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GE Healthcare	<p>Thank you for the opportunity to comment on the proposed amendments (link below) to Licence Conditions 17 and 36 (required to implement the Euratom Directive).</p> <p>GE Healthcare understands the need for these changes and is supportive of ONR's search for a pragmatic and proportionate solution to UK compliance with the Directive. Having said that there is some concern that inappropriate interpretation of the new wording "on the ground" by inspectors or operators might not reflect the assurances given in the consultation documentation. For that reason we would welcome, together with colleagues from other operators in the sector, the opportunity to be involved in influencing the detailed guidance/notes for inspectors etc.</p>
Individual response	<p>Please find the attached document that sets out my comments on the proposed changes to nuclear site licence conditions. You will see from the document that I believe there is no need to make any changes to licence conditions and that the current nuclear licensing regime is fully compliant with the requirements of the Council Directive (EURATOM 2009/71).</p> <p>Comments on the Proposed Changes to Licence Conditions</p> <p>General</p> <ol style="list-style-type: none">1. In the impact assessment it is stated that in order to fully comply with the Council Directive (EURATOM 2009/71) changes to the existing nuclear regulatory framework in Great Britain need to be made to implement the obligations set out in Articles 6(2), 6(4) and 6(5).2. The requirement under Article 6(5) in respect of financial resources appears to be new but in fact it has been an integral part of the nuclear licensing process for decades. Since the introduction of the Nuclear Installations Act in 1960 and its replacement Nuclear Installations Act 1965 as Amended (NIA 65) licensees have been required to demonstrate ability to cover nuclear insurance and be a corporate body. The other obligations set out in Articles 6(2), 6(4) and 6(5) are not new to the UK nuclear regulatory system and I would argue that they are adequately covered by the existing conditions attached to all Nuclear Site Licences.

3. The licensing of nuclear sites, as required by the NIA 65, is solely for the purpose of safety and the management of radioactive waste and hence the process of granting a licence is an integral part of the GB framework for the safety of nuclear installations.

4. Licence conditions are legal instruments and failure to comply with a licence condition is a criminal offence. Licence conditions must relate to a specific purpose and its objectives/requirements must be clear and understandable to an applicant or a licensee. Licence conditions must also be drafted in such a way that both compliance and non-compliance can be readily identified ie a licence condition therefore must be capable of being enforced.

5. Decommissioning and site cleanup is a nuclear safety related activity and the financial requirements to ensure that a nuclear licensee has the necessary financial resources to undertake this task is delivered through a decommissioning fund under arrangements managed by the sponsoring department and not by the nuclear safety regulator via licence conditions.

Article 6(5) Financial Resources

6. The proposed use of licence conditions to implement this requirement is not the most appropriate mechanism for the explicit requirement for adequate financial resource. It is also questionable because NIA 65, gives powers for “Conditions” to be attached to a licence when they are “...necessary or desirable in the interests of safety...” [Sections 4 (1)], or “with respect to the handling, treatment and disposal of nuclear matter” [Section 4 (2)].

7. I would argue that there are **no powers** to attach conditions in relation to financial resources and unless there can be shown to a clear link between nuclear safety and a particular level or type of financial resource. It is therefore questionable if the use of licence conditions is legal in this context.

8. To relate financial resources directly to a nuclear safety licence condition would be problematic as it would require nuclear inspectors to directly link a level or type of financial resource to a nuclear safety issue. This is not a skill that is currently required for nuclear safety regulators and could

present an unnecessary distraction from their normal activities at a time when there is already shortage of nuclear inspectors.

9. As indicated in paragraph 2 above, the Government and the nuclear safety regulator have taken financial strength into account in the process of granting nuclear site licences. Financial strength and corporate body status have traditionally been taken into account at the “application” stage of the licensing process.

10. HSE/NII in the past has relied on the sponsoring Department (now DECC) for civil nuclear activities to assess the economic viability of the applicant as part of the process of granting permission under the Electricity Act in the case of a reactor licence. For non-reactor licence applications the nuclear safety regulator has also sought assurances on financial and corporate body status from the appropriate sponsoring Department.

11. The responsibilities in relation to nuclear insurance were not transferred to the nuclear safety regulator when nuclear licensing responsibilities were transferred to HSE in 1975, and have remained the responsibility of the sponsoring Department.

12. If the sponsoring Department deemed an Applicant for a nuclear site licence not to be a fit and proper corporate body nor have inadequate financial resources, the nuclear safety regulator would not grant a nuclear site licence. This is not unique as the nuclear safety regulator would not grant a licence to an applicant if it had not obtained the necessary planning permissions.

13. At the application stage the nuclear safety regulator checks the Applicant’s licence condition compliance arrangements. These arrangements include the required organisational structure and staffing baselines to deliver nuclear safety. Again, if these were inadequate a licence would not be granted until the nuclear safety regulator was satisfied that they were adequate.

14. I believe, therefore, that any requirement placed upon the licensee to demonstrate the ability to provide and maintain adequate financial resources, should be a requirement for **granting** a Nuclear

Site Licence and **not** a requirement placed via Licence Conditions.

15. If a nuclear licensee were to get into financial difficulties such that it was incapable of effectively managing nuclear safety, routine inspection and enforcement activities are capable of detecting any serious deterioration in safety performance. Inadequate compliance with licence condition arrangements would be one of the indicators that would attract regulatory attention. The nuclear safety regulator, under the existing powers in the NIA 1965 [Section 5(1)], has the power to revoke a licence at any time. Hence if it became clear at any time that a licensee had difficulty in meeting its responsibilities, including financial or other capabilities, and this was having a demonstrably detrimental effect on nuclear safety at its site or sites, the nuclear site licence could be revoked.

16. I would argue, therefore that the current nuclear licensing regime covers the requirements of Article 6(5) in respect of financial resources and there is no need for a change.

17. If further clarity is required to show how the obligations of Article 6 (5) are delivered in respect of financial resource, it could be done via an explicit statement in the “Notes for Applicants” and if necessary a more formal articulation of the financial consultation process between the regulator and the sponsoring department. If responsibility for assessing financial and corporate body status were to be passed to the Office of Nuclear Regulation, it would need to have the necessary resources to be the intelligent customer to procure the appropriate financial expertise to make the necessary assessment of an Applicant’s corporate body and financial capability.

18. I believe the assessment of financial resources is best carried out at the nuclear site licence application stage. It is a more effective and efficient way of demonstrating compliance with the Directive and it would not carry the risk of Judicial Review of the legality of the use of a licence condition for such purposes.

19. For existing licensees that are covered by the Directive, it is within the nuclear safety regulator’s existing powers at any time to review a licensee’s capability to continue to hold a nuclear site

licence. Such a review could include financial capability. This does not require a licence condition.

