Member State.

2.6 In this scenario, the UK's environment agencies would no longer have access to the information currently gained through the prior written declarations on the destination of sealed sources being imported into the UK from the EU. These declarations help ensure the UK's robust radioactivity safety standards are maintained. This instrument revokes the Regulation and replaces it with similar provisions so that prior written declarations are still required. This also provides important continuity and clarity for operators.

What will it now do?

2.7 The instrument revokes the Regulation and replaces it with similar provisions so that the system of prior written declarations continues to function as it does now insofar as possible. However, as a result of the UK no longer being a Member State, and for jurisdictional reasons, the system cannot continue in exactly the same way. As such, some changes are made from current arrangements. The changes do not place any additional requirements or obligations on industry or regulators, and ensure the UK's robust safety standards are maintained.

2.8 Three main changes are made. Firstly, the requirement to submit a quarterly return will not be replicated in this instrument. Secondly, the obligation to make a prior written declaration will apply to UK imports from the EU only and not vice versa. Lastly, the obligation to make the prior written declaration is placed on the source receiver in the UK. Further detailed information on these changes and the rationale behind them is provided in paragraph 7.3-7.6 of this explanatory memorandum.

2.9 After exit, UK consignees will be required to make a prior written declaration demonstrating that they comply with national requirements for safe storage, use and disposal, before any shipment of sealed sources from the EU to the UK can take place. Declarations must be sent by the consignee to the relevant environment agency in the UK, which will acknowledge receipt of the declaration. The consignee will then forward the declaration and acknowledgement to the EU based source holder before a shipment of sealed sources can be made. These prior written declarations will last up to three years and may cover more than one shipment in the same way as they did under the Regulation.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This instrument was laid for sifting on 29 November 2018. After considering the instrument, the Secondary Legislation Scrutiny Committee confirmed it was content for it to remain subject to the negative procedure. The European Statutory Instruments Committee recommended at its meeting on 11 December 2018 that the instrument be upgraded to the affirmative procedure. As a result, the instrument will be laid under the affirmative procedure.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of this instrument includes Scotland and Northern Ireland.

3.3 The powers under which this instrument is made cover the entire United Kingdom (see Section 24 of the European Union (Withdrawal) Act 2018) and the territorial application of this instrument is not limited either by the Act or by the instrument.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is the United Kingdom.

4.2 The territorial application of this instrument is the United Kingdom.

5. European Convention on Human Rights

5.1 The Minister for Business and Industry, Richard Harrington MP, has made the following statement regarding Human Rights:

5.2 "In my view the provisions of the Shipment of Radioactive Substances (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 On 29 March 2017, the Prime Minister triggered Article 50 of the Treaty on European Union and started the UK's exit from the European Union. To give effect to the UK's exit in domestic law, the EUWA provides that the UK will cease to be a Member State of the EU at 11pm on 29th March 2019. However, to ensure business and legislative continuity for the UK, following over 40 years of EU membership, the EUWA will preserve EU-derived domestic legislation (such as the Regulation) so that it continues to have effect in domestic law after EU exit.

6.2 This instrument uses the power in section 8(1) of the EUWA in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. Specifically, this instrument revokes the retained Regulation, and puts in place new domestic regulations, so that the regime can continue to operate as it does now insofar as possible.

6.3 The instrument also relies on the power in section 8(5) of the 2018 Act to provide the Secretary of State with powers to prescribe the procedural form that must be completed by persons submitting a prior written declaration of shipments of sealed radioactive sources.

6.4 References in the Regulation to provisions of Council Directive 80/836/Euratom laying down basic standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation have been updated to the corresponding provisions contained in Council Directive 2013/59/Euratom. These cross-references are key to the scope and application of the instrument as they define the quantities and concentrations of substances that trigger the need for a prior written declaration to be completed.

6.5 No specific criminal offences have been created for non-compliance for the new Regulation. There were no specific criminal offences set out in the previous Regulation, and it would not therefore be appropriate to create new offences or penalties.

7. Policy background

What is being done and why?

7.1 The UK is leaving the Euratom Treaty on the same date as it is leaving the EU. On exit day, the Regulation will automatically become retained EU law through the EUWA, but it would be completely inoperable since it only applies to "shipments between Member States."

