Title:
Transposition of Directive 2011/75/EU of 2 September 2011 amending Council Directive 96/98/EC on marine equipment which updates the text of the technical Annex A to the Marine Equipment Directive bringing it in line with current international standards.

IA No: DfT00188

Lead department or agency:
Maritime and Coastguard Agency

Other departments or agencies:
Department for Transport

Impact Assessment (IA)

Date: 11/02/2013

Stage: Final

Source of intervention: EU

Type of measure: Secondary legislation

Contact for enquiries:
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Summary: Intervention and Options

RPC: RPC Opinion Status

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£0 - £5.2m	£0 - £5.2m	-£4.8m to £0	No	NA

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

Directive 2011/75/EU on marine equipment is the seventh annual update (Seventh Amendment) to the list of international standards required to maintain the uniform testing, approval and certification process of international standards for marine equipment within EU Member States. Without international standards the quality of marine equipment would vary significantly across the world. UK approval bodies can still undertake testing and approvals but from 5 October 2012 are no longer able to issue approval certificates until this Seventh Amendment is transposed. Government intervention is necessary to approve transpostion of the Seventh Amendment to allow the UK approval bodies to continue to issue approval certificates and to allow UK and non-UK manufacturers to have their equipment approved in the UK.

What are the policy objectives and the intended effects?

The transposition of the Seventh Amendment will update the list of international standards for marine equipment into UK law. This has the following policy objectives to:
1) protect UK approval bodies designated to issue approval certificate from potential loss of business as they are unable to provide this service at the moment; and
2) protect both UK and non UK manufacturers who would normally have their equipment approved in the UK from occurring additional costs to transport and approve their good in other Member States.

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

Transposition of the Seventh Amendment (option 1) does not introduce new legislation and does not affect existing policy. It only reflects the changes made within the year to any international standards on marine equipment. Do nothing is the baseline against which option 1 is assessed. Failure to transpose the Seventh Amendment would have detrimental effects of the UK maritime industry - on both UK approval bodies who would be unable to operate and also to UK and non-UK manufacturers who would not be able to obtain approval from UK approval bodies. Therefore, transposition of the Seventh Amendment is the only viable option and so is the preferred option. Existing UK legislation, Merchant Shipping (Marine Equipment) Regulations 1999 (SI 1999/1957) allows for transposition of the Seventh Amendment through amendments to two existing Merchant Shipping Notices (MSNs). This does not go beyond the minimum EU requirement to implement the EU Directive and is in line with the Coalition Government's Principles of Regulation.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** March 2013

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: Stephen Hammond Date: 16/04/2013

Summary: Analysis & Evidence

Policy Option 1

Description: Transpose the minimum requirements of Directive 2011/75/EU through amendments to two Merchant Shipping Notices to update the list of international standards for marine equipment into UK law.

FULL ECONOMIC ASSESSMENT

Price Base Year 2012	PV Base Year 2013	Time Period Years 1	Net Benefit (Present Value (PV)) (£m)		
			Low: £0	**High: £5.2m**	**Best Estimate:** NQ

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

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

Due to lack of evidence it has not been possible to quantify any of the costs in this IA but all costs are considered negligible as described in the next box.

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

Approval Bodies: Negligible - only action required from the transposition is merely adding the new Directive number to the existing certificate template. No familiarisation costs would be incurred.
Manufacturers: £0 - There are no anticipated costs to UK manufacturers because the approval and certification process will be maintained as per previous amendments and no familiarisation costs would be incurred.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A		£0	**£0**
High	N/A		£5.2m	**£5.2m**
Best Estimate	N/A		Not Quantified	**Not Quantified**

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

Approval Bodies: Maintaining approvals business - In long run, it is not possible for UK approval bodies to function in this capacity without pursing this option. The extent of this benefit depends on several factors (inc. how resources used to perform these services would be redeployed and extent of transition costs). Due to lack of evidence, it is not possible to provide a point estimate but a range is estimated between £0 and £5.2m. The upper end of the range is the annual size of the UK approvals industry.

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

Manufacturers: 1) Travel cost savings since manufacturers would not need to take their piece of equipment to a non-UK approval body to be tested or pay for the costs of the non-UK approval body to come to their site to test the equipment.
2) Possible cost savings for manufacturers because UK approval bodies could in some circumstances offer more competitive rates for testing equipment and issuing approval certificates.

