

Title: Transposition of Council Directive Establishing a Community Framework for the Nuclear Safety of Nuclear Installations (Euratom 2009/71) Lead department or agency: Department of Energy and Climate Change Other departments or agencies: The Health and Safety Executive	Impact Assessment (IA)
	IA No: HSE0058
	Date: 21/07/2011
	Stage: Final
	Source of intervention: EU
	Type of measure: Other
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Summary: Intervention and Options

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

Council Directive (Euratom 2009/71) establishing a Community Framework for the Nuclear Safety of Nuclear Installations was agreed at the European Environmental Council on 25 June 2009. The deadline for transposition is 22 July 2011. The intervention set out in this impact assessment is required to ensure that, in relation to Great Britain, the Nuclear Safety Directive has been fully transposed.

What are the policy objectives and the intended effects?

To comply with the obligation to fully transpose the Nuclear Safety Directive in a manner which imposes the minimal additional burden on business in Great Britain and which minimises the risk of legal challenge by the European Commission.

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

The policy options considered were: making the minimum amendments necessary to the existing regulatory framework with 'copy out'; doing the same without 'copy out'; and a non regulatory option. The Directive does not allow a non regulatory approach to be taken; and the use of copy out was considered likely to cause unnecessary uncertainty amongst licence holders. Thus no further analysis of these options has been performed. The preferred approach is to make the minimum amendments necessary to the existing regulatory framework but not using 'copy out', as this ensures that the EU law obligations are satisfied whilst revising the framework in a coherent way for nuclear site licence holders.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** N/A

What is the basis for this review? N/A **If applicable, set sunset clause date:** N/A

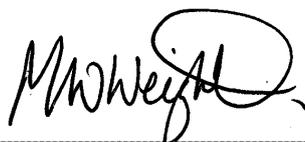
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review? N/A

Sign-off For consultation stage Impact Assessments:

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

Dr M Weightman

HM Chief Inspector of Nuclear Installations



Date: 21 July 2011

Summary: Analysis and Evidence

Policy Option 1

Description: Do Nothing

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Nil	High: Nil	Best Estimate: Nil

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

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

This is the notional baseline case and there are not expected to be any costs associated with this option.

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

N/a

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Nil	Nil	Nil
High	Nil	Nil	Nil
Best Estimate	Nil	Nil	Nil

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

This is the notional baseline case and there are not expected to be any benefits associated with this option.

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

N/a

Key assumptions/sensitivities/risks

N/a

Discount rate (%)

3.5

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: Nil	Benefits: Nil	Net: Nil	No	N/a

Summary: Analysis and Evidence

Policy Option 2

Description: **Do the minimum without using copy out –the preferred option**

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Nil	High: Nil	Best Estimate: Nil

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

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

NSD Article 6(4): The required changes are not anticipated to change current practices amongst nuclear site licence holders, and so no significant costs expected.

NDS Article 6(5): It is not anticipated that licensees will have to keep or provide material or documentation that goes beyond that which is already required or could easily be compiled, to show safe operation. No significant costs are expected.

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

On the rare occasion where (under NSD Article 6 (5)) the Regulator may need to seek external expert advice on financial resources information, the cost of this will be recovered from the licensee. At this stage, it is not possible to estimate how often this might occur and how long it could take and so this impact has not been quantified. Familiarisation costs are unquantified but expected to be insignificant.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Nil	Nil	Nil
High	Nil	Nil	Nil
Best Estimate	Nil	Nil	Nil

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

There are no health and safety benefits expected as no change to current practice is anticipated.

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

This approach avoids the risk of successful legal challenge by the EC and subsequent infraction proceedings. It is not possible to quantify this benefit however.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5

It is assumed that because the changes to the licence conditions do not result in significant change to current practices licensees won't be required to spend significant time familiarising themselves with the changes.

There is the possibility that external expert advice will be required to review financial records, but there is uncertainty around how many days of time could be required at this stage.

