

<b>REGULATORY OBSERVATION</b>	
<b>REGULATOR TO COMPLETE</b>	
<b>RO unique no.:</b>	RO-ABWR-0025
<b>Date sent:</b>	26th November 2014
<b>Acknowledgement required by:</b>	17th December 2014
<b>Agreement of Resolution Plan Required by:</b>	
<b>Resolution of Regulatory Observation required by:</b>	To be determined by the Hitachi-GE Resolution Plan
<b>TRIM Ref.:</b>	2014/438012
<b>Related RQ / RO No. and TRIM Ref. (if any):</b>	
<b>Observation title:</b>	Hitachi-GE Nuclear Energy Ltd. Safety Case Process and Capability
<b>Technical area(s)</b> 1. Internal Hazards 2. Civil Engineering 3. External Hazards 4. PSA 5. Fault Studies 6. Control & Instrumentation 7. Electrical Power Supply 14. MoS & QA 13. Human Factors 12. Structural Integrity 11. Mechanical Engineering 10. Radiation Protection & (Level 3 PSA) 9. Reactor Chemistry 8. Fuel Design 15. Radwaste & Decommissioning 20. Project 18. Severe Accident Analysis 19. Fire Safety 16. Conventional Safety & Decommissioning 17. Security	<b>Related technical area(s)</b> 1. GEP
<b>Regulatory Observation</b>	
<b>Summary</b>  Hitachi-GE needs to ensure that its organisational processes and competencies for the production of safety cases are robustly developed and implemented to deliver a complete, cogent and coherently developed modern standards safety case for the UK ABWR, which is consistent across all technical areas and takes cognisance of multiple relevant interfaces.	
<b>Regulatory Expectations</b>  The UK ABWR design contains many features, interfaces and dependencies that need to be analysed and designed to ensure their compatibility in delivering the safest reasonably practicable design. ONR expects this demonstration of safety to be documented in an explicit, coherent, and holistic manner in UK ABWR safety case (the Pre-Construction Safety Report (PCSR) and supporting documentation). The process of producing a suitable and sufficient safety case requires understanding, creativity and in particular, coordinated working, where specialists in different technical areas, envisage and recognise, not only potential safety issues associated with their discipline but also the variety of routes, interactions and dependencies with other technical areas through which potential radiological hazards and faults can arise. Preferred design options can then be identified, analysed and implemented to ensure risks are eliminated or reduced as low as reasonably practicable (ALARP).	

Hitachi-GE's process and resources used for producing the UK ABWR safety case need to take into account UK regulatory expectations for safety cases, and recognise how the different levels and types of safety analysis and design documentation link together to cover the full scope, interactions and content of the safety case, such that all arguments are cogent and coherently developed, the claims and conclusions are fully supported and follow logically from the arguments.

Based on ONR's initial assessment of the UK ABWR PCSR and regulatory interactions with Hitachi-GE across different technical areas, we have identified inconsistencies amongst various and often technically complex safety case documentation, and its formulation into a coherent safety case that takes cognisance of the multiple relevant interfaces. Left unresolved, this matter presents a significant project risk for Hitachi-GE in delivering a successful GDA safety case within the expected project timescale. ONR recognise that some of the organisational changes sought in the actions to this RO may require some time to implement; the key is continually developing Hitachi-GE's safety case capability throughout the early stages of GDA Step 3 in order to achieve a successful outcome.

**Regulatory Observation Actions**

*Action # 1 : Hitachi-GE are requested to develop a documented UK ABWR Safety Case strategy that will ensure that the UK ABWR PCSR and supporting documentation meet UK regulatory expectations. This should include the following:  
 Demonstration of Hitachi-GE 's understanding of the UK ABWR technical and safety case interfaces, with clear identification and definition of these and how they are being managed.  
 Definition of the architecture / hierarchy of safety case documentation, demonstrating how the different levels and types of UK ABWR safety case documentation and the arguments and evidence contained therein, will be produced and linked together to cover the full scope, interactions and content of the safety case.*

*Resolution required by 03/03/2015.*

*Action # 2: Hitachi-GE are requested to define and secure the necessary suitably qualified and experienced safety case professionals required to provide advice on and support writing of the UK ABWR safety case.*

*Resolution required as defined by Action # 1.*

*Action # 3: Hitachi-GE needs to ensure that its PCSR Safety Case Manager understands UK ABWR Technology, is conversant with UK regulatory expectations for modern standards safety cases and is adequately supported by persons with the requisite expertise in this area. The PCSR Safety Case Manager should be a clearly defined position within the Hitachi-GE organisation, as defined in Terms of Reference. This position should have the authority to direct and determine what type of safety case documentation is required, coordinate the different technical disciplines to ensure high quality and integrated safety case arguments and evidence are produced in a timely manner and documented in an adequate PCSR (Revision B) to be delivered at the end of GDA Step 3.*

*Resolution required as defined by Action # 1 but no later than August 2015.*

**REQUESTING PARTY TO COMPLETE**

**Actual Acknowledgement date:**

**RP stated Resolution Plan agreement date:**