

REGULATORY OBSERVATION	
REGULATOR TO COMPLETE	
RO unique no.:	RO-ABWR-0058
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.:	2015/200629
Related RQ / RO No. and TRIM Ref. (if any):	
Observation title:	Step 3 MSQA Improvement Actions
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
<i>Regulatory Observation</i>	
SUMMARY	
<p>On 20-24 April the ONR and EA carried out the planned inspection of Hitachi-GE's Generic Design Assessment (GDA) project arrangements to assess compliance with the guidance to requesting parties (RP) (http://www.onr.org.uk/new-reactors/ngn03.pdf) and the GDA interface arrangements between Hitachi-GE and the regulators. In addition to this a number of meetings were held to discuss the requirements for the MSQA information which must be submitted in Step 4 of GDA.</p> <p>The findings from the inspection and outcomes of the meetings are described in report ONR-GDA-CR-15-027 Revision 0.</p> <p>This regulatory observation formally advises Hitachi-GE of the shortfalls identified by the inspection and identifies the corrective actions needed to resolve the shortfalls in the management arrangements. It also identifies the actions needed in order for Hitachi-GE to be ready to submit the MSQA information needed for step 4.</p>	
REGULATORY OBSERVATIONS	
<u>Competence (SQEP) / GDA Specific Training</u>	
<i>Background:</i>	

The regulators found that the manner in which Hitachi-GE provide GDA specific training to their staff involved in GDA work is not achieving its intended aim; shortfalls were identified in terms of training materials available, as well as usage of suitably qualified and experienced people to deliver the GDA-specific training to all levels of Hitachi-GE's staff undertaking GDA work.

Examples were found where personnel appeared to have insufficient knowledge of UK safety cases and UK legislation. Also, no evidence was available to demonstrate that managers had evaluated the effectiveness of the GDA specific training as required by their own internal procedures, and Hitachi-GE's internal audit programme did not sample and assess the effectiveness of GDA specific training.

Inspection evidence therefore indicates that GDA specific training is not effective and does not provide GDA personnel with the intended level of awareness of UK safety cases and UK legislation. This is likely to adversely affect the quality of the GDA safety, security and environmental.

Regulatory Expectations:

The regulators expectations for training and competence are based on IAEA's systematic approach to training (SAT) and are summarised below:

- Learning objectives and training needs should be identified.
- A training programme should be designed and appropriate training methods and media should be selected.
- Training courses and associated training materials (e.g. presentations) should be developed by experts with suitable qualifications and experience in the subject.
- Training courses should be presented by experts with suitable qualifications and experience in the subject.
- The effectiveness of the training should be evaluated. This may be done by the trainees completing a questionnaire at the end of each training session and by monitoring GDA submissions or activities to ensure they are of good quality.

(see ROA 1.1 & 1.2)

Competence (SQEP) / Role Profiles and SQEP Assessments

Background:

The regulators found examples of non-conformities in role profiles and SQEP assessments and this means that in some cases the training/SQEP records did not fully demonstrate that the people in the roles are competent. The inspection found examples in the training documentation where:

- The role profile did not accurately describe the competence requirements for the role.
- The SQEP Assessment did not correctly show the nuclear safety significance.
- SQEP assessments did not demonstrate the SQEP requirements in the role profile and the GDA specific training had been completed.

Regulatory Expectations - Competence (SQEP) / Role Profiles and SQEP Assessments

The regulators expectations for training and competence are based on IAEA's systematic approach to training (SAT) and are summarised below:

- An analysis of roles and associated competencies should be carried out and the competence requirements (training, experience and other competencies) recorded in Role Profiles. Role

profiles should clearly specify the minimum qualifications and experience needed to carry out the task. Vague statements such as “experience of department” should be avoided.

- SQEP Assessments should be carried out to assess people’s competence. This assessment should demonstrate the requirements specified in the Role Profile have been fulfilled.
- Records (Role Profiles and SQEP Assessments) should be kept to demonstrate that people fulfil the competence requirements of their role profiles.

(Please see ROA #2)

Assessment Observation – RQ, RO and RI Commitment Capture Process

While discussing the arrangements for RQ, RO and RI commitment capture it became apparent that there was some confusion between:

a) Capturing the actions specified in a resolution plans which, when carried out, will address ROAs or RIAs and allow ROs or RIs to be closed. (Currently these are monitored by the Hitachi-GE tracking spread sheet). and

b) Capturing commitments to update higher level submission documents (e.g. PCSR or GEP) which are made when all ROAs or RIAs have been completed and the regulator has agreed closure of the RO or RI subject to the submission being amended. (This is the part of the arrangements which have not been developed).

Therefore Hitachi-GE does not have a process to capture commitments to update GDA submissions when ROs or RQs are closed. Hitachi-GE stated during the inspection that a method of doing this will be developed.

Regulatory Expectations - RQ, RO and RI Commitment Capture Process

Regulatory expectations for the commitment capture process are:

1. ROs or RIs should be closed when the ROAs and RIAs are complete and large numbers of ROs or RIs remaining open during the late stages of GDA should be avoided. The Regulators expect ROs and RIs to be closed out as soon as possible and commitments to update the safety or GEP submissions to be logged and carried out before a DAC or SoDA is issued.
2. Where appropriate the process should also log and track commitments made in RQs
3. When ROAs or RIAs have been completed and the Regulators have agreed an RO or RI may be closed Hitachi-GE must capture and log the commitment to amend the safety case or GEP before closing the RO or RI.
4. The commitment capture process should track commitments until they have been carried out and ensure records are kept to demonstrate this.

(See ROA #3)

Assessment Observation – Readiness Review

A meeting was held during the MSQA inspection to discuss the Step 2 to 3 readiness report and why some of the activities and improvements which Hitachi-GE had discussed with ONR before the start of Step 3 were not visible in the report. ONR concluded that these improvements were contained in the detailed review carried out by Hitachi-GE but had not been included in the final report as they were seen a plans rather than improvements. The meeting concluded that Hitachi-GE need to ensure that the next review report recognises and takes credit for planned actions which are

identified as necessary improvements for completing the next Step of GDA.

Regulatory Expectations — Readiness Review

Before each of the assessment Steps, the RP is required to conduct a readiness review to confirm that it can fulfil all the requirements for that Step. The review should identify any improvement or corrective actions needed and any planned changes to resources or organisation during the next step should be referenced from or visible in the report

(Please see ROA #4)

Regulatory Observation Actions

RO-ABWR-0058.A1

1.1 *Hitachi-GE should review the arrangements for GDA specific training against the regulators expectations to determine if the training is providing Hitachi-GE GDA personnel with sufficient knowledge to enable them to produce good quality GDA submissions for the UKABWR. Hitachi-GE should then take appropriate corrective action.*

1.2 *Hitachi-GE to review internal audit checklists to ensure the effectiveness of GDA Specific Training is adequately covered and assessed by internal audits.*

Resolution required by: 31st December 2015

RO-ABWR-0058.A2

2.1 *To resolve the non-conformities in Role Profiles and SQEP Assessments found during the inspection Hitachi-GE should:*

- 1. Hitachi-GE should review the Role Profile for the Departmental Manager responsible for the Class 1 RPS to ensure it adequately describes the qualifications and experience required for the role. Hitachi-GE should also review the SQEP Assessment and ensure it correctly identifies the nuclear safety significance of the role.*
- 2. Hitachi-GE to review the SQEP assessment (674195008) for the human factors (HF) Subject Matter Expert to ensure it is consistent with the SQEP assessment in the response to RO-ABWR-005 and the HF integration plan.*
- 3. Hitachi-GE should review SQEP Assessment Coversheets 310800272 & 310790164 to ensure they record and demonstrate that GDA personnel have undergone the required GDA specific training.*

2.2 *Hitachi-GE should also check and review other Role Profiles and SQEP Assessments to determine if they contain similar shortfalls and take appropriate corrective action as necessary.*

Resolution required by: 31st December 2015

RO-ABWR-0058.A3

Hitachi-GE to develop a method for capturing and logging commitments to update the safety case when RO or RI actions have been completed and ONR has agreed that the RO / RI can be closed subject to the safety case being updated. This method should also be applied to RQ responses when appropriate.

Resolution required by: 30th November 2015

RO-ABWR-0058.A4

Hitachi-GE to consider improvements to the readiness review report so that it captures and takes credit for planned improvements

Resolution required by: 31st July 2015

REQUESTING PARTY TO COMPLETE

Actual Acknowledgement date:

RP stated Resolution Plan agreement date: