

REGULATORY OBSERVATION

REGULATOR TO COMPLETE

RO unique no.:	RO-UKHPR1000-0024
Revision:	0
Date sent:	11/11/19
Acknowledgement required by:	18/11/19
Agreement of Resolution Plan Required by:	29/11/19
TRIM Ref:	2019/329416
Related RQ / RO No. and TRIM Ref: (if any):	
Observation title:	Control of Changes to the UK HPR1000 Design
Lead technical topic:	Related technical topic(s):
13. Management of Safety Quality Assurance	<ol style="list-style-type: none"> 1. Chemistry 2. Civil Engineering 3. Control & Instrumentation 4. Conventional Fire Safety 5. Conventional Health & Safety 6. Cross Cutting 7. Electrical Engineering 8. External Hazards 9. Fault Studies 10. Fuel & Core 11. Human Factors 12. Internal Hazards 14. Mechanical Engineering 15. Probabilistic Safety Analysis 16. Radiological Protection 17. RadWaste, Decommissioning & Spent Fuel Management 18. Security 19. Severe Accident Analysis 20. Structural Integrity 21. Environmental

Regulatory Observation

Background

As part of its normal design development process, the Requesting Party (RP) may wish to make changes to the generic design after the Design Reference Point (DRP) has been agreed. Changes to the design may also be necessary to respond to Regulatory Observations or Regulatory Issues. It is therefore important that a GDA design change process is implemented by the RP so that any impacts on the safety case (i.e. the Safety, Security, and Environment Reports and supporting documentation) and design reference can be fully understood and implemented effectively.

Early in Step 3, GNSL developed arrangements for controlling changes to the UK HPR1000 design, including a UK HPR1000 Modification Categorisation Procedure [1] and a UK HPR1000 Modification Control Procedure [2]. These arrangements were discussed with ONR and EA, who had been informed that they were being trialled ahead of their formal adoption at the DRP at the end of the step. In order to gain confidence in the effectiveness of the arrangements, ONR and EA sampled their implementation during the Step 3 MSQA Inspection of CGN Arrangements for the UK HPR1000 GDA in China in July 2019 [3].

The inspection found that the GNSL procedures were not consistent with CGN internal procedures and that the GNSL arrangements were only being applied to design changes arising directly from GDA. Design changes arising from Fangchenggang Unit 3 (FCG3, the reference design) were sentenced differently and so

were not considered at the Modifications Committee. ONR and EA raised its concerns regarding this approach and clarified that all design changes should be treated the same, in accordance with the RP's procedures, regardless of their source/origin.

During the MSQA workshops in China in October 2019, ONR and EA were informed that new design changes had arisen, both from GDA and from FCG3, and that they continue to be reviewed and approved using differing approaches [4]. Furthermore, ONR and EA were informed that the RP has developed an updated Modification Control Procedure [5] that differs from that previously discussed with ONR and EA. We scrutinised this procedure and found that it contains inconsistencies, and determined that it is not being applied in practice.

ONR and EA need to have confidence that the RP has robust arrangements for design change control and that it will effectively apply them after the DRP. The evidence provided from the trialling of these arrangements during Step 3 have not provided this confidence.

Relevant Legislation, Standards and Guidance

The Generic Design Assessment Guidance to Requesting Parties provides the following requirements for control of changes to the GDA design:

'The details of the change control system are for the RP to propose and ONR to agree. However, ONR will expect this to be a robust system such similar to those implemented by licensees to satisfy nuclear site Licence Condition 20 (modification to design of plant under construction). ONR will inspect these arrangements as part of GDA.

Features that ONR will expect to see include:

- *a categorisation system reflecting the potential safety and security impact of the change;*
- *change control committees to oversee the categorisation of the proposed changes and the overall running of the process; and*
- *a route for alerting ONR to the more significant changes to the safety or security case.*

If design changes are accepted into GDA by ONR the RP should consolidate them into the Design Reference and propose an updated Design Reference Point for agreement by ONR.'

Regulatory Expectations

In order to ensure alignment between the safety case and the reference design throughout GDA, ONR and EA expect GNSL to have adequate written arrangements in place for identifying, reviewing, authorising and implementing changes to the UK HPR1000 design. These written arrangements must be consistent with those used by CGN as the UK HPR1000 designer. Furthermore, GNSL and CGN must have effective MSQA arrangements in place to ensure that the arrangements are consistently complied for all design changes by all personnel with a role in design change management. These arrangements must also include information on how ONR and EA will be notified of any design changes and how they will be provided, in a timely manner, with sufficient information on any proposed changes so that the regulators can determine whether the design change can be brought within the scope of GDA.

References

- [1] UK HPR1000 Modification Categorisation Procedure, HPR/GDA/PROC/0033, Rev 000, January 2019, CM9 Ref. 2019/11624
- [2] UK HPR1000 Modification Control Procedure, HPR/GDA/PROC/0053, Rev 000, January 2019, CM9 Ref. 2019/11627
- [3] Step 3 MSQA Inspection of CGN Arrangements for the UK HPR1000 GDA, ONR-NR-CR-19-183, Rev 0, August 2019, CM9 Ref. 2019/236441
- [4] MSQA Workshops in China, ONR-NR-CR-19-312, Rev 1, November 2019, CM9 Ref. 2019/320443.
- [5] UK HPR1000 Modification Control Procedure, HPR/GDA/PROC/0053, Rev 001, July 2019, CM9 Ref. 2019/201517
- [6] New nuclear reactors: Generic Design Assessment, Guidance to Requesting Parties, ONR-GDA-GD-001, Revision 3 September 2016.

Regulatory Observation Actions

RO-UKHPR1000-0024.A1 – Conduct a review of written arrangements for the categorisation and control of changes to the UK HPR1000 Design

In response to this Regulatory Observation Action, GNSL should:

- Review its existing written arrangements for the UK HPR1000 design change control to ensure that they are suitable and sufficient and are consistent across GNSL and CGN.
- Submit the updated arrangements to ONR and EA.

Resolution required by '*to be determined by General Nuclear System Resolution Plan*'

RO-UKHPR1000-0024.A2 – Provide an implementation plan for the updated UK HPR1000 design change control arrangements

In response to this Regulatory Observation Action, GNSL should:

- Describe how it will ensure the updated arrangements described in RO-UKHPR1000-XXXX.A1 will be effectively applied in practice, including:
 - The approach and schedule for providing training to all personnel with a role in design change control so that they understand the expectations placed upon them.
 - How GNSL will ensure that there is sufficient oversight of the design change control arrangements to ensure that they will be applied in practice.
 - Any additional MSQA activities that will be used to determine the effectiveness of the arrangements, such as internal inspections and audits.
 - Whether any of the design changes that have arisen during Step 3 but have not been formally considered by the Modifications Committee will be retrospectively reviewed in accordance with the updated arrangements.

Resolution required by '*to be determined by General Nuclear System Resolution Plan*'

REQUESTING PARTY TO COMPLETE

Actual Acknowledgement date:

RP stated Resolution Plan agreement date: