Environment Agency

Preliminary detailed assessment of management systems for General Nuclear System Limited's UK HPR1000 design - AR01

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Executive summary

This report covers the Generic Design Assessment (GDA) of General Nuclear System Limited's (GNSL's) management for safety and quality assurance (MSQA) arrangements supporting the development of the United Kingdom Hualong Pressurised Water Reactor design (UK HPR1000). Our requirements and expectations as regards these arrangements are set out in Table 1, Item 2 of our Process and Information Document (P&ID) (Environment Agency, 2016).

Our aim in carrying out this assessment is to gain confidence in the quality of GNSL's GDA submission, and to confirm that adequate processes are in place to transfer the UK HPR1000 GDA information to a future operator.

We have carried out our assessment in 2 stages, in line with the process set out in our P&ID.

Stage 1 entailed an initial assessment of GNSL's arrangements, and the GDA arrangements in place in its service provider organisations (China General Nuclear (CGN) and Electricité de France (EDF)). This stage, completed in 2018, comprised a review of documents and records, and inspections of arrangements at GNSL's offices in the UK, CGN's offices in China, and EDF's offices in France.

The findings from stage 1 were set out in our Environment Agency initial report (Initial assessment of General Nuclear System's UK HPR1000 design: Statement of findings, Version 1, 2018.). Our conclusion was that GNSL and its service providers have sufficient suitably skilled resources, and use appropriate and adequate management systems and quality assurance arrangements, to develop the UK HPR1000 generic design and associated safety case documentation. Although at that time, some of these organisational and management arrangements were still being implemented, and the effectiveness of working arrangements was still evolving, we considered that the arrangements were satisfactory for that stage of the GDA process.

In the detailed assessment stage, we have examined the processes in more detail, sampling procedures, documents and records in greater depth to make sure they complied with our requirements and expectations. In addition, we have followed up on areas identified during the initial assessment where further work was required to meet the expectations set out in our P&ID. We carried out our detailed assessment through correspondence, meetings and further visits, inspections and workshops in the UK, China and France. We raised Regulatory Queries (RQ) and Regulatory Observations (RO), sometimes jointly with the Office for Nuclear Regulation (ONR), in relation to questions or observations arising from these engagements.

We provide the detail of our stage 2 assessment, up to and including 30 June 2020, in the main sections of this report.

Our assessments have confirmed that, in developing its MSQA arrangements, GNSL has considered relevant Environment Agency Radioactive Substances Regulation (RSR) Environmental Principles (REPs) (Environment Agency, 2010). GNSL has been able to demonstrate that it has adequate resources, management and quality assurance arrangements in place to support its UK HPR1000 GDA submission to, in turn, ensure that high standards of environmental protection can be achieved.

At the time of writing, we note that there are some aspects of the Requesting Party's GDA arrangements where further assessment work is ongoing or further work is required to demonstrate that they are adequate, notably in:

- developing processes to support a future operator in taking forward the design and underpinning a best available techniques (BAT) case for implementation at a site level
- effectively using operational experience (OPEX) in the safety case (an observation made jointly with ONR)
- managing requirements and assumptions in the safety case relating to environmental protection arrangements

GNSL has committed to complete these outstanding areas of work before the end of the UK HPR1000 GDA project. Nevertheless, at this stage, we have identified one potential Assessment Finding and one potential GDA Issue in relation to this ongoing work, as follows.

- **Assessment Finding 1: The future site operator shall develop arrangements for managing GDA assessment findings, requirements and assumptions relating to environmental aspects of the design.**
- **Potential GDA Issue 1: The Environment Agency and ONR have identified shortfalls across UK HPR1000 safety case documentation in identifying and using operating experience (OPEX). We expect relevant OPEX to be identified and considered to support the development of environmental protection functionality in the design, consistent with applying best available techniques (BAT).**

With ONR we are continuing our assessment of GNSL's MSQA arrangements though the remainder of the GDA process. This work will include reviewing GNSL's actions to address the above potential Assessment Finding and GDA Issue.