Key assumptions/sensitivities/risks **Discount rate (%)** N/A

Assumptions: 1) Appraisal period is set for one year since the Seventh Amendment will be replaced by the Eighth Amendment after one year; 2) The number of approvals undertaken over the Seventh Amendment period is assumed the same as the Sixth Amendment period and there is no seasonality in the number of approvals; 3) Nominated bodies (a type of approval body) are considered to rarely undertake approvals.
Risks: There are no risks identified with pursuing this option but if this option was not pursued the UK would be at risk of infraction proceedings and the associated fines.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: Negligible	**Benefits:** £0-£4.8m	**Net:** -£4.8m to £0	No	NA

Evidence Base (for summary sheets)

1. Background

Shipping accidents are of concern to the European Union, in particular those which cause loss of human life or major pollution in EU sea areas and along the coastlines of Member States. Therefore, the Commission considered it vital that an EU-level system of approvals for marine equipment was established capable of substantially reducing the risk of such accidents. A critical part of developing such a system was the development and implementation of high common safety standards for equipment carried on board EU-flagged ships. In particular, it was clear that establishing a consistent and high quality testing and approval methodology would have a very significant positive effect on the performance of equipment.

It is acknowledged that the maritime sector is a global industry and that the implementation of existing international standards varies greatly throughout the world. This poses a fundamental problem for any country, or regional association of countries, which would like to ensure high safety standards for ships operating in, or near to, their coastal waters.

Council Directive 96/98/EC on marine equipment (MED)

With these issues in mind, the EU introduced the MED, which applies the uniform application of the relevant international standards for equipment placed on board EU ships. Such equipment would require certificates that are issued by or on behalf of the EU Member States by approval bodies in accordance with international instruments. This is to ensure the free movement of such equipment within the EU.

The MED sets out an approval process and the appropriate international instruments, which together set out the standards applicable for equipment placed on EU-flagged ships and for equipment available on the EU market. Relevant marine equipment is listed in Annex A of the MED and this is annually updated by way of an amendment. It is important to note that the MED applies to the prototype of a piece of equipment rather than each individual item of equipment. Therefore, once a prototype has been approved, each individual item can be marked as MED approved and be placed on the market. It also provides the harmonized EU-wide framework for the issuing of approval certificates. This Impact Assessment (IA) considers the changes made under the "Seventh Amendment" which Directive 2011/75/EU introduced on 2 September 2011.

Equipment listed in Annex A of the MED is divided into two sections and are issued with an approval certificate stating under which Amendment of the Directive the equipment has been approved:

- Annex A.1 lists equipment for which detailed testing standards already exist in international instruments (such as the instruments of the International Organization for Standardization). An approval process is carried out by Notified Bodies and, if equipment meet the appropriate testing standard, the MED approval certificates are issued and equipment is mark with the symbol "wheelmark" to show compliance; and

- Annex A.2 lists equipment for which no detailed testing standards exist in international instruments and it provides guidance on appropriate testing standards. The UK approval process under Annex A.2 is carried out by Nominated Bodies and, if the equipment meets the appropriate testing standards, a type approval certificate is issued. Subject to the development of international standards, equipment from Annex A.2 can be transferred to Annex A.1.

Therefore, to be clear there are two types of approval bodies: Notified Bodies and Nominated Bodies. The former carries out the approval process for equipment listed under Annex A.1 and the latter for equipment under Annex A.2.

The MED contains a mechanism within Articles 17 and 18 to allow for regular amendments to Annex A mainly to update references to the international standards, and to introduce new equipment and transfer equipment within Annex A. The annual amendments also update Annex A by introducing new equipment and by transferring equipment from Annex A.2 to Annex A.1. This is due to the adoption of new international standards, including detailed testing standards, for a number of items of equipment

already listed in Annex A.2 or, albeit not previously listed in the MED, which are now considered relevant.

Directive 2011/75/EU amending the MED – the Directive under consideration in this IA

On the 2 September 2011 the EU issued Directive 2011/75/EU (the Seventh Amendment). This Directive is the seventh annual amendment to the technical Annex A of the MED. These amendments are an annual process and the **sole objective is to amend the text of Annex A to keep the list of equipment and international standards up to date but not implement the standards**.

There are no new items of equipment added to Annex A of the Seventh Amendment and only seven items of equipment have been transferred from Annex A.2 to Annex A.1. However, it is important to note that without transposing the Seventh Amendment the approval bodies cannot provide certificates for any equipment (including the seven items being transferred).