Article 6(5) Human Resources

20. **I would again argue that the current nuclear licensing arrangements cover this requirement and there is no need for a change.** Organisational structure and staffing levels are required as part of an Applicant's Management Prospectus. This is required to demonstrate that the Applicant will have sufficient "Suitably Qualified and Experience Persons" (SQEP) to be capable of being the "Controlling Mind" for its nuclear operations and the "intelligent Customer" for the procurement of nuclear related services.

21. If the nuclear safety regulator assesses that these are not adequate a nuclear site licence will not be granted to the Applicant until the regulator is satisfied. Once a nuclear site licence has been granted, Licence Condition 36 is used to control any subsequent changes.

Proposed Changes to LC 36

22. **I do not see any need to change LC 36 or its title.** The original Licence Condition 36 was introduced to control **organisation change** as a direct result of a deficiency in the nuclear regulatory system that was highlighted by the deterioration of nuclear safety at specific nuclear licensed sites. The introduction of LC 36 was at the time regarded as a significant contribution to nuclear safety and its intentions have been copied by many regulators around the world. We did not think there was a need to have a specific licence condition for "organisational capability" because it was at the time, and remains, adequately covered by licensing process and the requirements of the existing conditions attached in the "standard licence".

23. In relation to the proposed change clause (1), I have argued above that there are no powers under NIA 65 to attach such a clause in relation financial resources. I have also argued that financial and organisational capability is taken account of in the pre-licensing "Application" part of

the licensing process. Therefore, in relation to financial capability there is no need to introduce a requirement via licence conditions.

24. In relation to the Directive requirement to have adequate human resources to ensure nuclear safety, I have again argued above that the current nuclear licensing regime already covers this through the process of granting a nuclear site licence and the application of other licence conditions that are currently attached to a nuclear site licence.

25. For example, several licence conditions require the production of safety cases or safety documentation to demonstrate nuclear safety in certain activities, eg LC 19, LC 20, LC 21, LC 22, LC 23, LC 35 and LC 36. The production of these safety cases is in itself a safety related activity. The content of safety cases and safety documentation also identifies safety related activities to be carried out to ensure the intent of the safety case is delivered. Additionally, other licence conditions are specifically used to identify key safety related activities eg LC 2, LC 3, LC 4, LC 5, LC 6, LC 7, LC 8, LC 9, LC 10, LC 11, LC 13, LC 14, LC 15, LC 16, LC 17, LC 18, LC 24, LC 25, LC 26, LC 27, LC 28, LC 29, LC 30, LC 32, LC 33 and LC34.

26. Licence Condition 12 requires that only suitably qualified and experienced persons can carry out safety related activities. Therefore, through the process of obtaining a nuclear site licence and subsequent compliance with the current set of conditions attached to the licence, the licensee is required to provide, maintain and demonstrate that it has adequate human resources to deliver nuclear safety.

27. I therefore believe that the UK's existing nuclear licensing framework is fully compliant with Article 6(5) in respect of human resources and there is no need to change the current LC 36 as proposed.

Proposed Change to Licence Condition 17

28. At the time when the standard licence was developed in the late 1980s, we did consider

whether or not a specific licence condition relating to the licensee's management system. After due consideration it was decided that such a licence condition was not necessary. The principal reason for this decision was that the set of conditions attached to a nuclear site licence effectively defined the key elements of the licensee's nuclear safety management system and therefore compliance with the requirements of the conditions attached to a nuclear site licence would demonstrate that the licensee was effectively managing nuclear safety.

29. In response to the introduction of the standard licence in 1990 the licensees, as expected, set out their arrangements for compliance in the form of company management procedures that were consistent with their quality assurance/quality management systems. The monitoring of the licensee's compliance with licence conditions and hence its management of nuclear safety, is a normal part of the nuclear safety regulator's inspection and enforcement activity.

30. The philosophy of the application of a standard set of licence conditions to all nuclear site licences was, and I believe still is, to ensure that a nuclear licensee effectively manages nuclear safety to ensure that the risks to workers and the public from the activities being carried out on its nuclear licensed site(s) are as low as reasonably practicable.

31. In view of this, **I would argue that the current UK nuclear safety framework is fully compliant with Article 6(4) of the Directive. There is no demonstrable need to introduce a new requirement for a licensee to "establish and implement management systems which give due priority to nuclear safety" because such a requirement has existed for over 20 years via the standard set of conditions that are attached to all nuclear site licences in the UK.**

32. In relation to the title of the Condition, I favour the term Quality Assurance. At the time we specifically used this term to reinforce the importance of the application of quality assurance processes to all nuclear safety related activities. I would not wish to see this objective undermined or diluted. The term "Quality Management" seems to periodically come in and out of fashion. I personally think Quality Assurance is a stronger term than Quality Management but I accept that whenever possible our terminology should be consistent with national and international usage.

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	<p>However, given that existing licensees have tried and tested quality management/quality assurance arrangements that have successfully delivered the intention of LC 17 over many years, I would question the cost effectiveness of requiring them to make changes to their documentation just to change a name.</p>
Springfields Fuels Limited	<p>Thank you for the opportunity to comment on the proposed changes to Licence Conditions 17 and 36 in respect of the UK's implementation of the Directive 2009/71/Euroatom. We have already provided informal feedback through the Safety Directors Forum and welcome the opportunity to comment further here.</p> <p>In respect of the proposed changes to Licence Condition 17, we note that the substantive change is addition of reference to "... due priority to nuclear safety". We understand the need for this phrase from the Directive but find it rather meaningless without some clarification. We note the comment in the impact assessment that there will be no change in substance to the requirements in T/INS/017 however we would like to see and have opportunity to comment on the ONR's interpretation of "due priority" either within a revised Inspectors Guide (T/INS/017) or elsewhere.</p> <p>With regard to Licence Condition 36, we recognise the extant text from the current Licence Condition as ensuring that a licensee cannot change its organisation in such a way as to become deficient in terms of the requirements of being a Nuclear Site Licence holder. The basis of this demonstration is a change management process which assesses the impact of all organisation changes on safety. The inclusion of the financial element introduces an additional dimension which the ONR are stating will be demonstrable essentially through a licensee's ability to maintain a safe operating regime through normal business processes.</p> <p>The impact of the changes to the Licence Conditions 17 and 36 on the licensee is therefore dependent on the ONR's stated approach being adopted in practice. It is therefore important that these principles are promulgated into the ONR Inspectors and/or Assessment Guides (TAGs/TIGs) in a timely manner and the licensees are given opportunity to review and discuss the amendments in this respect before issue.</p>

Magnox South
Sites – Magnox
Limited

Magnox Limited Comments on the Proposed Amendments to LC17 and LC36

LC 17

LC 17 – Title as Management Systems – This could be interpreted as more than one management system. I would encourage that this be put in the singular rather than plural and again in LC 17(1), 17(2), 17(3), 17(4) (as detailed below).

LC 17(1) – The Introduction of nuclear safety within this section rather than safety, and section 17(2) to indicate ...quality management arrangements in respect of all matters that effect safety.

What is the intention behind these two statements, why are we differentiating between the two and what will the impact of this be?

‘Quality’ appears within the new LC clauses and I don’t think this adds value as we aim to have an integrated management system which in all encompassing which looks at quality, safety environment etc.

Apart from the title change I’m not sure why we are referring to Management system and quality management arrangements. My thoughts are within our management system sit our management arrangements of how we manage certain aspects.

2) LC 17(2) PROPOSED – *The Licensee shall, **within its management systems**, make and implement adequate quality **management** arrangements in respect of all matters which may affect safety.*

- If this is management system specific would wording such as ...*The Licensee shall, within its management system, make the implement adequate **management** arrangements in respect of all matters which may affect safety.*

3) LC 17(3) PROPOSED – *The licensee shall submit to the Executive for approval such part or parts of the aforesaid **management systems** or afore said **quality management arrangements** as the Executive may specify.*

- If the wording was amended to ‘*part or parts of the aforesaid **management arrangements** as the Executive may specify.*’

4) LC 17(4) PROPOSED – *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.*

- If the wording was clarified to ‘*.... no alteration or amendment is made to the approved management arrangements unless the Executive has approved the alteration or amendment.*’

5) LC 17(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.*

- As detailed above if it was to read - ...’ *The Licensee shall furnish to the Executive such copies of records or documents made in connection with the aforesaid **management** arrangements as the Executive may specify’...*

LC 36

I have no comments of the specific wording of the proposed LC 36 amendment as currently proposed in the consultation notes. Further, I do not foresee any significant problems with the introduction of this amendment. I have based this on the following assumptions:

The expectation for the initial justification is a one-off justification contained in the Safety and Environment Management Prospectus (SEMP) describing; the means of funding, the method of

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	<p>prioritising funding to safety (particularly nuclear safety), the means of obtaining additional funding to address nuclear safety concerns and the arrangements for funding in the event of a significant nuclear event.</p> <p>The justification that the extant funding and arrangements are adequate to ensure nuclear safety would be based on the historic and current safety performance of the company.</p> <p>There will not be a requirement to separate out a nuclear safety baseline level of funding.</p> <p>The arrangements to control and justify changes to funding would only be enacted if the changes could adversely affect nuclear safety. Therefore, overall funding levels and funding allocation could change without requiring justification under LC 36 so long as the changes did not change the arrangements described in the SEMP justification. As funding allocation within the business is changed on a monthly basis any requirement to control and justify all changes to funding levels and internal allocation would be impossible to implement.</p> <p>Significant changes to funding levels that could adversely affect nuclear safety would have to be assessed and justified prior to the change being made or, if the change could not have been foreseen, as soon as reasonably practical after the change was enacted.</p> <p>The above guidelines for application of the revised licence condition could be prescribed in the TAG and best practice for enacting them could be described the NICO P.</p>
Urenco	<p>Proposed Amendment to Licence Condition 17</p> <p>Whilst we are reassured that the Office for Nuclear Regulation does not expect any change in current industry practice or in regulatory behaviour to arise from the proposed amendment to Licence Condition 17, given that the amended Licence Condition now extends to management systems and quality management arrangements (rather than simply to quality assurance arrangements), we do consider that a degree of materiality should be introduced to Licence Condition 17(4).</p>

Without such, we believe that there is the possibility that any change to a licensee's safety-related management systems or processes or procedures (including those of a purely technical nature) could be construed as an infringement of the Licence Condition, which we do not believe is the intention.

Therefore, we believe that Licence Condition 17(4) should be refined to read:

“(4) The licensee shall ensure that once approved no **material** alteration or amendment is made to the approved **management systems** or approved **quality management** arrangements unless the Executive has approved the alteration or amendment”.

Proposed amendment to Licence Condition 36

Noting that the Office for Nuclear Regulation does not expect any change in current industry practice or in regulatory behaviour to arise from the proposed amendment to Licence Condition 36, we do not consider the addition of the new Licence Condition 36(1) to be unreasonable insofar as it appears to state what is already accepted wisdom, namely that “The licensee shall provide and maintain adequate financial and human resources to ensure the *safe operation of the licensed site.*” (Our emphasis).

Whilst we note the comments of the Office for Nuclear Regulation in Annex B as to how the obligation to “provide and maintain” adequate financial resources will be satisfied (per paragraphs 12 and 13 of Annex B), we also note that, in the event that the Office for Nuclear Regulation requests financial information, the costs associated with any such engagement (including the costs associated with the use of external financial advisers) will be recovered from the licensee (per paragraph 16 of Annex B). Although the suggestion is that such occurrences will be rare, since we believe that such acts will constitute an integral part of the activities of the Office for Nuclear Regulation we do not believe that the costs of undertaking those activities should be recoverable from the licensee.

We trust that you will find the abovementioned comments helpful to your deliberations and we look

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	<p>forward to hearing from the Office for Nuclear Regulation ahead of the implementation of the changes on or before 22 July 2011.</p>
Safety Directors Forum	<p>We discussed the changes to LC 17 and 36 at the SDF on Monday. We did have representatives from DECC and ONR present.</p> <p>We are reassured by ONR inspectors current practice and the reassuring comments made wrt the new wording.</p> <p>Our key concern is around interpretation and implementation with the potential for future drift away from the current intention. We would very much like to engage with ONR on the development of the detailed guidance in SAP's, TAG's and guidance for inspectors. I would expect licensee's submissions to contain such comments.</p>
Rolls-Royce	<p>Thank you for the opportunity to comment on the proposed changes to LC 17 and LC 36 which are required to implement Nuclear Safety Directive 2009/71/Euratom.</p> <p>Rolls-Royce welcomes the approach being taken to amend existing Licence Conditions rather than introduce new conditions; however, we are concerned that the proposed changes do significantly broaden the scope of the two licence conditions.</p> <p>Specifically, on LC 17, for a commercial entity to have the risk of having any of its management arrangements frozen and therefore to lose the ability to respond quickly and flexibly to the business environment is not acceptable. The Management System covers all of a licensee's activities (commercial, HR, financial etc) and for the regulator to be able (in theory) to call in any part of the Management System and approve (or freeze) appears to give a very broad power which is not required to satisfy the conditions of the directive. The change raises concerns unless guidance is provided to bound "Management System" with respect to its meaning and application ie which parts of the management system does the regulator need new powers over to comply with the directive which it does not have now?</p> <p>We note that assurances that ONR anticipates minimal costs and does not expect any resulting changes in industry practice or regulator behaviour and that ONR recognises that licensee</p>