Contents

1. Introduction

This report is based on information received up to and including 30 June 2020. It covers the assessment of GNSL's (Requesting Party's) management for safety and quality assurance (MSQA) arrangements for developing the UK HPR1000 generic design, and for producing documentary submissions of the appropriate quality to meet the Environment Agency's requirements as described in our GDA Process and Information Document (P&ID).

We use a 2-stage process to carry out generic design assessment: initial assessment, followed by detailed assessment.

GNSL describes its GDA management system in the 'Preliminary Safety Report, Chapter 20 - MSQA and Safety Case Management' (document reference HPR/GDA/PSR/0020). The initial assessment of this and supporting documents was completed in 2018, and included inspections of arrangements at GNSL's offices in the UK and at GNSL's service providers (CGN in China and EDF in France).

The findings from the initial assessment are set out in our report: 'Generic design assessment of candidate nuclear power plant designs, Initial assessment of General Nuclear System's UK HPR1000 design: Statement of findings', Version 1 - 15 November 2018. Our conclusion was that GNSL and its service providers use appropriate and adequate arrangements to carry out the UK HPR1000 generic design development, including providing adequate, suitably skilled resources; understanding and addressing relevant environmental protection standards in the design process; adequate management system and quality assurance arrangements, including governance, decision-making and continual improvement/learning from experience.

Although, at the time of our initial assessment, some organisational and management arrangements were still being implemented, and the effectiveness of working arrangements was still evolving, we considered that the arrangements were satisfactory for that stage of the GDA process.

The initial assessment has informed the stage 2 detailed assessment that is reported in this document. The method, findings, conclusions and identified areas for further assessment or action are presented in the following sections.

2. Assessment

2.1 Assessment method

The detailed assessment process for GNSL's management and quality arrangements supporting the UK HPR1000 project has entailed the following activities:

- review of responses to initial assessment findings
- assessment of management system documents and records
- inspections and workshops at GNSL and its service providers
- issuing Regulatory Queries (RQs) and Regulatory Observations (ROs), and assessing the RP's responses to these RQs and ROs

Our assessment of GNSL's management and quality arrangements has been carried out with reference to the requirements of relevant standards and guidance, including:

- the ISO 9001 and 14001 quality and environmental management standards
- International Atomic Energy Agency (IAEA) General Safety Requirements No. GSR Part 2: Leadership and Management for Safety
- Environment Agency guidance: Management arrangements at nuclear sites
- Relevant Office for Nuclear Regulation (ONR) technical inspection and assessment guides

For the management and quality topic area, we work closely with ONR. Our and ONR's detailed assessment process will continue through and beyond the period of Environment Agency public consultation, and consequently our work on this topic is ongoing. However, for the purpose of developing confidence that GNSL's management and quality arrangement meet the expectations set out in our P&ID, at the time of writing this report we have completed the majority of our expected document and record reviews. Areas of assessment yet to be concluded are identified in the following sections.

2.2 Requesting Party's responses to initial assessment conclusions

We have assessed GNSL's and its service providers' responses to our initial assessment conclusions as part of scheduled routine project meetings with GNSL, further topic-specific meetings that were carried out as necessary, and the inspections and workshops as described below.

Overall, we were satisfied that GNSL and CGN had made good progress in addressing issues that we identified in the initial assessment. Particular progress was noted with implementing management system arrangements and documentation, and improvements to document management and commitments tracking. Fuller implementation of BAT processes was apparent, as was enhancement of the CGN organisation safety culture, with clearer specific reference to environment protection.

2.3 Assessment of management system documents

During our initial assessment, we reviewed the management and quality arrangements in place, or being developed, for GDA and implemented in GNSL, CGN and EDF at that time. For the detailed assessment phase, we looked in particular at the documents identified in Table 1 below, to inform our assessment of their implementation and effectiveness in the inspections that we subsequently carried out.