Under provisions of MED, equipment fitted on board EU ships and placed on the EU market must meet the standards contained in the up-to-date versions of international standards and be issued with approval certificates. The certificates specify the relevant international instruments applied and latest Amending Directive number governing the approval and are valid up to 5 years.

The European Commission has already published the Eighth Amendment, Directive 2012/32/EU, on 24 November 2012 with an implementation date of 30 November 2013.

2. **Problem under consideration**

This Seventh Amendment came into force on the 5 October 2012 and transposition into the UK law system is required.

The problem under consideration is that until transposition of the Seventh Amendment is complete in the UK, it is not possible for the UK approval bodies to issue approval certificates for marine equipment. This has an impact on equipment which has either not previously been certified or which needs to be recertified, such as equipment which has been transferred within Annex A of the MED (this process is described further in the background section below). However, it is anticipated that this will not cause a significant immediate problem. This is because the majority of equipment has already been approved and certified under previous amendments. In addition, the equipment which was transferred within Annex A and certified under the Sixth Amendment is covered by a two year transitional period, so that for the next two years this equipment can be placed on the market and on board ships. The Seventh Amendment does not apply to equipment fitted on board ships prior to 5 October 2012 unless an item needs to be replaced. Nevertheless, the situation should be remedied to allow UK approval bodies to issue fully compliant approval certificates under the Seventh Amendment as soon as possible in order to not put UK approval bodies at a competitive disadvantage.

Furthermore, equipment manufacturers from both the UK and other countries who would normally have their equipment approved by UK approval bodies are currently incurring additional costs to transport and approve their products in other Member States.

Finally, without transposition of the Directive, UK manufacturers will be left at a competitive disadvantage to those in other EU Member States by not being able to issue type approvals certificates. In addition, in the case of the late transposition, the UK is subject to infraction proceedings which may result in a referral to the European Court of Justice and a one-off fine of approximately €9.6 million and possible daily levies.

3. Rationale for intervention

Government intervention is necessary to implement the Seventh Amendment in order for the UK to maintain the existing framework for issuing approval certificates for marine equipment. This will ensure that UK organisations that issue approval certificates for the marine equipment are not put at a competitive disadvantage to the rest of the EU and can continue to provide these services. In addition, UK manufacturers and those non-UK manufacturers whose products hold approval certificates issued by UK approval bodies can continue to obtain them from UK organisations if they choose to do so.

Furthermore, without the transposition of the Seventh Amendment, the full benefits of the MED cannot be realised. The MED introduced minimum international standards, which ensures the uniform testing, approval and certification process of international standards for marine equipment within EU Member States. Without the MED, standards would likely be compromised where competitive advantage could be derived by those manufacturers who are willing to entertain the manufacture of substandard equipment. The MED ensures that there is a level playing field for manufacturers who must all comply to minimum standards and go through a rigorous approvals process, which eliminates the commercial advantage gained by sub-standard manufacturers. Furthermore, the MED ensures that ship-owners who may not hold complete information regarding the standard of the equipment they are purchasing to be placed on their ships will meet a minimum set of standards. The MED therefore overcomes an information problem that ship-owners would face in the absence of the MED.

4. Policy objectives

The policy objectives are:

- protect UK Notified and Nominated Bodies designated to issue approval certificates for marine equipment from a potential loss of business as they would otherwise not be able to provide this services under the Seventh Amendment;
- protect UK manufacturers from incurring additional costs as they would otherwise have to certify their products in other Member States.

5. Policy options

The only viable option (option 1) is for the Seventh Amendment to be transposed through amendments to two existing MSNs which have legal force by virtue of SI 1999/1957. This SI was made under section 85 of the Merchant Shipping Act 1995 which allows the Secretary of State to impose requirements by reference to non-legislative documents, which can be amended from time to time.