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: Nil	Benefits: Nil	Net: Nil	No	N/a

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?		Great Britain			
From what date will the policy be implemented?		22/07/2011			
Which organisation(s) will enforce the policy?		Office for Nuclear Regulation (ONR) an agency of the Health & Safety Executive			
What is the annual change in enforcement cost (£m)?		Nil			
Does enforcement comply with Hampton principles?		Yes			
Does implementation go beyond minimum EU requirements?		No			
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)		Traded: N/a		Non-traded: N/a	
Does the proposal have an impact on competition?		No			
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?		Costs: N/A		Benefits: N/A	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	Micro	< 20	Small	Medium	Large 100%
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on...?	Impact	Page ref within IA
Statutory equality duties ¹ Statutory Equality Duties Impact Test guidance	No	12
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	12
Small firms Small Firms Impact Test guidance	No	12
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	13
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	13
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	13
Human rights Human Rights Impact Test guidance	No	13
Justice system Justice Impact Test guidance	No	13
Rural proofing Rural Proofing Impact Test guidance	No	13
Sustainable development Sustainable Development Impact Test guidance	No	13

¹ Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures.

No. Legislation or publication

- 1 Nuclear Safety Directive - 2009/71/Euratom - Copies of the Directive are available here: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:172:0018:0022:EN:PDF>
- 2 Copies of the consultation stage IA are still available here: <http://www.hse.gov.uk/nuclear/index.htm>.

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y ₀	Y ₁	Y ₂	Y ₃	Y ₄	Y ₅	Y ₆	Y ₇	Y ₈	Y ₉
Transition costs	0	0	0	0	0	0	0	0	0	0
Annual recurring cost	0	0	0	0	0	0	0	0	0	0
Total annual costs	0	0	0	0	0	0	0	0	0	0
Transition benefits	0	0	0	0	0	0	0	0	0	0
Annual recurring benefits	0	0	0	0	0	0	0	0	0	0
Total annual benefits	0	0	0	0	0	0	0	0	0	0

* For non-monetised benefits please see summary pages and main evidence base section

Evidence Base (for summary sheets)

Background and rationale for intervention;

1. The Nuclear Safety Directive (NSD) is intended to establish a Community framework to maintain and promote the continuous improvement of nuclear safety and its regulation, and to ensure Member States provide appropriate national arrangements for nuclear safety. The Department of Energy and Climate Change (DECC) led on the negotiation of the Directive in Council with technical support from HSE's Nuclear Directorate. It will be for the DECC Minister to write formally to the European Commission to confirm full implementation of the Directive by 22 July 2011.
2. The final shape of the adopted NSD closely reflects the philosophy underpinning the regulatory framework in Great Britain. As a result, most of the provisions of the Directive are considered to be transposed by Great Britain's current regime of nuclear safety regulation. In particular, Great Britain can rely in part on the Nuclear Installations Act 1965 (NIA65) and the standard set of 36 licence conditions (attached to all nuclear site licences in Great Britain) to meet the obligation to transpose several detailed provisions of the NSD.
3. However, following detailed policy and legal analysis, officials identified it was necessary to make changes to the existing regulatory framework to ensure, in relation to Great Britain, the obligation to fully implement the Directive had been met. The Articles in question are:-

Article 6(2): - "Member States shall ensure that the national framework in place requires licence holders, under the supervision of the competent regulatory authority, to regularly assess and verify, and continuously improve, as far as reasonably achievable, the nuclear safety of their nuclear installations in a systematic and verifiable manner." NSD Article 6(3) provides further details of the duties to be imposed on licence holders.

Article 6(4):- "Member States shall ensure that the national framework in place requires licence holders to establish and implement management systems which give due priority to nuclear safety and are regularly verified by the competent regulatory authority."

Article 6(5):- "Member States shall ensure that the national framework in place requires licence holders to provide for and maintain adequate financial and human resources to fulfil their obligations with respect to nuclear safety of a nuclear installation, laid down in paragraphs 1 to 4."

4. Article 6 sub-paragraphs (2)-(5) require Member States to ensure that the specific duties set out in those provisions are imposed upon the person who holds the nuclear site licence. Whilst under the existing framework HSE has a power to impose such duties on nuclear site licence holders in Great Britain, via conditions attached to their nuclear site licences, HSE is **not required to** impose those duties on licensees. DECC is taking forward action to ensure that HSE is under the relevant duty to impose the conditions and this measure is not therefore considered in this impact assessment
5. Article 6(4) requires that licensees establish and implement management systems that give due priority to nuclear safety, and that the competent regulatory authority subject these to regular verification. An amendment is required to licence condition 17 to ensure that site licensees are required to put the necessary management systems in place.
6. Article 6(5) requires Member States to ensure that site licensees provide for and maintain adequate financial and human resources to ensure compliance with their obligations in relation to nuclear safety. Whilst it is implicit in the current system that site licence holders must provide adequate financial and human resources, there is no explicit requirement to do so. There is also no specific requirement for licensees to maintain those resources. Consequently, amendments are required to licence condition 36 to ensure the Directive is fully transposed in Great Britain.
7. Following its meeting in September 2010 the HSE Board agreed the transposition approach above. The HSE Chair subsequently wrote to Ministers setting out the HSE views on this approach. Ministers have since responded positively.
8. DECC and HSE officials have followed better regulation principles and, since the 2010 election, taken into account the Government's better regulation policies and measures.

9. The 'one-in, one-out' rule will not apply as the changes are intended to transpose a European Directive. There will be no 'gold-plating' as the additional provisions necessary to ensure effective transposition of the Directive will not come into effect before 22 July and the changes proposed are the minimum consistent with the Directive requirements.

Policy objective

10. The existing regulatory framework is considered to be sufficient to transpose the majority of the Directive. The approach has therefore been to:

- make the minimum change necessary to the framework to ensure the provisions of the Directive are correctly transposed in Great Britain;
- ensure that the burdens to business and the regulator are minimised consistent with better regulation principles; and
- ensure the risk of successful legal challenge from the European Commission is minimised.

Description of options considered

11. This impact assessment considers the options for implementing Article 6(4) and Article 6(5) only.

Do the minimum using copy out

12. HSE (through the Office of Nuclear Regulation) is the independent Regulator charged with regulating licensed nuclear installations. It is for HSE, as the Regulator, to add to, amend, vary, or revoke the licence conditions attached to a nuclear site licence to ensure nuclear safety in Great Britain. The use of copy out was considered not to be in keeping with the current set of 36 licence conditions; likely to cause uncertainty amongst licence holders; and require greater reassurance/guidance to show that the required changes would not lead to significant changes in practice. Thus no further analysis of this option has been performed.

Non regulatory

13. The Directive requires Member States to establish a national legislative, regulatory and organisational framework for nuclear safety of nuclear installations (Article 4). The national framework must place various requirements on those who hold licences to operate nuclear installations in the relevant Member State (Article 6). The Directive does not allow a non regulatory approach to be taken. Not implementing the Directive as required could result in legal challenge from the EC and the possibility of infraction proceedings, and, if successful, lead to substantial fines. Thus no further analysis of this option has been performed. To allow the preferred option (set out below) costs to be analysed a notional base line case of 'do nothing' is required. The notional 'do nothing' provides the baseline whereby, in the absence of the Directive, the costs and benefits would be zero. This enables additional costs only of the Directive to be compared to this baseline case reflected in the summary option pages above.

Do the minimum without using copy out – The preferred option

14. HSE regulates civil nuclear sites primarily through a nuclear site licensing regime under the Nuclear Installations Act 1965 (NIA65). The licensing provisions of NIA65 are relevant statutory provisions of the Health & Safety at Work Act 1974, which means that both Acts (and associated Regulations) are enforced in an integrated way by HSE through the Office for Nuclear Regulation (which is an agency within HSE).