7.2 This instrument revokes the Regulation and replaces it with similar provisions so that it continues to function as it does now insofar as possible. However, as a result of the UK no longer being a Member State, and for jurisdictional reasons, the system cannot continue in exactly the same way.

7.3 Three changes are made from current arrangements. Firstly, unlike the Regulation, this instrument will apply only for imports from the EU into the UK. The position in relation to UK exports into the EU sits within the EU's competence after exit, as domestic regulations could not obligate EU Member States' competent authorities to comply with the aspects obligating them to confirm receipt, process and return declarations.

7.4 Secondly, only the obligations in the Regulation relating to the making of a prior written declaration are replicated in this instrument. The obligation for Member State source holders to submit a quarterly return detailing all of the shipments (both sealed and unsealed) made during the preceding quarter to the relevant competent authorities in the destination Member State will fall away. This is because, for jurisdictional reasons, the UK cannot place an obligation on EU source holders to submit a quarterly return to a UK based competent authority. As the quarterly return was the only part of the Regulation which extended to unsealed sources, this also means that this instrument will only extend to sealed sources. Not continuing the requirement to make quarterly returns poses no concern. The UK environmental permitting regime allows the environment agencies across the UK to require permitted sites who receive both sealed and unsealed sources to record receipt of those sources.

7.5 Thirdly, under the Regulation, the obligation to obtain the prior written declaration sits with the source holder. Again, for jurisdictional reasons, this instrument places that obligation on the consignee in the UK. In practice, this change places no additional requirements on UK operators.

7.6 The differences between this instrument and the Regulation are necessary in order to put in place an operable regime in the context of the UK no longer being a Member State, and the jurisdictional constraints of domestic regulations. The changes to the system ensure the prior written declarations can continue for imports from the EU into the UK. This means that the environment agencies will continue to receive advance information regarding shipments of sealed sources into the UK from the EU and the UK's robust safety standards are maintained.

7.7 The changes to the system do not in practice place any additional requirements or obligations on industry or regulators.

7.8 The effect of this instrument is that after exit, before a shipment of sealed radioactive sources can take place from the EU into the UK, consignees will be required to make a prior written declaration demonstrating that they comply with national requirements for their safe storage, use and disposal. Declarations are sent by the consignee to the relevant environment agency in the UK, which will acknowledge receipt of the

declaration. The consignee will then forward the declaration and acknowledgment to the source holder before a shipment of sealed sources can take place. These prior written declarations will last up for to three years and may cover more than one shipment. Any extant prior written declarations for shipments from the EU to the UK stamped prior to exit day under the provisions of the Regulation, and which have not reached the end of their three year lifespan, will continue to be recognised as valid after exit.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument is being made using the power in section 8(1) of the European Union (Withdrawal) Act 2018 in order to address failures of retained EU law to operate effectively or other deficiencies arising from the withdrawal of the United Kingdom from the European Union. The power in section 8(5) of the 2018 Act is also utilised to provide the Secretary of State with powers to prescribe the procedural form that must be completed by persons submitting a prior written declaration under the provisions of this instrument. In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 This instrument does not involve consolidation.

10. Consultation outcome

10.1 Officials have drafted the Regulations collaboratively with colleagues in the Devolved Administrations and in the UK's environment agencies. No public consultation has been undertaken for this instrument as it does no more than is necessary to correct deficiencies in retained EU law and seeks to maintain current policy arrangements insofar as possible.

11. Guidance

11.1 Administrative guidance will be provided alongside the new standard document for declarations for shipments of radioactive substances into the UK. The guidance will set out the administrative procedures for completing the documentation for the benefit of UK operators and the competent authorities who are responsible for collecting and acknowledging receipt of the information provided in the prior written declarations.

11.2 The administrative guidance will be published online alongside the new standard form for the prior written declarations at least a month prior to the coming into force of this instrument. The guidance will be maintained by the Department for Business, Energy and Industrial Strategy.

11.3 The Government published a technical notice on the arrangements that would be in place in a no-deal scenario for civil nuclear regulation on the 23 August 2018. Attention has been drawn to the technical notice via email communication to the relevant stakeholders.

12. Impact

12.1 There is no significant impact on business, charities or voluntary bodies.

12.2 There is no significant impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument as there are limited costs to business as a result. This instrument provides important continuity and clarity for the importers of radioactive sources in the UK. Without this SI, inoperable legislation would be retained on exit, which could cause confusion for operators.

12.4 No ongoing costs to businesses are expected as a result of this SI. The SI replicates the existing process for UK importers insofar as possible. We do not expect that importers will need to change their activities, so we do not expect any additional ongoing costs.

12.5 There will be very minor familiarisation costs associated with this SI for businesses, essentially related to the need for an official at each enterprise affected to read the SI. We estimate there are around 100 businesses that ship radioactive sealed sources in the UK. Using an assumption of enterprises needing between one to three hours to familiarise themselves, and a range of hourly wage rates from ONS (using "Professional, Scientific and Technical Activities" sector), we estimate one-off familiarisation costs of between £1,400 and £9,100.

13. Regulating small business

13.1 There may be small businesses that ship radioactive substances. All businesses, regardless of size, will be required to familiarise themselves with these regulatory changes. There is no alternative way of implementing the measure other than making changes to legislation. However, the overall impact on businesses will be very minor and familiarisation with the changes will be a one-off activity. The instrument will impose no ongoing impacts on small businesses for the reasons stated above.

14. Monitoring & review

14.1 As this instrument is made under the EUWA, no review clause is required.

15. Contact

15.1 Abigail White at the Department for Business, Energy and Industrial Strategy, telephone: 020 7215 3942 or email: abigail.white@beis.gov.uk, can be contacted with any queries regarding the instrument.

15.2 Katrina McLeay, Deputy Director for the Euratom Exit Programme at the Department for Business, Energy and Industrial Strategy, can confirm that this Explanatory Memorandum meets the required standard.

15.3 Richard Harrington MP, Minister for Business and Industry at the Department for Business, Energy and Industrial Strategy, can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/Sifting Committees
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising sections 8(1), 9, and	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		23(1) or jointly exercising powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising sections 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Schedule 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s. 2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s. 2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Minister for Business and Industry, Richard Harrington MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

1.2 "In my view the Shipment of Radioactive Substances (EU Exit) Regulations 2019 does no more than is appropriate".

1.3 This is the case because the instrument is designed solely to correct a deficiency in UK law stemming from the UK's exit from the European Union. This will ensure that inoperable legislation is not retained on the UK statute book. No substantive policy changes are brought in by this instrument.

2. Good reasons

2.1 The Minister for Business and Industry, Richard Harrington MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

2.2 "In my view there are good reasons for the provisions in this instrument, and I have concluded they are a reasonable course of action".

2.3 These are that this instrument, in line with section 8(1) of the European Union (Withdrawal) Act 2018, corrects deficiencies as necessary to ensure imports of radioactive substances into the UK from the EU continue to be declared to the relevant environment agency in the UK.

3. Equalities

3.1 The Minister for Business and Industry, Richard Harrington MP, has made the following statement:

3.2 "The draft instrument does not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts."

3.3 The Minister for Business and Industry, Richard Harrington MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

3.4 "In relation to the draft instrument, I, Richard Harrington have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

3.5 This instrument does not raise any issues relevant to the public sector equality duty under section 149(1) Equality Act 2010 because the measures it implements do not have a human or social policy dimension.

4. Explanations

4.1 The explanations statement has been made in section 2 of the main body of this explanatory memorandum.

5. Legislative sub-delegation

5.1 The Minister for Business and Industry, Richard Harrington MP, has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

5.2 "In my view it is appropriate to create a relevant sub-delegated power in the Shipment of Radioactive Substances (EU Exit) Regulations 2019".

5.3 The instrument contains provisions allowing the Secretary of State to prescribe the form that must be completed by persons submitting prior written declarations of shipments of sealed radioactive substances. This is to permit the Secretary of State to work collaboratively with the competent authorities in the United Kingdom to design an appropriate UK-wide form to replace the form that was previously prescribed by the EU in Euratom Regulation 1493/93.