Therefore, changes introduced by the Seventh Amendment can be transposed administratively through amendment of MSNs 1734 “Type Approval of Marine Equipment (EC Notified Bodies)” and 1735 “Type Approval of Marine Equipment (UK Nominated Bodies)”. The changes included in the Seventh amendment are to transfer seven items of equipment from Annex A.1 to annex A.2 of the MED. The practical effect of pursuing this option is to enable UK approval bodies to resume issuing approval certificates and for both UK and non-UK manufacturers being able to choose to use UK approval bodies for seeking approval for maritime equipment,

Option 1 is the only policy option that has been fully assessed in this Impact Assessment (IA). The ‘Do nothing’ scenario is the baseline against which Option 1 has been assessed. UK approval bodies can still undertake testing and approvals but from 5 October 2012 are no longer able to issue approval certificates until this Seventh Amendment is transposed. Under the ‘Do nothing’ option, UK approval bodies would no longer be able to issue certificates and both UK and non-UK manufacturers would need to go to another EU member’s approval bodies who have implemented the Seventh Amendment. The UK would also be at risk of infraction proceedings.

6. Costs and benefits of Option 1

The implementation of the Seventh Amendment affects directly two different parts of the UK maritime industry: approval bodies and manufacturers. This section will examine the costs and benefits of implementing Option 1 – the transposition of the Seventh Amendment into UK law –relative to Option 0 – doing nothing - on these two groups. Because the Seventh Amendment will be replaced by the Eighth Amendment on 30 November 2013 the impacts (apart from those that are transitional in nature) on these groups will have a duration of less than one year only. Consequently, the appraisal period for this IA is set at one year.

Benefits – Approval Bodies

It is anticipated that the main impact of Option 1 is on UK approval bodies who are not currently able to issue approval certificates under the Seventh Amendment. Until transposition is complete in the UK, it is not possible for the UK approval bodies to issue approval certificates under the Seventh Amendment. This has an impact on equipment which has either not previously been certified or which needs to be recertified, such as equipment which has been transferred within Annex A (described further in the background section above). However, it is anticipated that this will not cause a significant immediate

problem. This is because the majority of equipment has already been approved and certified under previous amendments. In addition, the equipment which was transferred within Annex A and certified under the Sixth Amendment is covered by a two year transitional period under the Seventh Amendment, so that for the next two years (until 5 October 2014) this equipment can be placed on the market and on board ships. The Seventh Amendment does not apply to equipment fitted on board ships prior to 5 October 2012 unless an item needs to be replaced. Nevertheless, the situation should be remedied to allow UK approval bodies to issue fully compliant approval certificates under the Seventh Amendment as soon as possible in order to not put UK approval bodies at a competitive disadvantage.

Transposition of the Seventh Amendment would generate benefits for the UK approval bodies by enabling them to issue compliant certificates. This is their business and they sought approval from the Secretary of State to undertake this activity. So, it can be assumed that these bodies would only undertake this activity if it benefited them. Furthermore, we understand that UK approval bodies have been continuing with approvals since 5th October 2012 under the assumption that they would be able to issue the approval certificate once this amendment is in place.

In the longer term, it would not be possible for UK approval bodies to function as approval bodies without the transposition of the Seventh Amendment (and subsequent annual amendments). The extent of the benefit to these bodies would depend on a number of factors, including how the resources used to perform these services would be redeployed if these bodies would not be able to perform these services and the extent of the transition costs that would arise. No evidence is available regarding the most likely alternative use of these resources and the likely transition costs. Therefore, it has not been possible has to provide a point estimate of this potential benefit.

However, the range of the scale of this benefit can be estimated. At the lower end it is theoretically possible that the approval bodies would be able to fully redeploy the resources used for approvals to other purposes which generate as much economic benefit as their approvals business. Therefore, at the lower end of the range the benefit of the implementation is estimated to be £0. However, in light of the UK approval bodies requests to the Secretary of State as described above, it is judged to be very likely that the benefit is greater than zero – the lower end of the range.

The upper end of the range is quantified by estimating the annual size of the UK approvals industry. This is judged to be the upper end of the range of benefits to approval bodies because it is possible that none of the resources used for approvals could be redeployed for other purposes in the absence of the implementation of the Seventh Amendment. Broadly speaking, this is estimated by calculating the number of approvals made over the course of a year multiplied by the average fee charged by approval bodies as set out below.