Table 1. GNSL documentation reviewed for this assessment

Title	Document no.
Quality Management Manual	HPR/GDA/REPO/0004
Pre-Construction Environmental Report (PCER) Delivery Quality Plan	HPR/GDA/REPO/0038
Design Control Strategy	HPR/GDA/REPO/0006
Design Reference Configuration Management Procedure	HPR/GDA/PROC/0054
Modification Categorisation Procedure	HPR/GDA/PROC/0033
Modification Control Procedure	HPR/GDA/PROC/0053
Management of Commitments for UK HPR1000	CGN procedure GH-40M-020
Requirements Management Summary Report	CGN report reference GHX00100127DOZJ03GN
Summary of General Nuclear System Limited to BRB transition arrangements: as understood at end of Step 3	HPR/GDA/REPO/0125
Management for UK HPR1000 Generic Design Assessment (GDA) Project	

2.4 Inspections

During detailed assessment, we carried out further inspections and workshops at GNSL and its service providers, CGN and EDF, with the aim of evaluating the degree and effectiveness of implementation of the GDA arrangements. The main summary findings from these inspections are as follows.

2.4.1 GNSL inspection - April 2019

Our focus for this 4-day inspection was the implementation of the management arrangements for the design process, associated decision-making, and GNSL's oversight and influence in the identifying, categorising and approving modifications to the design reference.

We noted that processes and procedures governing design modification and control, including those identified in Table 1, looked to be logical and comprehensive.

We did provide some advice on a number of areas where we believed that improvements could be introduced, including management system document change approval; guidance on aspects of the GNS modification control procedure; opportunity for GNSL to carry out quality assurance of its service provider activities; consistency of task-raising and tracking between GNSL and CGN. This advice was captured in Contact Record ONR-NR-CR-19-029.

We considered the function of the technical committee, and observed that it was important to ensure that the capacity and focus of this committee was adequate to support effective decision-making for safety and environmentally-important design considerations, including BAT.

We assessed the extent of development of arrangements to support the transfer of GDA information to a future licensee. We noted that interface arrangements with the potential future licensee were evolving and looked to be adequate for that stage of the project.

Overall, we considered that the arrangements demonstrated during this inspection were adequate.

2.4.2 CGN inspection - July 2019

Our focus for this 4-day inspection was on project management, design control, and arrangements for developing and maintaining the safety case for the design.

We sampled a number of documents and records, and carried out interviews with CGN staff to understand how the organisation's MSQA arrangements were being implemented in practice.

We noted that CGN had introduced a number of improvements to its management and quality arrangements since our previous inspection in 2018, notably in relation to:

- developing and implementing process procedures

- quality management arrangements, including additional assurance activities and using improved performance metrics; fuller implementation of BAT processes

- enhancements to training and the GDA organisation safety culture to more fully address UK context and environment

Our sampling of documentation allowed us to develop a clearer understanding of how the 'gap' analysis was carried out on the Fangchenggang Unit 3 (FCG3) design versus UK requirements. We were able to gain increased confidence that suitable reference to relevant good practice (RGP) had been used, and that the findings had been used appropriately to inform the design modification proposals for UK HPR1000.

We did note apparent shortcomings in relation to the application and effectiveness of some procedures, specifically associated with:

- the rigour of application of the design change management process

- some lack of clarity and consistency with respect to identifying 'significant' technical issues warranting consultation with the technical committee

- incompleteness of the commitments log

We provided advice to GNSL and CGN on these matters, captured in contact record ONR-NR-CR-19-183, and committed to following up on these issues on a further visit to CGN in October 2019.

Overall, we considered that the arrangements demonstrated during this inspection were adequate, albeit with a need to follow up on a number of areas as identified above.

2.4.3 CGN workshop - October 2019

Our focus for this 3-day workshop was to follow up on our observations from the July inspection, and also to review in greater detail CGN's design and safety case management arrangements. This included specifically commitments, requirements and assumptions management, and use of the CGN 'integrated design platform' for design management.

We noted that arrangements for managing GDA commitments had been improved, including improved procedures for capturing and owning commitments arising from Regulatory Queries and technical regulatory meetings. We provided advice on further opportunities for improvement, including using unique reference numbers/codes; mapping commitments across to the submission document list (SDL); and recognition that design change proposals deferred to the site licensing phase need to be captured formally in GDA documentation. We noted that work on developing arrangements for requirements and assumptions management was progressing in line with the resolution plan for Regulatory Observation (RO) RO-UKHPR1000-0004 (this RO related to developing a suitable and sufficient safety case).

We again looked at design change control. We sampled records and determined that CGN and GNSL were not fully following their defined GDA processes. We expressed concerns that this could result in such changes not having been adequately and demonstrably assessed against UK requirements. With ONR we raised Regulatory Observation RO-UKHPR1000-0024 on this matter.

We identified potential improvements in the extent of engagement and level of communication between CGN and GNSL. We also identified that CGN did not appear to fully appreciate the Environment Agency's detailed assessment phase timescales being different to ONR’s step 4 assessment schedule.

We provided the RP with advice in relation to these matters. This advice was captured in contact record ONR-NR-CR-19-312.

2.4.4 EDF workshop - January 2020

Our focus for this 1-day workshop was to assess the effectiveness of EDF’s technical review role in the UK HPR1000 GDA process.

We noted progress in a number of areas compared to the previous inspection at EDF in 2019, notably on work planning and delivery; embedding GDA processes; co-ordination internally and with GNSL; and EDF engagement with main GDA committees and working groups.

There was greater confidence evident in EDF's access to adequate BAT suitably qualified and experienced (SQEP) resources, both within its own organisation and via affiliates (supply chain). We encountered no indications of shortcomings in this respect regarding EDF’s role.

There was evidence that EDF was effectively involved in the GDA modification and technical committees.

Overall, we considered that the arrangements demonstrated during this inspection were adequate, although we did identify potential improvements in relation to the provision and availability of information to EDF to carry out its technical review role; and the use of EDF OPEX in the UK HPR1000 GDA process. Advice in relation to these points was captured in contact record ONR-NR-CR-19-507.

2.5 Regulatory Queries and Regulatory Observations

During the detailed assessment stage we issued, or worked with ONR in issuing, the following RQs and ROs:

Table 2. MSQA RQs and ROs issued during detailed assessment

Title	Document no.
Environment Agency comments on GHX00100127DOZJ03GN Rev A GDA for UK HPR1000 - Requirements management summary report	RQ-UKHPR1000-0929
Development of a suitable and sufficient safety case	RO-UKHPR1000-0004
Control of changes to the UK HPR1000 design	RO-UKHPR1000-0024
Identification and use of operational experience (OPEX) in the UK HPR1000 generic design and safety case	RO-UKHPR1000-0044

RO-UKHPR1000-0024 relates to the control of changes to the UK HPR1000 design during GDA, and follows on from our visits to China in July and October 2019. GNSL developed and completed a resolution plan for this RO. This essentially entailed revising the existing procedures on modification categorisation, modification control and configuration change management as identified in Table 1, and implementing these modified procedures. We have confirmed, by assessing the revised procedures, that the changes are appropriate, and will assess their implementation via further inspection and engagement during the remainder of the GDA process.

RQ-UKHPR1000-0929 and associated aspects of RO-UKHPR1000-0004 relate to how GNSL will manage requirements and assumptions relating to environmental protection functionality. The response to the RQ, and resolution plan for the RO, remain as work in progress at the time of writing. We consider that there is a high likelihood that the outstanding tasks associated with this RQ and RO will be completed by the end of GDA. However, some aspects of the management of requirements and commitments relating to environmental aspects of the design could potentially be directed at the future licensee to resolve. We consider that this represents a potential Assessment Finding.