15. Section 1(1) of the NIA65 prohibits any person installing or operating nuclear facilities without a nuclear site licence. The issuing of a licence makes the licensee responsible for all nuclear safety matters on the site. Section 4(1) of the NIA65 provides for the HSE to attach conditions to nuclear site licences. There are 36 standard conditions attached to all licences in Great Britain which cover all arrangements for managing safety. They also require licensees to document their arrangements for ensuring safety on site to HSE's satisfaction. It is an offence under Section 4(6) of the NIA65 to breach any of these conditions. It is for HSE to make any changes to nuclear site licence conditions as the powers to attach, vary, or revoke licence conditions lie with the Regulator.

Amending Licence Condition (LC) 17

NSD Article 6(4):- “Member States shall ensure that the national framework in place requires licence holders to establish and implement management systems which give due priority to nuclear safety and are regularly verified by the competent regulatory authority.”

16. This Article requires that licensees establish and implement management systems that give due priority to nuclear safety, and that the Regulator subject these to regular verification. A small change to licence condition 17 is needed to ensure that licensees are required to put the necessary management systems in place. The verification aspect of the obligation is met by Great Britain’s current regulatory framework. The table below (Fig. 1) highlights the amendments to licence condition 17 needed to achieve this.

17. In addition, we are proposing to change the term quality “assurance” to quality “management”. This is not a change of substance required by the Directive but is consistent with the terminology used by the industry.

Fig. 1

Existing Licence Condition 17	Amended Licence Condition 17 with changes highlighted
<p><u>Licence Condition 17: Quality Assurance</u></p> <p>(1) Without prejudice to any other requirements to the conditions attached to this licence the licensee shall make and implement adequate quality assurance arrangements in respect of all matters which may affect safety.</p> <p>(2) The licensee shall submit to the Executive for approval such part or parts of the aforesaid arrangements as the Executive may specify.</p> <p>(3) The licensee shall ensure that once approved no alteration or amendment is made to the approved arrangements unless the Executive has approved such alteration or amendment.</p> <p>(4) The licensee shall furnish to the Executive such copies of records or documents made in connection with the aforesaid arrangements as the Executive may specify.</p>	<p><u>Licence Condition 17 Management Systems</u></p> <p>(1) Without prejudice to any other requirements of the conditions attached to this licence, the licensee shall establish and implement management systems which give due priority to safety.</p> <p>(2) The licensee shall, within its management systems, make and implement adequate quality management arrangements in respect of all matters which may affect safety.</p> <p>(3) The licensee shall submit to the Executive for approval such part or parts of the aforesaid management systems or part or parts of the aforesaid quality management arrangements as the Executive may specify.</p> <p>(4) The licensee shall ensure that once approved no alteration or amendment is made to the approved management systems or approved quality management arrangements unless the Executive has approved the alteration or amendment.</p> <p>(5) The licensee shall furnish to the Executive such copies of records or documents made in connection with the aforesaid quality management arrangements as the Executive may specify.”</p>

Amending Licence condition 36

NSD Article 6(5):- “Member States shall ensure that the national framework in place requires licence holders to provide for and maintain adequate financial and human resources to fulfil their obligations with respect to nuclear safety of a nuclear installation, laid down in paragraphs 1 to 4.”

18. This Article requires licensees to provide and maintain adequate financial and human resources to ensure it can fulfil its obligations in respect of nuclear safety. Whilst it is implicit in our current system that site licence holders must provide adequate financial and human resources, there is no explicit requirement to do so.

19. There is no express requirement to “maintain” financial and human resources for the future in the existing framework. A further small change to licence condition 36 will address this point. The table below (Fig. 2) highlights the amendments to licence condition 36 needed to achieve this.

Fig. 2

Existing Licence condition 36	Amended licence condition 36 with changes highlighted
<p><u>Licence condition 36: Control of Organisational Change</u></p> <p>(1) The licensee shall make and implement adequate arrangements to control any change to its organisational structure or resources which may affect safety.</p> <p>(2) The licensee shall submit to the Executive for approval such part or parts of the aforesaid arrangements as the Executive may specify.</p> <p>(3) The licensee shall ensure that once approved no alteration or amendment is made to the approved arrangements unless the Executive has approved such alteration or amendment.</p> <p>(4) The aforesaid arrangements shall provide for the classification of changes to the organisational structure or resources according to their safety significance. The arrangements shall include a requirement for the provision of adequate documentation to justify the safety of any proposed change and shall where appropriate provide for the submission of such documentation to the Executive.</p> <p>(5) The licensee shall if so directed by the Executive halt all change to its organisational structure or resources and the licensee shall not recommence such change without the consent of the Executive.</p>	<p><u>Licence condition 36: Organisational Capability</u></p> <p>(1)The licensee shall provide and maintain adequate financial and human resources to ensure the safe operation of the licensed site.</p> <p>(2) Without prejudice to the requirements of paragraph (1), the licensee shall make and implement adequate arrangements to control any change to its organisational structure or resources which may affect safety.</p> <p>(3) The licensee shall submit to the Executive for approval such part or parts of the aforesaid arrangements as the Executive may specify.</p> <p>(4) The licensee shall ensure that once approved no alteration or amendment is made to the approved arrangements unless the Executive has approved such alteration or amendment.</p> <p>(5)The aforesaid arrangements shall provide for the classification of changes to the organisational structure or resources according to their safety significance. The arrangements shall include a requirement for the provision of adequate documentation to justify the safety of any proposed change and shall where appropriate provide for the submission of such documentation to the Executive.</p> <p>(6)The licensee shall if so directed by the Executive halt the change to its organisational structure or resources and the licensee shall not recommence such change without the consent of the Executive.</p>

20. There is already a requirement in licence condition 6 for licensees to make adequate records (6(1)) and furnish copies as the Executive may specify (6(5)). These requirements will explicitly apply to new licence condition 36(1) above. It is HSE’s understanding that licensees already produce the necessary documentation even though not specifically required to do so.

Costs & benefits of amending Licence Conditions

Licence Condition 17

21. The purpose of the existing licence condition 17 is to ensure that the licensee applies quality assurance to all activities associated with the design, construction, manufacture, commissioning, operation and decommissioning of the installations on the site including the preparation and review of safety documentation. The revision to licence condition 17 requires that licensees establish and implement management systems that give due priority to nuclear safety as mentioned in paragraph 16 above. In practice, this is already the case.

Benefits

22. This approach should minimise the risk of successful legal challenge by the EC and subsequent infraction proceedings. There are no health and safety benefits in this approach as no change to current practices is anticipated.

Costs to industry

23. The primary responsibility for the safety of a nuclear installation rests with the licensee. At present, before granting a nuclear site licence, and periodically thereafter, HSE must be satisfied that the licence applicant /holder will have/has an adequate management structure, safety management arrangements and resources to discharge the obligations associated with operating a nuclear site. In practice, licensees have management systems in place that already give due priority to safety. Licensees are at present required to set out the managerial and procedural arrangements that may affect safety. This will include all procedures and arrangements made by the licensee to comply with all licence conditions. As

the required changes to licence condition 17 are not anticipated to change current practices amongst licensees, it is not envisaged that licensee costs in complying with the revised licence condition 17 will differ from those that accrue from demonstrating compliance with the current licence condition 17.

Familiarisation

24. Given the minimal impact of the Directive on actual current practice and the proposed change in terminology which brings licence condition language in line with industry, familiarisation costs are anticipated to be minimal, particularly as ONR have advised licensees that any changes to each licensee's own arrangements and documentation can be made in the course of normal business updating.

Costs to HSE

25. Minimal costs are anticipated as the verification aspect of this Article (which falls to the Regulator) is met by Great Britain's current regulatory framework. At present a broad assessment of licensees' management systems is carried out by the Regulator during its routine assessment and inspection activities. Site inspectors will, as they do now, continue to monitor the effectiveness of the implementation of arrangements particularly as they relate to all other licence conditions.

Licence condition 36

26. The two aspects to the revised licence condition 36 are the need to have and maintain adequate financial and human resources.

Financial resources

27. The purpose of the existing licence condition 36 is to ensure that the licensee has adequate arrangements in place to control any change to its organisational structure or resources which could affect safety.

28. The amended licence condition 36 now makes express a duty on licensees to provide and maintain adequate financial resources which, by implication, they would have demonstrated they had at the point of initial licensing, and which the Regulator could ask for at any time during the course of planned programmes of assessment and inspection. The industry has supplied a list of material it currently has available which should provide sufficient evidence that the requirement is satisfied. It includes: the safety management prospectus (SMP); annual financial accounts, plans for construction and key financial decision points; investment plans; Lifetime Plans (LTP); and the nuclear baseline amongst others. [NB. The list is for illustrative purposes only; it is not an exhaustive or definitive list of what may be necessary to satisfy this requirement]

Human resources

29. With regard to human resources the amendment to licence condition 36 makes explicit the Article 6(5) requirement to provide and maintain adequate human resources.

Benefits

30. This approach should minimise the risk of legal challenge by the EC and subsequent infraction proceedings. There are no health and safety benefits in this approach as no change to current practice is anticipated.

Costs to Industry

Financial Resources

31. As mentioned in the section above dealing with amendment to licence condition 17, the primary responsibility for the safety of a nuclear installation rests with the licensee. Presently, before granting a

nuclear site licence, and periodically thereafter, the Regulator must be satisfied that the licence applicant /holder will have/has an adequate management structure, safety management arrangements and resources to discharge the obligations associated with operating a nuclear site.

32. The Regulator expects the licensee, at the time of licensing and thereafter, to demonstrate continuing licensability throughout the lifetime of the site. A coherent approach to safety management incorporating organisation, resources, and management systems, is expected to remain visible to the licensee's senior management, and to be reviewed from time to time, and updated as necessary to reflect changing needs.

33. The Regulator does not therefore anticipate that licensees, as a matter of course, will have to keep or provide material or documentation which goes beyond that which is already required or could easily be compiled (see para 28) to show the safe operation of the licensed site. Ensuring finances are in place and maintained throughout the lifetime of a nuclear installation, is integral to the licensee's ability to demonstrate nuclear safety. If the Regulator has reason to be concerned that a licensee may not have the finances to ensure and maintain nuclear safety, it could currently ask to see **any** relevant documents, including financial documents. In practice, this has not been necessary. We do not anticipate that making this requirement explicit in licence condition 36 will lead to routine requests for this information. On the rare occasions where the regulator deems it necessary, in the context of a nuclear safety question, to seek external expert advice on financial resources information provided by the licensee, the cost of that advice will be recovered from the licensee (see para 36). The extent of the total annual costs of such external reviews will depend on the severity of the Regulator's concerns and the length of time required to be spent by the auditors, plus the quality of the licensees' record keeping.

Human resources

34. HSE considers that licensees will already comply with this new requirement by preparing their 'Nuclear Baseline'. The Nuclear Baseline is the means by which the licensee demonstrates that its organisational structure, staffing and competencies are, and remain, suitable and sufficient to manage nuclear safety throughout the full range of the licensee's business. It also provides the foundation from which organisational changes can be assessed in accordance with the licensee's arrangements made under the existing licence condition 36.

Familiarisation

35. Licensees are already familiar with the compliance requirements of the existing licence condition 36 (see the table above and para.27). The supplementary note, which set out ONR's view of the effects of the financial resources aspect of the revised licence condition 36, was developed for consultation (see - <http://www.hse.gov.uk/nuclear/index.htm>). In acknowledgement of comments received during consultation, ONR will use the explanatory note to inform existing ONR guidance (e.g. Notes for Inspectors) to ensure that the minimal changes in ONR regulatory behaviour, discussed in that document and this IA, are reflected in those documents. It is therefore anticipated that licensees familiarisation costs will be minimal. Existing guidance on the human resources aspect of the amendment to licence condition 36 is unchanged. Therefore the effective familiarisation costs of the amendments proposed are considered to be 'de minimis', particularly as ONR have advised licensees that any changes to each licensee's own arrangements and documentation can be made in the course of normal business updating.