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	<p>management arrangements change regularly and that the ONR would not wish to use the power of 'approval' to constrain these changes.</p> <p>On LC 36, the inclusion of the financial element introduces a significant change in emphasis to the Licence Condition from one which focuses on Organisational Change (as embodied in the recently issued Nuclear Industry Code of Practice) to one of Organisational Capability. We welcome the recognition by ONR that the licensee's budget is sometimes controlled by another body; however we do have reservations about practical application and criteria for interest. We also acknowledge the proposal to use external Auditors "where the Regulator deems it necessary" however we are concerned that this will become the norm, thus leading to an increase in cost to the licensee.</p> <p>Again we note ONR's assurances that minimal changes will be required to current practices amongst licensees, however, it is not clear how a licensee would demonstrate the required level of financial resource.</p> <p>Given the above uncertainties with respect to the interpretation of the two new conditions, we strongly believe there is the need for guidance for both licensees and regulators. We would welcome the opportunity for the industry to contribute to the drafting of this guidance and Rolls-Royce would be pleased to be involved in this activity.</p>
Rosyth Royal Dockyard Limited	<p>We note the changes intended and ONR's expectation that any consequential amendment of the licensee's documentation will be made in the normal course of periodic review.</p> <p>Notwithstanding the explanation and guidance on the change to LC 36 given in Annex B to the reference, we believe that consolidation of the regulator's expectations in a Technical Assessment Guide (TAG) would be appropriate. As several licensees are funded for their operations and safety obligations by third parties (mainly government bodies that may not be subject to the same regulatory authority), we suggest that the TAG should give guidance on the regulatory expectations for an adequate demonstration of adequate financial resources under these circumstances. It would be most helpful if that guidance could be made available before licensees are required to have defined their arrangements.</p>

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	In other aspects of the proposed changes, we foresee no insurmountable difficulty in complying.
Nuclear Decommissioning Authority	<p>I have looked at the proposed changes to Licence Conditions 17 and 36 as set out on the links to ONR's web page. I am responding on behalf of the Nuclear Decommissioning Authority (NDA), the publicly funded NDPB who are the formal owners of the licensed sites at Sellafield, Dounreay, Harwell, Winfrith, Springfields, LLWR, the 10 Magnox reactor sites and part owner of the Capenhurst site. Through the Energy Act 2004 NDA are charged with decommissioning and remediating these sites. We are also the prospective SLC for the design and operation of the Geological Disposal Facility (GDF) as part of the Government's Managing Radioactive Waste Safely (MRWS) programme. Our sites are operated by SLC contractors who hold the relevant nuclear site licences and other regulatory permits. The ability of our contractors to operate and decommission our sites while complying with the site licence conditions is a major factor in the pursuit and achievement of NDA's decommissioning mission.</p> <p>It is difficult to comment authoritatively on the potential consequences of the proposed changes without sight of the prospective guidance notes on how these will be regulated and enforced, though we note the reassurances in the explanatory notes to the proposals that the implications should be minor.</p> <p>LC 17. We note that there is no expected 'change in substance' in the SLC arrangements. However we are concerned that this will become a matter of scope or interpretation as the arrangements and wider management systems themselves become an extension of the compliance footprint. We believe that the guidance will need careful wording to bound any unintended scope creep.</p> <p>LC 36. The prerequisite financial capabilities of SLCs has long been a policy matter for Government which Government has already implemented via an alternative legal structure when it established NDA via the 2004 Energy Act. As the agency set up for this specific purpose, NDA owns the legacy civil nuclear sites and the liabilities thereon, sets the decommissioning strategy and funds the operational and decommissioning work on these sites against agreed plans and annual funding limits, which in turn are ultimately set and agreed with Government. The SLC contractors</p>

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	<p>are 'enduring' in the sense that they need to cogently retain the expertise to understand and control the day to day operations on the site, but the SLCs do not own the nuclear liability and carry only limited risks of programme failure – principally those of a contract delivery nature. While we recognise the external imperatives for the proposed changes, we are not convinced that they have been appropriately conceived for the NDA owned sites and believe they will either need to be effectively suspended or significantly re-interpreted through regulatory guidance for our sites. It is not possible to comment on the likely impact on NDA's work without sight of the proposed detailed guidance notes as we recognise these will be key to avoiding any overlap or potential conflict with NDA's Energy Act obligations as well as any significant extension to the compliance footprint. For information NDA already has its own guidance published in this area – see Annexe 1 of the attached, referenced NSG31.</p>
Dounreay Site Restoration Limited	<p>Dounreay Site Restoration Limited (DSRL) has previously provided a response on the type of information that is currently available to demonstrate compliance with the proposed amendment to Licence Condition 36, relating to Nuclear Safety Directive 2009/71/Euratom.</p> <p>I support the comment of the (Nuclear Industry) Safety Directors Forum (SDF) that licensees should be consulted on the amendment to the Technical Assessment Guide for Inspectors.</p> <p>DSRL do not have any additional comments on the proposed amendments to Licence Condition 17 and 36.</p>
Devonport Royal Dockyard	<p>Thank you for providing an opportunity to formally comment on ONR's plans to amend Licence Conditions 17 and 36 in response to the requirements of Nuclear Safety Directive (NSD) 2009/71/Euratom.</p> <p>Devonport Royal Dockyard Limited (DRDL) are broadly content with the proposed amendments and agree that they are appropriate for ensuring compliance with the NSD. However, we cannot agree that they will be without impact as we are yet to see the supporting guidance notes against which they will be implemented. Although we understand the need for haste to ensure compliance with the NSD by the 22 July deadline it does concern us that this will result in a change to the conditions of our nuclear site licence before we have had the opportunity to understand the potential impact</p>

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(from our experience this is not the normal way in which we would expect a licence condition to be introduced or amended).

We agree, from a financial point of view, that the changes to LC 36 will not introduce any major differences to the way we do business or cause us to generate additional information if you do not challenge our judgement that we have adequate finances and human resources. However, as there appears to be no criteria available for judging “adequacy” we envisage some very difficult (and expensive) debates should you choose to challenge our judgements. It is not clear to us how in the absence of objective criteria, we could defend such a judgement made by the ONR (using your external experts) that we were non-compliant with this LC. This is of particular concern to DRDL due to the long term and strategic nature of our contracts with the MoD, which are inter alia dependent on our compliance with licence conditions, not a third party’s perhaps less than SQEP or subjective interpretation of those conditions. Consequently, a protracted and potentially expensive consultation may be required with our long term strategic partner and customer, the MoD concerning the prospective impact and consequences of matters that could be outside of our control under the new LC 36. Also, as there is no additional information available at this time, it is unclear to how this requirement would implicate parent companies (ie Babcock International Group as opposed to Devonport Royal Dockyard Limited, the licensee in our case).