RO-UKHPR1000-0044 relates to effectively identifying relevant OPEX during the GDA process and using it in developing the UK HPR1000 design. Considering relevant operational experience is important when the designer is identifying and implementing Best Available Techniques and ALARP. For this RO, again there is a resolution plan in place, to implement improved formal arrangements for identifying and using relevant OPEX, and this remains as work in progress at the time of writing. Although it is expected that GNSL will resolve these issues in a timely way and well before the end of GDA, if this does not happen, then a significant shortfall in identifying and using OPEX would correspond to a GDA Issue.

Assessment Finding 1: the future site operator shall develop arrangements for managing GDA assessment findings, requirements and assumptions relating to environmental aspects of the design.

Potential GDA Issue 1: the Environment Agency and ONR have identified shortfalls across UK HPR1000 safety case documentation in identifying and using operating experience (OPEX). We expect relevant OPEX to be identified and considered to support the development of environmental protection functionality in the design, consistent with applying best available techniques (BAT).

2.6 Further assessment work

The detailed assessment conclusion outlined above highlighted a number of areas where work to demonstrate adequate MSQA arrangements is either ongoing or required, or where further assessment is proposed in relation to new or modified arrangements that have been put in place. In summary those areas are:

i. Completion of the RO-UKHPR1000-0004 resolution plan and response to RQ-UKHPR1000-0929, and the assessment by regulators of the implementation of any associated modified arrangements to ensure that safety case requirements relating to environmental aspects of the design are adequately captured in the safety case, and identified to a future licensee.

ii. Completion of the RO-UKHPR1000-0044 resolution plan, and the assessment by regulators of the implementation of any associated modified arrangements.

iii. The further development and implementation of arrangements for the transfer of GDA information to a future licensee.

iv. The assessment of implementation of revised procedures on modification categorisation, modification control and configuration change management, following on from actions in response to RO-UKHPR1000-0024.

For these areas, we intend to continue assessment jointly with ONR in the MSQA topic area through the remainder of the UK HPR1000 GDA project, using a combination of technical and project meetings, document reviews, workshops and inspections, as necessary.

2.7 Compliance with Environment Agency requirements for GDA

Table 3. Compliance with Environment Agency requirements

Requirement from P&ID or REPs	Comments
MLDP1 – Establishing and sustaining leadership and management	GNSL has developed effective management and quality arrangements that recognise and address environmental requirements. The arrangements are broadly equivalent to (but not formally certified to) the ISO9001 and 14001 standards. For 2 aspects of the management system - OPEX (below) and transfer arrangements for the future licensee – at the time of writing, the arrangements are in the process of being implemented. GNSL is committed to completing the implementation of these arrangements by the end of GDA.
MLDP 2 – High standards of environment protection	GNSL's design development arrangements draw on well-established processes in its service provider

Requirement from P&ID or REPs	Comments
	organisations, chiefly CGN, supplemented by clear provisions to take environmental requirements (including the use of BAT) into decision-making processes. The processes incorporate requirements for the design to meet high environmental standards.
MLDP3 – Capability	GNSL can draw on substantial suitably qualified and experienced (SQEP) resources in its service provider organisations. Significant training has been given to design engineers and safety case authors on BAT and UK context. GNSL has supplemented its resources by using specialist contractors to provide specific advice and support on radioactive waste, BAT and UK environmental permitting requirements.
MLDP4 – Decision making	GNSL's processes and governance structure clearly identify decision making, and include specific arrangements for safety and environmentally-important decisions. Formal arrangements are in place for checking, reviewing and auditing decisions, and for assessing the implementation and effectiveness of GDA governance and decision-making arrangements.
MLDP5 – Learning from experience	GNSL has management system arrangements in place to identify and consider OPEX in the development of the UK HPR1000 design. Other topic area assessments have highlighted some shortcomings in applying these arrangements, and improvements are being sought via a Regulatory Observation (RO-UKHPR1000-0044) on this issue, the responses to which remain in progress at the time of writing.

3. Public comments

GNSL received 2 public comments up to 30 June 2020 concerned directly with MSQA.

- On 17 December 2018, GNSL received a comment expressing concern that problems exist with respect to the design management process, especially the configuration management and change control process.