Costs to HSE

36. As mentioned above, it is not anticipated that the Regulator will require information relating to the licensees financial resources as a matter of course during day-to-day enforcement activity (assessment or inspection). However, the Regulator may seek further information, and the views of an external independent expert, to satisfy themselves of the financial resources aspect of a broader nuclear safety question or concern that may arise from regulatory assessment or inspection. The costs of these services will be recovered from the licensees.

Risks and assumptions

37. In relation to paragraph 33 (above), There is the possibility that, on rare occasions, ONR will need to call on external expert advice to review financial records, with costs charged to licensees. However the potential costs cannot be quantified as the daily rate and number of days of expert time per annum is uncertain and would depend on the severity of the Regulator's concerns and the adequacy of the Licensee's record keeping.

38. It is also assumed that because the changes to the licence conditions are minimal, that licensees will only spend a minimal amount of time familiarising themselves with the changes.

Direct costs and benefits to business calculations (following OIOO methodology);

39. Measures stemming from the need to transpose European Directives are not presently required to follow OIOO methodology.

Summary and preferred option

40. Doing the minimum not using 'copy out' is the preferred approach. It delivers the changes needed to ensure that the obligations of the Directive have been fully implemented in Great Britain, and that this has been achieved in a way that minimises the administrative and cost burdens to business.

Description of implementation plan.

41. Implementation of these measures will require statutory consultation of licensees under Section 4(4) of the Nuclear Installations Act 1965. This will be published on the ONR/HSE website to facilitate wider consultation. The conditions attached to the existing nuclear sites licences in Great Britain will be amended and those amendments will come into effect on 22 July 2011.

42. DECC will need to submit the overall transposition approach to the European Affairs Cabinet Committee for clearance of the transposition approach ahead of the 22 July deadline. Following EAC clearance, DECC will need to write to the European Commission confirming that the Directive has been fully implemented.

Wider Impacts

43. Wider impacts per the specific impacts checklist on page 4 have been considered further below.

Statutory Equality Duties

44. An equality impact assessment 'screening' has been performed , Since no additional benefits or adverse impacts arise from the measures set out in this IA, a full EIA was not conducted.

Economic Impacts

Impact on Competition

45. Amending the Nuclear Licence conditions will not directly or indirectly limit the range of operators. Nor will it limit the licence holders' ability to compete or reduce their incentives to compete rigorously.

Impacts on Small Businesses, Charities and Voluntary Organisations

46. Nuclear site licence holders in the UK are typically large companies or part of larger corporate bodies. No impact is expected for small or medium enterprises or voluntary organisations.

Environmental Impacts

Greenhouse gas assessment

47. The amendments to the Licence Conditions will not have any effect on the capacity of the nuclear industry to operate in GB and so it is not thought the amendments will have a direct effect on greenhouse gas emissions.

Wider Environmental Issues

48. The proposed amendments to the licence conditions will not have any wider environmental impacts.

Social Impacts

Health and Well being

49. No impacts on health and well being are expected

Human Rights

50. No impacts on human rights are expected

Justice

51. No impacts on justice are anticipated

Rural Proofing

52. No impacts on rural issues are expected.

Sustainability

53. No impacts on sustainability are expected.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Reasons for not planning a review:

The measures considered in this impact assessment contribute to the UK's implementation of the Directive 2009/71/Euratom. A review of the UK's implementation of the Directive, including the measures set out in this impact assessment, is required under Article 9 of the Directive (see below). A separate PIR is not therefore necessary.

Article 9

Reporting

- 1. Member States shall submit a report to the Commission on the implementation of this Directive for the first time by 22 July 2014, and every three years thereafter, taking advantage of the review and reporting cycles under the Convention on Nuclear Safety.*
- 2. On the basis of the Member States' reports, the Commission shall submit a report to the Council and the European Parliament on progress made with the implementation of this Directive.*
- 3. Member States shall at least every 10 years arrange for periodic self-assessments of their national framework and competent regulatory authorities and invite an international peer review of relevant segments of their national framework and/or authorities with the aim of continuously improving nuclear safety. Outcomes of any peer review shall be reported to the Member States and the Commission, when available.*