In the UK, there are currently nine Notified Bodies and six Nominated Bodies[1]. Lists of all equipment approved under the original MED and its subsequent amendments by all EU Notified Bodies is provided by the MarED database (but not by Nominated Bodies). The MarED database was established by the European Commission to fulfil the requirements of Article 10.4 of the MED to keep an up-to-date list of marine equipment approved by all EU Notified Bodies. It is not possible to establish how many pieces of equipment which have not been previously certified and would require certification under the Seventh Amendment. However, the MarED database does provide details of how many pieces of marine equipment were approved under the previous Sixth Amendment by the UK Notified Bodies. There are no reasons to expect that there will be significantly more or less equipment approved under the Seventh Amendment and therefore the number of Sixth Amendment approvals is judged to be a reasonable assumption for the number of approvals under the Seventh Amendment. By searching the MarED database it was established that during the period from 6 December 2011 (Sixth Amendment application date) till 23 July 2012 (date when the research was conducted) UK Notified Bodies approved 1320 pieces of equipment. 842 pieces of this equipment were approved for UK applicants and 478 for non-UK applicants. If it is assumed that there the number of approvals during this period is not affected by any seasonality of approvals, this estimate implies that approximately 2000[2] pieces of equipment is expected

[1] Note three of the UK approval bodies are both Notified and Nominated Bodies. When reference is made in this IA to the approvals of Notified Bodies, the approvals of all Notified Bodies (including the three bodies who have both functions) are considered but where these bodies have more than one approval function only the approvals in respect of their Notified Body's functions are referred to. An equivalent interpretation is made to approvals of Nominated Bodies.

[2] The exact figure is 2086 = 1320 pieces of equipment approved during the research period x (365 days in a year / 231 days covering the research period).

to be approved over the course of a year and consequently it can be assumed that the number of approvals to be made under the Seventh Amendment will be around 2000.

Unfortunately, sources of information (such as MarED) do not exist for equipment approved by the Nominated Bodies. However, because there are fewer Nominated Bodies (six) than Notified Bodies (nine) and because the only evidence available suggests that Notified Bodies undertake substantially fewer approvals per body than Nominated Bodies[3], it is estimated that there would be substantially fewer total number of approvals made over the course of a year for Nominated Bodies. As with approvals made by Notified Bodies, there is no reason to believe that Nominated Bodies to expect that there will be significantly more or less equipment approved under the Seventh Amendment. However, because there is no evidence available to quantify the number of approvals made by Nominated Bodies, it is assumed for the purpose of calculating the upper range of the benefits that there are zero approvals. Despite this it is recognised that because of this assumption the assessment of the upper range is a conservative estimate.

Both Notified and Nominated Bodies from the UK and other EU Member States were approached to provide an estimate of fees associated with the approval process. Many parties approached during this exercise raised concerns about their fees being published. Despite providing assurances that any information would be held in strict confidence and would not be disclosed in any way that could allow identification of their organisation, many were not prepared to provide information regarding their fees due to confidentiality and the fact that often equipment approved by the Nominated Bodies would tend to be one-off costs which the organisations did not necessarily have fees readily available for. However, based on the limited responses received only by UK Notified Bodies, the average fee was estimated to be approximately £2500 per piece of equipment[4].

When taken together with the number of pieces of equipment approved by UK Notified Bodies during the seven month research period (1320), the order of magnitude of the total fees received by UK Notified Bodies for performing these services in the period between 6 December 2011 and 23 July 2012 (a 231 day period) were estimated at approximately £3.3 million. If it is assumed that the average fees received each day in this period is representative of the annual average, this estimate implies that the total fees received by UK Notified Bodies could be of the order of magnitude of approximately £5.2 million per year[5]. This estimate provides some context regarding the scale of these activities but does not represent an estimate of the potential benefits to these bodies. Furthermore, because these figures are based only on approvals from UK Notified Bodies (and not UK Nominated Bodies), these estimates are conservative to the size of the annual UK Marine Equipment Approvals industry and the upper range of the benefits to approval bodies from the implementation of the Seventh Amendment.

However, as described above it is unlikely that the upper range of this benefit would be realised since it is unlikely that approval bodies would be completely unable to redeploy the resources used to perform these services for other purposes that derive some value to these bodies. Since no evidence is available regarding the most likely alternative use of these resources and the likely transition costs it has not been possible has to provide a point estimate of this potential benefit but only the range of the magnitude of this benefit being between £0 and £5.2m over the course of the duration of the Seventh Amendment (i.e. one year).

It is important to note that for the purpose of this Impact Assessment, this benefit to approval bodies is not considered a transfer from manufacturers, who pay approval bodies for their services, to approval bodies. Even in the absence of option 1, it is assumed manufacturers would still incur these costs because without an approval certificate; manufacturers could not place the relevant equipment on board ships. Consequently, subject to additional transportation costs not being inhibitive, under option 0 manufacturers would still obtain approval certificates but from non-UK approval bodies whose Member States have implemented the Directive. Therefore, option 1 relative to option 0 does generate a transfer of driving business from non-UK approval bodies to UK approval bodies. However, in line with HMT

[3] Evidence was received from two Notified Bodies, which suggests the number of approvals could be very low. One Notified Body informed the Maritime and Coastguards Agency that they had not made an approval under Annex A.2 in three years whilst another informed the Maritime and Coastguards Agency that they "rarely" carry out this type of approval.

[4] This is the weighted average fee. It reflects the number of pieces of equipment that were approved in relation to each item of equipment listed in Annex A.1 and the average fee per piece of equipment estimated for each item of equipment listed in Annex A.1.

[5] £3.3 million x (365 days in a year / 231 days covering the research period).

Green Book guidance, this Impact Assessment does not consider the impact of policy on non-UK persons or firms.

Costs – Approval Bodies
It is expected that any potential costs to approval bodies associated with the transposition of the Seventh Amendment would be negligible, because the only action required from approval bodies from the transposition is merely adding the new Directive number to the existing certificate template. Once the template is changed, there are no further changes required until the next annual amending Directive.

In addition, approval bodies are fully involved throughout the development of standards and amendments to the MED, therefore negligible familiarisation costs would be incurred. UK approvals bodies will automatically be notified when the new MSNs are issued.

Benefits – Manufacturers
Without transposition of the Seventh Amendment (both UK and non-UK) manufacturers cannot receive approval certificates from UK approval bodies. Consequently, manufacturers must go to a foreign approval bodies to receive an approval certificate for their piece of equipment and in doing so is likely to face increased transportation costs. Depending on the type of equipment manufacturers can have either take their piece of equipment to the sites of the approval bodies to be tested or the approval bodies travel to the manufacturer to have their equipment tested. In either case, the manufacturer will face the travel costs, which for UK manufacturers will likely be higher than if a UK approval body was to test the equipment since there is a greater distance to travel.

It is also possible that the transposition of the Seventh Amendment has the potential to provide cost savings for both UK and non-UK manufacturers because UK approval bodies could offer more competitive rates for testing equipment and issuing approval certificates.

However, it has not been possible to monetise either of these potential benefits, as there is no evidence available on the extent of any difference in price or distance required to travel between UK between the UK approval bodies and their counterparts in other EU Member States nor the costs of transportation.

It is possible that any cost savings on the part of manufacturers would be passed onto their customers and operators of UK ships, which would benefit them. In economic theory, competitive firms pass on their costs to their customers. Unfortunately, there is limited evidence available on the competitiveness of the European maritime manufacturing industry. Although, evidence from the MarEd website suggests that there are 161 European maritime manufacturers, which would suggest that the market could be very competitive[6].

However, UK manufacturers will still be able to receive approval for their equipment from non-UK approval bodies; it is therefore assumed that availability of the equipment would not be affected. Therefore, except for the potential benefit if manufacturers pass on any of the potential costs savings to their customers, transposition of the Seventh Amendment will have no impact on UK ships as they are required to use equipment that fulfils the up-to-date requirements regardless of UK transposition.

Costs – Manufacturers
There are no anticipated costs to UK manufacturers from the transposition of the Seventh Amendment because the approval and certification process will be maintained as per previous amendments.

There will be no familiarisation cost as the maritime industry[7] regularly take part in the work of the bodies which negotiate and adopt the international instruments and which develop amendments or new testing standards. Manufacturers also have representation in these bodies via trade associations, and they are therefore aware of changes to the international instruments as they occur, and not through the annual amendment to the MED's Annex A.

The maritime industry also regularly takes part in the work of the standardisation organisation to develop amendments or new testing standards. They also have representation in these bodies via marine equipment manufacturers' associations. They are also involved and consulted on the work on

[6] However, there is no available evidence of the market shares of these 161 manufacturers and therefore whether there is a low market concentration, which would provide a better assessment of the competitive nature of the sector.
[7] In this IA 'marine industry' means UK marine equipment manufacturers and approval bodies

amendments to Annex A of the MED and are therefore aware of the agreed changes to the standards as well as about work on amendment to Annex A. In addition, directives which amend Annex A are always published well in advanced before their application date.