We welcome your offer of a draft copy of the updated inspector guidance on LC 17 (T/INS/017) and will provide comment on that as requested. We will also continue to engage with the SDF’s LC 36 sub-group and through that forum seek to work with industry and the ONR to develop consistent and appropriate guidance in SAPs, TAGs and guidance for inspectors, as appropriate.

Finally, please note that our concern does not relate to the intent of these changes; we have had sufficient assurances verbally and in writing to be convinced that there is genuinely a desire to ensure compliance with the NSD with the minimum impact on industry. However, our experience has taught us that intent often drifts unintentionally if not captured adequately in the aforementioned documents and this is why we seek to work with ONR on their development.

AWE	<p>Thank you for the correspondence detailing proposed changes to Licence Conditions 17 and 36 and the opportunity for AWE to feedback its comments. The changes to the wording of the licence conditions and corresponding detail of Annex A and B of your letter have been most useful in assessing the likely impacts; each condition has been dealt with in turn and outlined below.</p> <p>Licence Condition 17</p> <p>As highlighted in your letter, amendments to the wording of this licence condition make it explicit that licensees have in place ‘management system arrangements’ to support nuclear safety. AWE already has in place robust management arrangements that allow the requirements of the licence conditions to be met. These are subject to ONR scrutiny through routine inspection and review.</p> <p>AWE has always interpreted the term ‘adequate quality assurance’ as expressed in the existing Licence Condition to be aligned with the language of other standards across the business and represents a change in terminology rather than to the obligations that underpin it.</p> <p>Licence Condition 36</p> <p>This condition has been broadened and renamed ‘Organisational Capability’ although the main change consists of the requirement to demonstrate ‘adequate financial and human resource to ensure safe operation’. In the context of maintaining the site and demonstrating suitability of management arrangements AWE agrees with the ONR interpretation that this is consistent with a licensee being able to demonstrate adequate maintenance of capability, with provision of acceptable safety cases and adherence to its Nuclear Baseline. Failure to support these areas financially would be manifested through non-compliance with AWE’s management system and would be identified through the ongoing AWE/ONR inspections.</p> <p>In addition to the operational deficiencies that may point towards an underpinning financial constraint, the revised Licence Condition also highlights non-routine requests for financial information and inspection. In this context, it is interpreted that a review of the Company’s financial planning arrangements would be sought at a strategic and business level which would point towards</p>
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	<p>our commitment to implement safety improvement programmes and related activities.</p> <p>Whilst AWE can interpret the context of the change, it is not clear whether the proposed re-wording will lead to revision in ONR inspection scrutiny. Your letter indicates limited changes to current inspection and compliance requirements, but more detail is required to support and confirm this.</p> <p>In conclusion whilst limited impacts are suggested from these changes, we would welcome involvement in the development of relevant Technical Assessment Guidance (TAG) notes in order to understand the inspection requirements in greater detail and to further clarify the likely effects and impacts upon AWE.</p>
Greenpeace	<p>Greenpeace welcomes the opportunity to comment on the ONR's consultation on the <i>Nuclear Safety Directive 2009/71/Euratom Note on changes to licence condition 17 and 36</i>.</p> <p>Greenpeace has asked some questions of the ONR concerning the regulations and their possible relationship to other Government measures concerning financial arrangements for nuclear operations. We thank the ONR for taking time to respond to our questions (attached below) and raise the following points.</p> <p>Nuclear regulation/Funded Decommissioning Programme (FDP): In the ONR's reply to Greenpeace there is a reference to how the ONR might work with the Secretary of State on Funded Decommissioning Programmes – FDPs' – which will be agreed between the SoS and the operators of new nuclear reactors.</p> <p>As part of its commitment to openness and transparency the ONR should provide examples of areas where there may be commonality of interests between the regulators/SoS and operator finances. For example, there may be matters under an FDP concerning spent fuel management at reactor sites which could impact on spent fuel disposal. Communities at both a reactor site and disposal site will be interested in issues around the management of spent fuel and funding/financing may be the factor which decides which option is chosen. Alternatively, the costs associated with</p>

certain activities could potentially result in conflict between communities eg if costs are a key factor in whether spent fuel storage takes place at reactors sites or a central location. It appears that all industry has to do under the regulations is to prove it has the money for a preferred option – possibly arranged under a closed-door agreement such as an FDP? It is not clear how the ONR will be involved in such a discussion and how it or other organisations concerned will work (with the public) to resolve such a situation.

Most importantly however, in such a case as the an FDP will be negotiated behind closed doors and because the regulators have not explained how they might make public relevant information on such an agreement the public/communities which may be affected will have no input on the matter if the regulatory situation remains as it is now. Further, there is no commitment to informing the public, even after a decision is made, on the issue of how finances have impacted on any particular chosen route.

Annex B (notes on the regulations) state: 12. *On a day-to-day basis, compliance with legal duties to maintain an appropriate level of nuclear safety is likely to be sufficient evidence of compliance with the licence condition regarding the licensee's existing financial resources.*

It is Greenpeace's view that a company always having the necessary finance cannot be taken as a 'given' – we refer here to the situation in 2002 when British Energy became bankrupt.

Further, in the event of a major accident (major offsite releases, invoking of the liability regime and other matters notwithstanding) a company's financial situation could go from relatively fluid to at-risk in quite a short space of time. This is an issue Greenpeace raised in its response to the consultation on Funded Decommissioning Programme Guidance in March 2011. The ONR should have provided more explanation of what measures it takes (if any) to ensure any associated company is in a position to meet safety requirements, and maintain such funds, in the event of insolvency of an operator (or sudden decrease in funding). It is surprising the changes to Licence Condition 36 to not make explicit the need to demonstrate the ability to maintain 'adequate' financial and human resources – by the company and associated companies (eg see 2a.31, 2c.68 in the

revised FDP guidance, December 2010).

On ensuring operators can meet financial requirements (Para 16 Annex B) it is mentioned that if the ONR needs to make a request on financial information: *it may need to draw on the expertise of external financial advisers, in addition to seeking suitable assurances from Government, and the costs of such engagement would be recovered from the licensee.'*

Para 28 of the Impact Assessment notes: *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: financial annual accounts, plans for construction and key financial decision points; investment plans; lifetime Plans (LTP); and 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]*

Again, there is no explanation of how the public or Parliament get access to the information which provides assurance that the relevant financial provisions are in place or can be met fully. On this we note Para 33 states that: *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.* This begs the question of what happened with BE – and if it happens again can the ONR guarantee there would not be repeat of the same situation?