  GNSL responded on 9 January 2019 explaining that formal configuration management and change control processes have been established, that all design changes are subject to review and scrutiny, and that the most safety-significant changes will be subject to regulatory scrutiny.

As described in section 2 above, we have assessed GNSL's design modification and change control arrangements as part of our review of documents, and via inspections/workshop in the UK and China. Following the workshop in China in October 2019, we identified some shortcomings in GNSL's arrangements, and as a result, issued Regulatory Observation RO-UKHPR1000-0024 in which we specified actions for GNSL to complete to address the shortcomings. At the time of writing, GNSL has completed its responses to these actions, as described in section 2. With ONR, we will review the effectiveness of these responses as part of our ongoing inspection and assessment work on this project.

- On 28 December 2018, GNSL received a response highlighting 3 questions relating to the specification and control of GDA document chapter layout; the consistent use of English spelling in the documents; and the physical form of the final documents.

  GNSL responded on 21 January 2019. The original questions, and GNSL's response, relate to quality aspects of the GDA submissions. Our expectation in assessing the GDA documents is that they will be coherent and logical, and in a suitable format to effectively hand them over to a potential future licensee. Our assessment will continue to take into account these and other quality issues. At the time of writing this report, we are content with GNSL's ability to produce GDA documentation of sufficient quality in these respects.

4. Conclusion

The assessment detailed in this report relates to GNSL's development and implementation of its management for safety and quality assurance (MSQA) arrangements for the UK HPR1000 reactor generic design development.

The assessment considers the matters described in Item 2 of the P&ID, and at the time of writing, is ongoing. The information presented in this report refers to information received and assessment work completed up to and including 30 June 2020.

Our assessment indicates that most of GNSL’s GDA management and quality assurance arrangements are fully developed, implemented and satisfactory, and meet the requirements of the P&ID.

We and ONR have provided observations on arrangements for gathering and using OPEX as part of the UK HPR1000 GDA. This area is subject to an RO for which, at the time of writing, GNSL has a resolution plan in place to address.

GNSL has developed processes for transferring technology to a future operator, which include systems for identifying environmental requirements and assumptions. At the time of writing, implementation of these arrangements was incomplete. We have an RQ in place on aspects of this process, and GNSL is committed to responding to this within a defined timescale. Overall, we are satisfied that GNSL is committed to addressing our questions and completing this process by the end of GDA.

We are continuing to work with ONR on maintaining scrutiny of GNSL’s management and quality arrangements to the end of the GDA process. This will include meeting with GNSL MSQA staff and further sampling GNSL’s and its service providers’ processes to continue to review compliance with the P&ID.

We have identified one potential Assessment Finding and one potential GDA Issue, as follows.

Assessment Finding 1: The future site operator shall develop arrangements for managing GDA assessment findings, requirements and assumptions relating to environmental aspects of the design.

Potential GDA Issue 1: The Environment Agency and ONR have identified shortfalls across UK HPR1000 safety case documentation in identifying and using operating experience (OPEX). We expect relevant OPEX to be identified and considered to support the development of environmental protection functionality in the design, consistent with applying best available techniques (BAT).

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Abbreviations

Acronym	*Meaning*
AF	Assessment finding
ALARP	As low as reasonably practicable
BAT	Best available techniques
BRB	Bradwell B
CGN	China General Nuclear
EDF	Electricité de France
FCG3	The Fangchenggang Unit 3 new nuclear build project in Guangxi, south-western China
GDA	Generic design assessment
GNSL	General Nuclear System Ltd
HPR	Hualong Pressurised Reactor
ONR	Office for Nuclear Regulation
OPEX	Operating experience
P&ID	Process and Information Document
PCER	Pre-Construction Environmental Report
RI	Regulatory Issue
RO	Regulatory Observation
RP	Requesting Party
RSMDP	Radioactive Substances Management Developed Principle
RSR	Radioactive Substances Regulation
SQEP	Suitably qualified and experienced person

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