Summary
The costs incurred in implementing the Seventh Amendment (Option 1) on both UK manufacturers and UK approval bodies is expected to negligible whereas there could be substantial cost savings to UK manufacturers and potentially substantial benefits to approval bodies who would be able to continue to carry out their business and would not be able to in the longer-term without implementation of the Seventh Amendment.

On the basis of the available evidence, it is considered very likely that the overall costs to business would be significantly below £1 million per year and would in fact likely lead to a net benefit to business.

The impacts of Option 1 are summarised in the following table:

	Costs	**Benefits**
UK Approval Bodies	Negligible	£0 to £5.2m
UK Manufacturers	£0	Not quantified

Overall, it is assessed that is very likely that the benefits of Option 1 (relative to Option 0) will outweigh its costs and therefore **Option 1 is our preferred option.**

7. Risks

7.1.1. Risks associated with Option 1 – Implementing the Seventh Amendment
There are no identified risks associated with transposing the Directive 2011/75/EU into UK law. Though there is a risk in principle that the costs associated with the new testing standards contained in the Directive are too great for manufacturers to cope with, this is not a risk associated specifically with the UK's transposition of the Directive, as UK manufacturers are legally bound by the testing standards contained in the Directive irrespective of the UK's transposition of it. Regarding this in principle risk, the exercise undertaken to estimate costs associated with the new testing standards as part of this impact assessment (see section 6 of this impact assessment) suggests this risk is likely to be negligible given the relative scale of additional costs identified.

7.1.2. Risks associated with Option 0 - Do Nothing
The UK, as a member of the European Union, is obliged to transpose the requirements of the 2011 Directive into national law by its application date 5 October 2012. There are two groups of risk associated with not transposing the Directive. Firstly as a result of late or no transposition at all UK manufacturers will be left at a competitive disadvantage to those in other EU Member States by not being able to issue type approvals certificates under Directive 2011/75/EU. In addition, in case of the late transposition the UK would be subject to infraction proceedings which may result in a referral to the European Court of Justice and a one-off fine of approximately €9.6 million and possible daily levies.

8. Wider impact

8.1 Competition assessment
The 2011 Directive applies equally to all sea-going ships under the flag of an EU Member State. Therefore, issues would not arise in respect of competition as the Directive is required to be implemented equally by all Member States. In fact, competition would be hampered across the EU if the preferred option was not pursued as UK approval bodies would not be able to compete with other member states.

8.2 Small firms Impact Test
There are no restrictions regarding who the MED (and the Seventh Amendment) applies to and there is no scope within the Directive to exempt small firms from any of its provisions. Therefore small firms will need to adhere to the MED as amended by the Seventh Amendment. However, it is unclear of the impact on small firms because data on the size of manufacturers and approval bodies is not available.

8.3 Equalities Impact Assessment

There is no effect, positive or negative, on outcomes for persons in relation to their age, disability, gender reassignment, pregnancy and maternity, race, religion or belief, sex and sexual orientation. An equalities pro-forma is included at Annex 1 of this IA.

8.4 One-in, Two-out status

This measure is not in scope of One-In, Two-Out (OITO) as it is of an EU origin and does not extend the existing gold-plating of the UK's original transposition of the MED.

The existing UK Regulations (SI 1999/1957), as amended, originally implemented the MED with some gold-plating. It extends the requirements to apply to all UK ships regardless of their areas of operation, whereas the MED applies only to seagoing ships, for which safety certificates are issued according to the Conventions of the International Maritime Organization. Convention requirements apply typically to ships over 500gt and to ensure there are no gaps in legislation within smaller elements of the UK fleet, the UK through risk assessment, may extend international requirements as appropriate.

The rationale for extending the requirements to all UK ships was to ensure that the equipment provided on a ship of any type would perform adequately, if relied upon in an emergency. However, the rigorous approval process under the MED means that it is not always suitable for equipment provided on smaller ships or ships that engage in limited domestic operations, where the safety risks are generally far smaller than those safety risks that the international rules are designed to mitigate.

This existing gold-plating is being considered under the Maritime Red Tape Challenge. It has been proposed to improve the existing Regulations by giving the Secretary of State the power to exempt certain ships from the requirement to carry MED-approved equipment and instead to use a relevant code of practice.

Given that this is an EU measure with no gold-plating, the "Net cost to business per year" and "Business Net Present Value" boxes on the "Summary: Intervention and Options" sheet and the boxes in the "Direct impact on business (Equivalent Annual) £m" section of the "Summary: Analysis & Evidence" sheet take into account all of the direct impacts on business that have been identified in this IA (even though none of these impacts are in scope of One-In, Two-Out).