Consultation: The basis for the consultation is not explained (eg if there are statutory guidelines the ONR observes). This is not the first time the ONR has done such a consultation, in terms of it not seeming to conform with any particular codes. In future the ONR should explain the basis of its consultations.

Questions re Changes to Licence Conditions

I am writing on behalf of Greenpeace UK concerning the ONR's consultation on the Nuclear Safety Directive 2009/71/Euratom Note on changes to licence condition 17 and 36.

We would like to ask a few questions, which we hope you will be able to answer, before we submit a response to the consultation.

a) What are the links, if any, between the Secretary of State's powers to propose or agree a modification to Funded Decommissioning Programmes and those of the regulators (as per the licence conditions changes) in terms of financial arrangements by operators to cover all requirements under an FDP and a licence?

On this we refer, for example, to Paras 2b.21-2b.22 Consultation on revised Funded Decommissioning Programme Guidance for New Nuclear Power Stations (<http://www.decc.gov.uk/assets/decc/Consultations/fdp-guidance-new-nuclear/985-consultationrevised-fdp-guide.pdf>)

Can you provide an explanation of the different roles/powers of the SoS and the ONR in ensuring funding is available as per the proposed FDP and the relevant licence conditions? For example, do the SOS's powers relate only to overall funding of an FDP? Do the ONR's cover both overall funding and implementation of specific safety technology? If not, we would be grateful if you could provide some further explanation.

How might the proposed changes to the Energy Act 2008 impact on the role of the ONR under the proposed licence conditions. On this we refer to DECC's brief that: The agreement will fetter the Secretary of State's discretion over the exercise of the power to propose modifications to the FDP. (<http://www.decc.gov.uk/assets/decc/legislation/energybill/544-energy-security-bill-brief-nuclear-operate.pdf>).

b) What relation, if any, do the proposed regulatory changes to licence condition 17 and 36 have to

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	<p>the proposals to Implementation of changes to the Paris and Brussels conventions on nuclear third party liability (DECC consultation January 2011)?</p> <p>Thank you for your attention to this matter.</p>
Magnox North Sites – Magnox Limited	<p>Thank you for the opportunity to comment on the amendments that you are considering making to the licence conditions attached to nuclear site licences.</p> <p>As a member of the Safety Directors Forum, XXXXXXXXXXXX we have already provided feedback on the draft impact assessment and our view remains broadly the same. XXXXXXXXXXXX</p> <p>Overall we accept that the wording changes have to be made to the LCs to conform to the directive. Our detailed comments are intended to influence the wording primarily to provide for clear interpretation albeit that we acknowledge that the guidance to follow should address any issues arising in this respect.</p> <p>On this point it is now important that you capture all the good words, reassuring statements and current practice of ONR in your formal guidance (SAP's, TAG's and guidance for Inspectors).</p> <p>Indeed we would wish to be involved in developing such guidance and I look forward to hearing from you on your planning and programme of engagement with licensees on this aspect.</p>
BAE Systems	<p>A Consultation on the Proposed Changes to Nuclear Site Licence Conditions 17 and 36</p> <ol style="list-style-type: none">1. Thank you for the opportunity to review the proposed changes to Nuclear Site Licence Conditions 17 and 36, and opportunity to express our views and any related concerns.2. While we have no fundamental objections to the proposed changes to these Licence Conditions we do not understand why it is necessary to go through the considerable process of modifying the Conditions if the position stated in the Regulatory Impact Assessment (RIA) is valid, ie that “The required changes are not anticipated to change current practices amongst nuclear site licence holders, and so no significant costs expected.” If the changes are not to affect a difference what is

the purpose of change?

3. Notwithstanding the above, it is of concern that the RIA indicates that the cost impact of this change is Nil. Any change to Licence Conditions, however small, will give rise to an administrative burden in changing compliance records, policies and documentation.

4. Our specific responses to the proposed changes are outlined below.

Licence Condition 17 – Quality Assurance

5. As stated above we have no objections to the proposed changes to this Licence Condition in that for a significant period of time, practice has been to consider this Licence Condition as applying to Management Systems in the round and this is consistent with current published regulatory guidance.

Licence Condition 36 – Control of Organisational Change

6. The concept of adequate financial resources has not been defined for the UK Nuclear Industry. Certain aspects of financial provision are defined for UK Licensees, eg Command 2919, application of the ALARP principle and the requirements of the Paris and Vienna conventions. However the success criteria for adequacy and the standards required for demonstration and maintenance of adequacy are not. The implication of the RIA is that this will require funding of financial specialists to review company records, but unless the records are scrutinised against a standard of adequacy for nuclear safety we do not see how the revised Licence condition can be considered to have been met.

7. The general understanding of the current Licence Condition 36 amongst Licensees and Regulators has developed since its inception in 1999 and it is now supported by five Technical

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	<p>Assessment Guides. These provide a comprehensive platform for regulatory assessment and dialogue on the subject of adequate human resources. We do not believe any additions to the Licence Condition or its supporting requirements are necessary to reinforce the approach to regulation of adequate human resources.</p> <p>8. There is an inconsistency between the RIA and the Chief Inspector's letter to licensees in that the RIA states that the Licence Condition changes will 'not cause licensees to do anything different in practice'. However the Chief Inspector's letter indicates that he does not anticipate significant change in Regulatory behaviour. We are concerned that the RIA has not comprehended the impact that the change to the Licence Condition will produce.</p> <p>9. In some instances, the company which holds the site licence may differ from that which controls the management and financial framework under which the relevant duties are discharged. This is the case in Barrow. Therefore, the proposed licence condition amendment or supporting documentation should recognise this potential relationship.</p> <p>10. We look forward to your response to the consultation and continuation of the dialogue on these changes to the Licence Conditions.</p>
Studsvik	<p>Thank you for your letter dated 12th May and the opportunity to comment on the proposed amendments to Licence Conditions 17 and 36.</p> <p>We fully understand why these amendments are required and agree that the proposed wording is necessary to reflect the requirements of the Council Directive.</p> <p>Whilst we agree with the proposed changes we share the concerns relayed to ONR through the Safety Directors Forum (SDF) ie concern regarding the interpretation and implementation with potential for future drift away from the current intention.</p> <p>Specific areas are highlighted below for your consideration.</p>

	<p>Amendment to LC 17 – Introducing the term ‘Management System’ provides a route to all aspects of a company business system and not just quality assurance. From the communications between ONR and SDF we recognise that ONR intend to continue to work in line with the requirements of T/INS/017 however there is potential for any aspect of a company Business Management system to be requested by ONR. Such documents would therefore be subject to approval by ONR prior to change and this could restrict business activities.</p> <p>We understand that T/INS/017 is being revised XXXXX and welcome the opportunity to comment upon the revised guidance.</p> <p>Amendment to LC 36 – The information required to demonstrate adequate financial resources could be subject to interpretation. The example documents referenced by ONR are typical of documents produced by a commercial organisation and are readily available. We would therefore not expect to undertake any additional work to produce extra supporting documents.</p> <p>It is possible that the example documents identified may not provide the level of detail required for a specific site as many of the documents are produced at a corporate level. In addition, specific detailed information will vary between sites and in particular between licensees funded by UK government and private commercial organisations.</p> <p>Recent correspondence from ONR to SDF members indicates that licensees will be given the opportunity to comment upon proposed changes to inspector guidance. We welcome this opportunity and support the SDF proposal for licensees to be engaged in the development of detailed guidance in SAP’s, TAG’s, Guidance Notes etc.</p>
EDF Energy	<p>Following your consultation letter published on the HSE website, we have considered the impact of the change for EDF Energy Nuclear Generation Limited (NGL) as follows.</p> <p>LC 17 Quality Assurance</p> <p>The company compliance arrangements currently provide an approach which is aligned to the new</p>

proposal, hence the change can be adopted with minor documentation updates.

LC 36 Human Resources

The company compliance arrangements currently provide for preparation and maintenance of organisational baselines which reflect the company's human resources. The format and content of these is under further development in an industry working group under the Safety Director's Forum. Following this, it is expected that this change can be adopted with minor process enhancements.

LC 36 Financial Resources

The company maintains financial control systems, and provides company level financial and business plans to ONR annually. However, this information is not currently retained in lifetime records nor produced in accordance with procedures designed to demonstrate site licence compliance as required in Annex B Item 13 of your letter. As part of adoption of this part of the change we request that:

1. ONR inspection procedures and guidance are made available which outline the depth and extent of information expected to demonstrate compliance and which are consistent with the consultation letter and attachments;

2. the impact assessment is updated to reflect:

- NGL implementation cost for new procedures and record formats
- NGL ongoing costs for routine preparation and storage of records

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	<ul style="list-style-type: none"> ▪ ONR costs for development of new inspection procedures, standards and guidance expected to be recovered from the licensee(s); and <p>3. ONR procedures are reviewed to confirm adequate control over the release of company financial information under Freedom of Information Acts or other routes which could prejudice the company's commercial interests.</p> <p>With the above provisions, NGL can put arrangements in place to support the proposed changes within reasonable timescales following communication of a firm date for implementation. XXXX.</p>											
<p>Research Sites Restoration Limited</p>	<p>Please find attached the RSRL response to the ONR Consultation on the proposed amendments to Licence Conditions 17 and 36 to implement the Nuclear Safety Directive 209/71/Euratom.</p> <p>Consultation Response from Research Sites Restoration Limited</p> <table border="1" data-bbox="566 762 1968 1197"> <thead> <tr> <th data-bbox="566 762 1227 799">Section</th> <th data-bbox="1227 762 1968 799">RSRL Comments</th> </tr> </thead> <tbody> <tr> <td colspan="2" data-bbox="566 799 1968 836">LC17 Management Systems</td> </tr> <tr> <td colspan="2" data-bbox="566 836 1968 873">General Comments</td> </tr> <tr> <td data-bbox="566 873 1227 1197"> <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 nuclear safety.</p> </td> <td data-bbox="1227 873 1968 1197"> <p>The importance of making nuclear safety a priority is recognised in the RSRL management system. RSRL commitment to safety is reflected in its adoption and external certification to BS OHSAS 18001. RSRL also subscribes to the principles of IAEA GS-R-3 and has used these principles in the recent review and updating of its management system. Therefore RSRL have no concerns over this proposal.</p> </td> </tr> <tr> <td data-bbox="566 1197 1227 1340"> <p>(2) The licensee shall, within its management systems, make and implement adequate quality management arrangements in respect to all matters which may affect</p> </td> <td data-bbox="1227 1197 1968 1340"> <p>This requirement is consistent with the adoption of GS-R-3 principles, see above. Therefore RSL have no concerns over this proposal.</p> </td> </tr> </tbody> </table>		Section	RSRL Comments	LC17 Management Systems		General Comments		<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 nuclear safety.</p>	<p>The importance of making nuclear safety a priority is recognised in the RSRL management system. RSRL commitment to safety is reflected in its adoption and external certification to BS OHSAS 18001. RSRL also subscribes to the principles of IAEA GS-R-3 and has used these principles in the recent review and updating of its management system. Therefore RSRL have no concerns over this proposal.</p>	<p>(2) The licensee shall, within its management systems, make and implement adequate quality management arrangements in respect to all matters which may affect</p>	<p>This requirement is consistent with the adoption of GS-R-3 principles, see above. Therefore RSL have no concerns over this proposal.</p>
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	(3) The licensee shall submit to the Executive for approval such part of parts of the aforesaid management systems or aforesaid quality management arrangements as the Executive may specify.	No significant change to current requirements. Therefore RSRL have no concerns over this proposal.
	(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.	No significant change to current requirements. Therefore RSRL have no concerns over this proposal.
	(5) The licensee shall furnish to the Executive such copies of records or documents made in connection with the aforesaid quality management .	No significant change to current requirements. Therefore RSRL have no concerns over this proposal.
	LC 36 Management of Organisational Change	
	General Comments	
-		The changes to LC 36 are potentially more significant as there will be a duty on the licensee to provide and maintain adequate financial resources to ensure the safe operation of the licensed site. RSRL recognise the principles behind the proposed changes but are of the view that a lot will depend on the time period over which this is judged. As RSRL receive its Annual Site Funding Limits annually provided by NDA (and ultimately Government), it would be difficult for RSRL to fully demonstrate that it has adequate financial resources to cover the out years.

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	<p>Title – Licence condition 36: Organisational Capability</p>	<p>Title change – no comments.</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>Given the way by which RSRL is funded by the NDA it is difficult for RSRL to be in a position to be able to demonstrate control to “provide and maintain” resources, although RSRL recognises its responsibilities as Licence Holder to ensure the safe operation of the site. If funding drops below the needs of the safety baseline we recognise the need to carry out a structured financial impact assessment whereby skill or resource levels are changing. In implementing this change RSRL would seek assurances regarding the proportionality of regulation under this Licence Condition for NDA funded sites.</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 organisation</p>	<p>No significant change to current requirements. Therefore RSRL have no concerns over this proposal</p>
<p>Sellafield Site</p>	<p>Sellafield Limited is of the view that the way its arrangements under the current text of Licence Condition 17 have been developed and implemented anticipates, in practice, the revised wording now being proposed. In effect, the necessary management systems are in place. On this basis we concur with the Impact Assessment of Nil cost.</p> <p>The position with Licence Condition 36 is a little different. As a licensee funded by the taxpayer, through the Nuclear Decommissioning Authority (NDA), we comply with our contractual obligations to NDA to prepare and implement a costed Life Time Plan (LTP) – the most recent edition being LTP 2010. This information has been made available to our Regulators, including ONR.</p> <p>Financial issues, including changes to the funding position, have not of themselves engaged</p>	

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	<p>Licence Condition 36 through our arrangements: although proposed consequential changes to the organisation structure or human resources have been considered under these arrangements.</p> <p>Sellafield Limited believes that this is the right balance. Strategic financial issues have been, and will continue to be, discussed openly with Regulators, including ONR. We do not see a nuclear safety benefit arising from making consideration of financial matters a routine aspect of day-to-day compliance with Licence Condition 36. Indeed, such a routine consideration has the potential to become an unhelpful distraction for managers tasked with understanding and mitigating as far as reasonably practicable nuclear safety risks associated with a proposed change to organisation structure or human resources.</p> <p>Sellafield Limited welcomes the statement by HM Chief Inspector of Nuclear Installations and Head of ONR "...The proposed changes to licence condition 36 will therefore explicitly require licensees to provide for and maintain financial and human resources to ensure nuclear safety. We are not anticipating that this will lead to significant change in regulatory behaviour by ONR. In particular, we do not expect ONR inspectors to routinely request detailed financial information. We anticipate that we will look to Government to provide continuing assurance on this matter after initial assurance before granting a nuclear site licence..."</p>
Horizon Nuclear Power	<p>Consultation Response by Horizon Nuclear Power</p> <ol style="list-style-type: none">1. Horizon Nuclear Power (Horizon) welcomes the opportunity to respond to the Office for Nuclear Regulation's (ONR) consultation on proposed amendments to nuclear site Licence Conditions (LCs) 17 and 36 in order to implement the Nuclear Safety Directive 2009/71/Euratom.2. Horizon is a joint venture between E.ON UK and RWE npower. We aim to develop and construct around 6GW of new nuclear power station capacity in the UK and have already acquired interests in land at Wylfa on Anglesey in Wales and at Oldbury in Gloucestershire. We also have grid connection agreements for both sites.

3. Both the Oldbury and Wylfa sites were nominated into the Government's Strategic Siting Assessment (SSA) and we are pleased that both have subsequently been identified in the Nuclear NPS as suitable sites for nuclear power station development.

4. Horizon is therefore replying to the ONR's consultation as a prospective nuclear site licensee at the aforementioned sites. Our comments on the proposed amendments are set out below.

Licence Condition 17

The proposed amendments to Licence Condition 17 are acceptable to Horizon.

5. Horizon believes that the proposed amendment to Licence Condition 17, which requires licensees to establish and implement management systems giving due priority to nuclear safety, is acceptable.

6. The proposal to revise the terminology in Licence Condition 17 by replacing references to 'Quality Assurance' arrangements with 'Quality Management' arrangements is acceptable. Such changes will bring the language of the licence condition in to line with that employed in modern standards in particular with IAEA GS-R-3 and across the industry.

7. We also share ONR's view that there should be no change in substance to what is currently required by T/INS/017 – Quality Assurance and we expect this to be confirmed in the update to guidance for inspectors.

Licence Condition 36

The requirement for Licensees to provide adequate human resources is already implicit within the existing Licence Condition 36 and therefore this aspect of the proposed change is acceptable to Horizon. However, we are concerned over the potential implications of the requirement on licensees to demonstrate adequate financial resources to the ONR.

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8. Horizon believes that the proposed amendment to Licence Condition 36 to require licensees to provide adequate human resources to ensure safe operation of the licensed site is acceptable. We believe that this is already implicit within the existing Licence Condition 36 and we share ONR's view that existing licensees already comply with this requirement by virtue of their Nuclear Baseline which demonstrates that the licensee's organisational structure, resources and competencies are suitable to manage nuclear safety. By developing and implementing a Nuclear Baseline, prospective licensees will also be made to demonstrate compliance with this requirement.

9. We agree that adequate financial resources to manage safety are essential. The ONR has suggested in broad terms what the expectations to fulfil this requirement are. However, we believe that the proposed amendments, especially when read in conjunction with the Nuclear Safety Directive are at risk of broad interpretation above and beyond the expectations outlined by the ONR.

10. Horizon is concerned that, given the broad way in which the requirements could be interpreted, their scope could be widened beyond their original intent. A further concern is that the new provision may overlap with other regulatory requirements administered by other bodies such as the need for an approved Funded Decommissioning Plan (FDP). Therefore, the proposed licence amendments will need to avoid duplication in regulation. For example, we do not believe that the ONR should need to examine separately the adequacy of financial resources to manage waste and decommissioning activities as this is independently scrutinised by the Nuclear Liabilities Financing Assurance Board (NLFAB) under an FDP approved by the Secretary of State for Energy and Climate Change.

11. Horizon expects that as the ONR becomes established as an independent regulator, it will clearly define how it will work with other bodies such as DECC to avoid duplication in regulation. Where other legislation and obligations exist they should be explicitly excluded from the Licence Condition 36 remit. For example, a licensee's compliance with an approved FDP is considered to be demonstration of providing and maintaining adequate financial resources in respect of waste management and decommissioning. No further evidence would be required by the ONR in this respect. Horizon expects that this would provide licensees with the assurance that they would need

that they would not be subject to further regulation by the ONR.

12. Furthermore, Horizon expects that when the ONR develops guidance to accompany the amendment, it will clearly define the scope and boundaries of the Licence Condition to ensure that the interpretation of adequate financial resources is not extended beyond its original intent. Horizon believes that such boundaries could include confining the assessment of adequate financial resources to annual budgets rather than long term financial arrangements which are scrutinised by other bodies.

13. The implicit expansion of the ONR's regulatory remit to include financial matters is also a cause for concern. Should the ONR believe that it needs to draw on the expertise of external financial advisors, Horizon would expect greater clarity to licensees as to the circumstances under which it would need to do so, how often this would be likely to occur and what the expected costs would be.

14. The funding structures for prospective new build licensees are likely to differ significantly from those of existing licensees. Moreover, new build licensees will also be subject to additional funding obligations such as the FDP. Horizon believes that the ONR should develop guidance for inspectors which recognises the different funding structures and additional funding obligations of new build licensees.

15. In order to provide greater clarity on the revised Licence Condition 36 requirements and ensure a consistent interpretation and approach to regulation, Horizon believes it is essential that the ONR develops supporting guidance documentation for this purpose (eg Technical Inspection Guides and Technical Assessment Guides) in consultation with the nuclear industry.