

Regulatory Triage Assessment

Title of measure	
Lead Department/Agency	
Expected date of implementation	
Origin	EU
Date	24/08/17
Lead Departmental Contact	Azmi Sbaiti (BEIS)
Departmental Triage Assessment	Low-cost regulation (fast track)

Rationale for intervention and intended effects

This RTA examines the transposition of Emergency Planning and Response (EP&R) elements of the Basic Safety Standards Directive (Council Directive 2013/59/Euratom), referred to hereafter as the BSSD 2013, as they apply to the transport of radiological material. This relates to part of a wider consultation on the EP&R elements of the BSSD and other consultations on Public Exposures and Occupational Exposures.

The BSSD 2013 consolidates and updates existing Euratom provisions for protection against the harmful effects of ionising radiation. It establishes minimum standards for radiological protection of workers, medical patients and the public in existing, planned and emergency situations. The BSSD 2013 replaces the Basic Safety Standards Directive 1996 (BSSD 1996) together with a number of other related directives. BSSD 2013 applies to practices, including the transport of radiological materials.

Implementing the BSSD 2013 will align current UK legislation with current regulatory guidance as current regulatory guidance meets the minimum standard of the BSSD 2013. Reinforcing regulatory guidance by transposing the BSSD 2013 will improve public protection and reduce any adverse consequences in the event of an emergency. Government intervention to provide such safety standards is generally required as the impact of events they seek to mitigate is not borne by those industry participants with the ability to mitigate these impacts and therefore are not incentivised to do so (i.e. there is a negative externality market failure). In the absence of such standards, the risk of emergencies arising from the transport of radiological materials and cost to society of these emergencies would be significant. Safety standards reduce the risk of long-term damage to society and the wider environment as a result of accidents involving radioactive materials. Industry already comply with similar safety standards. However, this measure will create a single standard to be adhered to by removing any discrepancies that exist between regulations and pre-existing guidance. Current and future businesses will benefit from additional clarity over what is required to operate in a way that is compliant with safety standards and minimises the negative externalities that could arise from accidents involving radiological material.

The specific policy objectives are to:

- maintain a proportionate approach to radiological emergency planning;
- maintain or increase public confidence in the radiological sectors;
- minimise the burdens on business and local authorities where complying with regulations can be made simpler.

The Government intends to make a number of minor changes to the CDG 2009 to deliver on these policy outcomes. We plan to use powers in the Energy Act 2013 to

make the required changes to the CDG 2009. The regulator, the Office for Nuclear Regulation (ONR), may choose to issue supplementary or updated guidance in addition to the changes to regulation as per their role set out in the Energy Act 2013.

Viability policy options (including alternatives to regulation)

BEIS undertook a thorough gap analysis to identify the legislative changes required to transpose the Directive. The BSSD 2013 requires Member States to enforce the provisions of the Directive so this requires a basis in legislation.

Alternatives to regulation have been considered, but were not deemed to be viable as they would not fulfil the UK's obligations under Euratom. Moreover, a 'do-nothing' option would mean BSSD is not fully transposed into UK law. This would not be in line with the UK's commitment to adhering to the highest standards of nuclear safety, and would result in a lower level of safety to the public and the environment when compared to other countries.

The preferred policy option is to transpose the relevant EP&R articles of the BSSD 2013 into GB law, where our current regulations are either outdated and do not meet the latest requirements; or where there is a gap in our requirements.

To meet the requirements of the directive, we propose to make three changes:

1. Expand the definition of an emergency to make explicit reference to property and the environment
2. Revise the high-level requirements for consignors and carriers to adhere to when developing emergency plans;
3. Introduce a requirement for the carriers and consignors to produce a handover report for key agencies involved in transitioning to business as usual. This will facilitate the transition from an emergency exposure situation to an existing exposure situation and consider wider contamination.

These proposed changes will allow the UK to fully transpose the BSSD 2013. These are the minimum required changes to meet the requirements of the Directive. Changes beyond the minimum were considered, but would result in further associated costs and would not have led to a further increase in public protection, for example greater oversight of emergency plans by the regulator. However, this was not required by the Directive and was not requested by the regulator.