It has not been possible to calculate point estimates of direct benefits to business for the purposes of this IA. However, these impacts are expected to be greater than £0 and possibly as large as £5.2m (£4.8m in Equivalent Annual terms). Therefore, a range of "£0-£5.2m" has been entered in the "Benefits" box in the "Direct impact on business (Equivalent Annual) £m" section of the "Summary: Analysis & Evidence" sheet.

Only negligible (unquantifiable) direct costs to business have been identified in this IA. Therefore, it is very likely that the direct impact on business is a negative net cost to business (i.e. a benefit to business). Because it is not possible to calculate a point estimate of the benefits the range of "-£4.8m to £0" has been entered in the "Net cost to business per year" box on the "Summary: Intervention and Options" sheet and "Net" box on the "Direct impact on business (Equivalent Annual) £m" section of the "Summary: Analysis & Evidence" sheet.

8.5 Use of copy out

The 1999 Regulations, as amended, allows for the 2011 Directive to be implemented administratively under Article 2(1) and Article 6(3). No amendments are required to the Regulations themselves, only minor amendments to the supporting MSNs are needed.

8.6 Statutory Duty to Review and Post Implementation Review

The requirement for the Ministerial statutory duty review every five years would apply to this measure. It is considered that a review clause may not need to be added to the Regulations at this time as the MED is amended annually. For the same reason details for conducting a Post Implementation Review (PIR) are not included. Should these annual arrangements change, or a revision of the SI be required, the inclusion of the statutory duty to review clause and the PIR will be reconsidered.

9. Summary

The 2011 Directive, the Seventh Amendment to the MED, was introduced in response to changes to international conventions and applicable testing standards since the adoption of the last amending directive.

These annual revisions can be implemented administratively into UK law via amendments to the two existing MSNs. The existing 1999 Regulations, made under section 85 of the Merchant Shipping Act 1995, already provide for any amendments to be implemented in this way.

The Seventh Amendment applies equally to all seagoing ships under the EU flag for which safety certificates are issued pursuant to international conventions, therefore all Member States must implement this Directive into their national laws. Implementation of the 2011 Directive ensures that UK maritime industry will not be placed at a competitive disadvantage compared to the other Member States as it provides them with the framework for EC approval of their equipment. There is also no risk in respect of competition with other EU Member States.

There is clear evidence that the implementation of the Seventh Amendment (Option 1) is likely to have a significant positive impact on the UK maritime industry (in particular UK approval bodies and UK manufacturers) and **therefore Option 1 is the preferred option**.

Annex 1: Equalities Pro-forma

Name of the function, policy or strategy: Commission Directive 2011/75/EU of 2 September 2011 amending Council Directive 96/98/EC on marine equipment

Current or Proposed: Amendments to the current proposal;

Person completing the assessment: Ewa Kowiranda **Date of assessment: 30 January 2013**

Purpose of the function, policy or strategy: To incorporate amendments to the international instruments adopted since the last MED amendment (Directive 2010/68/EU), which reflect changes in the equipment and development of the technology and to keep the list of international instruments in Annex A up-to-date in accordance with changes to these instruments

Questions - Indicate Yes, No or Not Known for each group	Gender	Religion or Belief	Age	Disability	Ethnicity and Race	Sexual Orientation	Transgender
Is there any indication or evidence that different groups have different needs, experiences, issues or priorities in relation to the particular policy?	No	No	No	No	No	No	No
Is there potential for, or evidence that, this policy may adversely affect equality of opportunity for all and may harm good relations between different groups?	No	No	No	No	No	No	No
Is there any potential for, or evidence that, any part of the proposed policy could discriminate, directly or indirectly? (Consider those who implement it on a day to day basis)?	No	No	No	No	No	No	No
Is there any stakeholder (staff, public, unions) concern in the policy area about actual, perceived or potential discrimination against a particular group(s)?	No	No	No	No	No	No	No
Is there an opportunity to better promote equality of opportunity or better community relations by altering the policy or working with other government departments or the wider community?	No	No	No	No	No	No	No
Is there any evidence or indication of higher or lower uptake by different groups?	No	No	No	No	No	No	No
Do people have the same levels of access? Are there social or physical barriers to participation (e.g. language, format, physical access/proximity)?	No	No	No	No	No	No	No