

REGULATORY OBSERVATION	
REGULATOR TO COMPLETE	
RO unique no.:	RO-ABWR-0057
Date sent:	1st June 2015
Acknowledgement required by:	22nd June 2015
Agreement of Resolution Plan Required by:	<i>To Be Determined By Hitachi-GE Resolution Plan</i>
Resolution of Regulatory Observation required by:	<i>To Be Determined By Hitachi-GE Resolution Plan</i>
TRIM Ref.:	2015/200543
Related RQ / RO No. and TRIM Ref. (if any):	
Observation title:	Hitachi-GE's development of arrangements for the safety case to be met in practice.
Technical area(s) 14. MoS & QA	Related technical area(s) 1. Internal Hazards 2. Civil Engineering 3. External Hazards 4. PSA 5. Fault Studies 6. Control & Instrumentation 7. Electrical Power Supply 8. Fuel Design 9. Reactor Chemistry 10. Radiation Protection & (Level 3 PSA) 11. Mechanical Engineering 12. Structural Integrity 13. Human Factors 14. MoS & QA 15. Radwaste & Decommissioning 16. Conventional Safety & Decommissioning 17. Security 18. Severe Accident Analysis 19. Fire Safety 20. Project 21. Generic Environmental Permitting
Regulatory Observation	
Summary:	
<p>This RO provides ONR expectations for moving the safety case into the operating regime and for demonstrating that the constructed plant will be capable of being operated within safe limits by ensuring and assuring that safety claims and assumptions are realised in the final as-built design. This includes expectations for the identification, collation and cataloguing of the requirements and assumptions in the safety case and transferring them into construction commissioning, operational and maintenance documentation.</p>	
Background and expectations	
<p>ONR's guidance to requesting parties' shows Hitachi-GE should submit arrangements for moving the safety case to an operating regime at the beginning of GDA Step 4. This requirement is shown below.</p>	
<p>4.3 <i>Arrangements for moving the safety case to an operating regime; i.e. the arrangements to ensure that the requirements of, and assumptions in, the safety case have been clearly identified and can readily be captured in:</i></p>	
<p>(a) <i>technical specifications;</i></p>	
<p>(b) <i>maintenance schedule;</i></p>	
<p>(c) <i>procedures (normal operation, emergency, accident management);</i></p>	
<p>(d) <i>training programmes;</i></p>	
<p>(e) <i>emergency preparedness;</i></p>	
<p>(f) <i>operating limits;</i></p>	
<p>(g) <i>radiation protection arrangements for operators;</i></p>	

- (h) *lifetime records;*
 (i) *commissioning requirements, etc.*

In the guidance for step 4 Hitachi-GE are required to submit a demonstration that the constructed plant will be capable of being operated within safe limits (4.2) and ONR assess the arrangements for ensuring and assuring that safety claims and assumptions are realised in the final as-built design (4.15).

The text in revision A of the safety case does not clearly show, identify or give unique identity to the requirements of, and assumptions in the safety case. It is therefore unclear how this information will be extracted from the safety case and included in the operational documents shown in (4.3) above and in the construction documents that will ensure safety case requirement are realised in the final as built design. There does not appear to be a method for moving the safety case into the operating regime.

The safety case for a facility or activity should demonstrate that the associated risk and hazards have been assessed, appropriate limits and conditions have been defined and adequate safety measures have been identified and put in place. It is therefore essential that the text in the safety case should clearly identify the requirements of, and assumptions in, the safety case so they can be captured and included in construction, commissioning and operational documentation.

Regulatory Observation Actions

RO-ABWR-0057.A1

Develop a method of clearly identifying requirements and assumptions in the text of the safety case and supporting documents. This method should address:

- *Unique identification of each requirement and assumption.*
- *The collation and cataloguing of the requirements and assumptions into a table or list in the safety case*
- *Consolidating the information and the resolution of inconsistencies and non-conformities.*

Resolution required by: Early in Step 4 and No Later than 30th October 2015

RO-ABWR-0057.A2

Produce guidance to the authors of the safety case chapters on the method described in action #1. This guidance should include examples of the types of requirements and assumptions that should be identified. For example requirements and assumptions relating to:

- *Construction and commissioning.*
- *Operation including accident conditions (e.g. operating limits and conditions).*
- *Maintenance.*
- *Radiological protection*

Resolution required by: Early in Step 4 and No Later than 30th October 2015

RO-ABWR-0057.A3

Produce the arrangements required by (4.3) showing how the requirements and assumptions will be moved to the operating regime. This should include:

- *How the requirements and assumptions are collated and catalogued.*
- *How they are graded based on safety significance.*
- *How they will be passed to the operator (e.g. Safety Case, Standard Tech Specs, Manuals, etc)*
- *How Hitachi-GE will ensure the requirements and assumptions from the safety case are included in the standard Tech Specs, Manuals etc which will be supplied to the operators and in construction and commissioning documentation.*

Resolution required by: 29th October 2016

REQUESTING PARTY TO COMPLETE

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Actual Acknowledgement date:	
RP stated Resolution Plan agreement date:	

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