Initial assessment of impact on business

ONR estimates there are approximately 1,300 carriers and consignors of radioactive material in GB. All carriers and consignors are required under the CDG 2009 regulations to develop an emergency plan appropriate for the package and type of radioactive material being transported. To comply with our proposed changes to legislation, these businesses will have to make a number of minor changes to their emergency arrangements.

The government does not foresee significant impacts on businesses. This is because our legislative changes will incorporate existing ONR guidance so, provided dutyholders have followed this, they should be at least familiar with our proposed changes. The proposed changes will affect all of the carriers and consignors in GB.

The estimated costs to business of this policy lie in a range of £156,000 to £1.68 million, with our best estimate of costs being £455,000. We are expecting these costs

to be a one off as it involves the update of the templates used for future emergency plans, and will all be associated with the familiarisation with the new regulations. In estimating these costs we have assumed that all dutyholders undertake a one-off update of their arrangements, rather than (as may be more likely and more efficient) make changes as part of scheduled updates. This is because carriers and consignors will have established processes in place for creating emergency plans already, and these are minor changes to that process.

BIT status/score

Given that this RTA is for the transposition of an EU Directive, and the preferred policy option is designed to directly bring UK legislation in line with the EU standard and nothing more, this RTA is considered as a Non-qualifying regulatory provisions (NQRP).

BIT Score	Total Net Present Value	Net Direct Cost To Business Per Year
£0.0mn	£0.5mn	£0.0mn

Rationale for Triage rating

The proposed measure is a low-cost regulation that qualifies for the fast-track process because the gross costs to business do not exceed £1 million. The high estimate would only be realised if the entire industry required two days for the full familiarisation process and recruited a Dangerous Goods Safety Advisory (DGSA) at the most expensive hourly rate. We deem this to be highly unlikely as the requirements for dutyholders and ability to meet this cost would vary considerably across the sector.

Departmental signoff (SCS):Rhiannon Harries **Date:** 23/08/2017

Economist signoff (senior analyst): Joel Davis **Date:** 24/08/2017

Supporting evidence

1. The policy issue and rationale for Government intervention

The Basic Safety Standards Directive (2013/59/Euratom), referred to hereafter as the BSSD 2013, consolidates and updates existing Euratom provisions for protection against the harmful effects of ionising radiation. It establishes minimum standards for radiological protection of workers, medical patients and the public in existing, planned and emergency situations. The BSSD 2013 will repeal and replace the BSSD 1996 in addition to consolidating a number of other, related directives. The Directive applies to practices including the transport of radioactive materials.

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. The UK government's approach to EU Directives post EU referendum is therefore that the UK should continue to negotiate, implement and apply EU legislation to the timelines laid down for transposition and maintain such standards thereafter.

In GB the transport of radioactive materials is subject to a number of regulations, including the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (referred to hereafter as the CDG 2009), and the Ionising Radiations Regulations 1999 (referred to hereafter as the IRR 1999). In Northern Ireland, the transport of radioactive materials is regulated by the Carriage of Dangerous Goods and Transportable Pressure Equipment (Northern Ireland) 2010. Northern Ireland will be consulting separately on any changes they will be making to their regulations.

BEIS undertook a thorough gap analysis to identify the legislative changes needed to transpose the Directive and this is detailed in Chapter 2 of the consultation document. While the CDG 2009 is generally compliant with the requirements of the BSSD 2013, our gap analysis identified three areas that will need to be amended. These are: the definition of an emergency, the principles guiding emergency plans, and the transition from an emergency to recovery.

2. Policy objectives and intended effects

The Government's policy objective is to ensure that GB is fully compliant with BSSD 2013. The intended effect of these amendments is to strengthen GB's emergency management system for radiological emergencies during the carriage of UN Class 7 dangerous goods by road, rail and inland waterway. Furthermore, where possible, we will seek to clarify in legislation the duties on carriers and consignors in the CDG 2009 (currently set out in ONR guidance). Finally, we intend to minimise any burdens placed on business through these changes by making regulations clearer and compliance easier as a result.

3. Policy options considered, including alternatives to regulation

Do nothing option

This does not amend the CDG 2009 and would result in GB not being compliant with BSSD 2013. There are no additional costs associated with this option, but as it does not meet the policy objective, it is not a viable option.

Preferred option

The government's preferred option is to make minor amendments to the CDG 2009. These amendments will ensure GB's emergency management system is fully compliant with the requirements of the BSSD 2013.

The minor amendments proposed are as follows:

1. Definition of an Emergency

The CDG 2009 defines an emergency as “a situation arising during the course of the carriage of a consignment that requires urgent action in order to protect workers, members of the public or the population (either partially or as a whole).” We have concluded that by comparison to the CDG 2009, the scope of the BSSD 2013 definition is broader and more comprehensive. It includes explicit reference to the protection of “property or the environment”. Therefore in order to fulfil these requirements of the Directive, we will need to amend the CDG 2009 definition of an emergency to include these.

In making this amendment, the government will aim to improve consistency across the UK's legislative framework for emergency preparedness. We propose to align the CDG 2009 (with 2018 amendments) with the updated Radiation (Emergency Preparedness and Public Information) Regulations 2018 (referred to hereafter as the REPIR 2018). See the consultation document published alongside this assessment for more details. This definition makes clear that an emergency includes those events which require action to mitigate adverse consequences to human life, health, property or the environment.

We consider that, in practice, this will make little or no difference to the requirements placed on dutyholders to plan for emergencies. This is because it is hard to conceive of an emergency in which protection to the public can be achieved without considering the impacts on the environment and property. Therefore, the impact of this change – beyond familiarisation – will be negligible.

Guidance¹ produced by the ONR states a consignor and carrier's plan must consider actions “to protect workers, members of the public, attending emergency services and the environment”. Our proposed change to the

¹ <http://www.onr.org.uk/transport/emergency-arrangements-guidance.pdf>

regulations will make explicit the importance of considering environmental contamination when planning for radioactive transport emergencies.

2. Emergency Preparedness – development of emergency plans

Under the current CDG 2009, consignors and carriers are required to prepare emergency plans and respond in certain ways in the event of an emergency. These regulations require that before the carriage of a package begins, both the consignor and carrier must ensure that they have an emergency plan that sets out the emergency arrangements as are appropriate for the carriage of that package. This plan must be prepared having regard to four points, Schedule 2, paragraph 4(2):

- “(2)The plan must be prepared having regard to—
- (a) the principle that intervention is to be undertaken only if the damage due to the radiation resulting from the radiation emergency is sufficient to justify the potential harm and the potential cost (including the social cost) of that intervention;
 - (b) the principle that the form, scale and duration of the intervention should ensure that the benefit to health will be greater than any harm that might be associated with the intervention itself;
 - (c) the dose limits provided for in Schedule 4 to the Ionising Radiations Regulations 1999; and
 - (d) the levels of radiation dose applicable in an emergency that are specified by the Health Protection Agency pursuant to its functions under section 3 of the Health Protection Agency Act 2004(a).”

These were introduced following the requirements of the previous BSSD 1996. The government plans to update these regulations to fully transpose the BSSD 2013.

The update that the government intends to make will be in line with existing ONR emergency arrangements guidance². The guidance sets out the immediate notifications to be made, actions to protect the driver, actions to protect the public, actions to protect the emergency services, how to prevent the situation from escalating, actions to ensure the radioactive materials remain secure, and the actions to be taken by the consignor.

The ONR has produced this guidance to aid dutyholders with the development of emergency arrangements that will be reviewed as part of its targeted inspection regime. Failing an inspection would result in an improvement or prohibition notices being issued by the regulator which would affect a dutyholder’s ability to trade and operate. Therefore we assume that, in their best interest, the dutyholders already take note of this guidance and, as a result, that any associated burden of complying with this change, beyond familiarisation, will be negligible.

² <http://www.onr.org.uk/transport/emergency-arrangements-guidance.pdf>

3. Transition from an emergency exposure situation to an existing exposure situation

The BSSD 2013 introduces a new requirement to make provision in plans for the transition from an emergency exposure situation to an existing exposure situation. This transition process is often referred to as the transition to recovery in the UK. While we recognise that the responsibility of overseeing the transition to recovery would fall out of the carrier and consignor's scope and they do not need to plan for it, our regulations can ensure they support this process through planning.

In the event of a transport emergency, CDG 2009 places a duty on the driver, carrier and consignor to notify the GB Competent Authority (the ONR) and to assist in any intervention that is made in connection with that emergency. The carrier also has a duty to "arrange for the examination of the load so as to determine whether contamination has arisen and, if it has, to arrange for the safe disposal of any part of the load that has been decontaminated and for the decontamination of the transport unit or train."

The ONR has developed guidance on radiation and contamination monitoring requirements to help dutyholders interpret their duties under the CDG 2009. This guidance suggests that, in the event of an accident, an assessment should be conducted to determine the extent of any contamination and radiation levels associated with the package. Information regarding any radiological implications to people, property and the environment should follow from this assessment to inform next steps. We want to ensure that this information is made available to the relevant authorities who are responsible for this recovery process.

In order to facilitate an effective transition from an emergency exposure situation to an existing exposure situation, we plan to introduce a requirement for a handover report to be produced and submitted to the relevant authority. This report will document and collate any contamination and radiation assessments that have been conducted, as well as any relevant information that would be helpful in facilitating this transition process. This handover will take place following the completion of the intervention protocols (CDG 2009 Schedule 2, paragraph 5) enacted by the consignor and carrier.

In reality the different components to be included in this handover report will already exist under current protocols and arrangements created through compliance with ONR guidance. Introducing the need for a report to consolidate these documents into regulations will help formalise this arrangement and ensure that all relevant information is provided to the relevant authorities with which they can facilitate the transition to an existing exposure situation.

We anticipate that the impact of this change will be minor. To address this requirement, existing emergency plans should only require minor updates, making clear that the information is to be collated and shared with the relevant

authorities. As such, any burdens created for carriers and consignors at the planning stage would be negligible and are included in familiarisation costs.

Making these amendments to the CDG will help to align our regulations with pre-existing guidance and will ensure that any and all impacts of an emergency scenario are considered within a carrier's or consignor's emergency arrangements. In considering the additional aspects of property and the environment, this will improve public protection and reduce any adverse consequences of any transport radiological emergency.

Alternative Options

Alternative options to amend guidance to meet these requirements were considered in detail, but did not offer an effective way to achieve our policy objective. Changes beyond the minimum requirements were considered but would result in further associated costs and would not have led to a further increase in public protection, for example greater oversight of emergency plans by the regulator. However this was not required by the Directive and was not requested by the regulator. The BSSD 2013 requires Member States to transpose into legislation and to be able to enforce the requirements of the Directive so non-legislative options were not viable.

4. Expected level of business impact

Summary

Overall, we expect the proposed measures to have very limited associated costs to dutyholders beyond familiarisation costs.

Existing guidance developed by the ONR already incorporates the basis of two of our proposed changes: the definition of emergency addressing property and the environment; and the revision of the criteria which should be considered when developing one's emergency plans. We envisage that our third change will require minor revisions to emergency plans.

The government acknowledges it will be necessary for the existing ONR guidance to be revised to ensure the new statutory requirements of the CDG 2009 (with 2018 amendments) are reflected in their entirety. Costs associated with the development of guidance are not considered in this RTA.

Any costs associated with any of these changes will be a one off. Furthermore, costs incurred in the event of an emergency would be negligible, with the majority of them linked to the handover report.

We have considered costs to other parties (first responders) and concluded that there will be none because our proposed changes to the CDG regulations will only place duties on carriers and consignors and not other parties. Furthermore, we do not expect any costs these policies place on these businesses to have any significant indirect impact on other parties, particularly as the bulk of costs pertain to familiarisation costs.

Number of businesses affected

These proposed changes will affect all of the carriers and consignors that are involved with the transport of radioactive materials. The ONR estimates there are approximately 1,300 consignors and carriers in GB across both the nuclear and non-nuclear sectors.

Benefit to business

The main benefit of these policies will be to maintain the highest standards of safety and keep GB in line with international standards, improving public confidence in industry. This, in turn, will support a safe and prosperous future for businesses involved in the transport of radiological materials by ensuring public confidence is improved. In the event of an emergency, these changes will mitigate adverse consequences and support business continuity and resilience.

General assumptions

That all dutyholders are compliant with existing regulations.

That all dutyholders note and follow ONR guidance.

That any costs associated with the ONR revising this guidance to reflect the changes to the CDG will be taken in to account by the ONR as they will be revising their current guidance irrespective of the transposition.

Familiarisation costs associated with policy decisions

Familiarisation will apply to all dutyholders involved with the transport of radioactive materials, as well as those who have an interest in the CDG. It is assumed that all dutyholders adhere to these regulations once they come into force in February 2018. We do not foresee any further applicable implementation costs following the revision of these regulations.

For the purposes of these changes, the government has considered familiarisation to include: reading and understanding any legislative changes; providing advice to others in the organisation where necessary; assessing compliance against new arrangements; and making necessary revisions to emergency arrangements.

We expect a dutyholder to utilise the service of a Dangerous Goods Safety Advisor (DGSA) to advise on any changes to regulations, update their organisation's emergency arrangements and plans. ONR recommends that these specialists are consulted for such purposes and their appointment is required as part of compliance with wider transport regulations (the European agreements: Accord européen relatif au transport international des marchandises dangereuses par route (2015) (ADR) and Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)). The level of dependency an organisation will place on a DGSA to revise their emergency arrangements will be determined by the dutyholder's competency and understanding of the regulations and guidance. As an organisation's level

of competence is a difficult variable to predict, we will assume that all dutyholders will require advice from a DGSA. This assumption is purposefully conservative to ensure we are not underestimating any potential impacts.

The status of DGSAs is likely to vary from organisation to organisation. Small Medium Enterprises are likely to hire a DGSA as a consultant as and when required. DGSAs have stated that, if hired as a consultant, their likely fee ranges between £30-90 per hour. Larger organisations are likely to have DGSAs hired as full-time employees and it is likely that larger organisation will have a team of full-time DGSAs.

The costs associated with a DGSA employed on a full-time basis updating the relevant emergency arrangements are also difficult variables to predict. To be conservative we will assume that all dutyholders will hire and seek advice on a consultative basis. We anticipate that the one-off costs associated with seeking the advice and input of a consultant will be higher than those of a full-time employee.

Advice from industry stakeholders and the ONR was to be conservative with any assumptions for familiarisation. As such, we assume that familiarisation and the aspects it involves will take a DGSA, or team of DGSAs approximately one day (seven hours). We appreciate the size and scale of a dutyholder's emergency arrangements will affect this assumption. To be conservative in our analysis, we will introduce two other time scales to reflect the low and high scenarios. The standard assumptions for reading and comprehension based on estimates from ReadingSoft(<http://readingsoft.com/>) would suggest familiarisation time to be between 30 minutes and two hours. After a provisional consultation, it was deemed these estimates were not practical in this instance as they would not be representative of the time taken to address all aspects involved with familiarisation. As a result we have adopted a more conservative approach, in which we expect familiarisation of the new regulations to be half a day (four hours), one day (seven hours) and two days (14 hours) for the low, central and high scenarios, respectively.

The familiarisation cost to dutyholders is estimated as:

DGSA hourly fee x time taken to read amendments to CDG regulations x
number of dutyholders (consignors and carriers – estimated at 1300)

This results in estimated familiarisation costs of:

Table 1: Costs associated with familiarisation.

Cost of DGSA (per hour, 2017 prices)	Low	Central	High
£30	£156,000	£273,000	£546,000
£50	£260,000	£455,000	£910,000
£90	£468,000	£819,000	£1,638,000

Note: time taken to update emergency arrangements: low = half day (4 hours). Central = one day (seven hours) High = two days (14 hours).

The CDG 2009 regulations state that emergency plans should be tested at suitable intervals, with ONR supporting guidance expecting that this testing should be carried out annually. This guidance also suggests that training should be delivered to ensure that each person with a role in the emergency plan understands their duties in the event that the plan needs to be used, that these plans should be revised where necessary to meet the requirements of testing criteria, and that all relevant people should be made aware of any changes as and when they occur.

As such, we can assume that there will be no additional costs associated with training because these additional requirements, in particular the production of a handover report, would be subsumed into dutyholders' existing annual testing and training budgets.

Total cost to business

The low, central and high scenarios have been estimated for the costs to businesses varying the time taken for familiarisation, the time taken to revise emergency plans, and the fees associated with hiring a DGSA. The costs to business are in a range of £0.16 million to £1.64 million. We expect these business costs to be one off. Our most reasonable case scenario is the central cost of £455,000. This gross cost to business does not exceed £1 million so therefore it is concluded that this policy is suitable for fast-track assessment as a low-cost measure.

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