

OFFICIAL



Generic design assessment of new nuclear power plants

Management systems for the UK HPR1000 design - AR01

Detailed assessment – final report

10 January 2022

Version 1

OFFICIAL

We are the Environment Agency. We protect and improve the environment.

We help people and wildlife adapt to climate change and reduce its impacts, including flooding, drought, sea level rise and coastal erosion.

We improve the quality of our water, land and air by tackling pollution. We work with businesses to help them comply with environmental regulations. A healthy and diverse environment enhances people's lives and contributes to economic growth.

We can't do this alone. We work as part of the Defra group (Department for Environment, Food & Rural Affairs), with the rest of government, local councils, businesses, civil society groups and local communities to create a better place for people and wildlife.

Published by:

Environment Agency
Horizon House, Deanery Road,
Bristol BS1 5AH

www.gov.uk/environment-agency

© Environment Agency 2022

All rights reserved. This document may be reproduced with prior permission of the Environment Agency.

Further copies of this report are available from our publications catalogue: www.gov.uk/government/publications or our National Customer Contact Centre: 03708 506 506

Email: enquiries@environment-agency.gov.uk

Executive summary

This report covers the assessment of the Requesting Party's (RP's) management for safety and quality assurance (MSQA) arrangements supporting the development of the United Kingdom Hualong One Pressurised 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 the Requesting Party's (RP's) generic design assessment (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 the RP's arrangements, and the GDA arrangements in place in its service provider organisations (China General Nuclear (CGN) and Électricité de France (EDF)). This stage, completed in 2018, comprised a review of documents and records, and inspections of arrangements at GNSL's offices in England, 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 the RP had enough suitably skilled resources, and used 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, and to move to stage 2.

Stage 2 detailed assessment began in November 2018. During detailed assessment, we 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 followed up on areas identified during the initial assessment where further work was required to meet fully the expectations set out in our P&ID. We carried out our detailed assessment through correspondence, meetings and further visits, inspections and workshops in England, 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.

The detail of our stage 2 assessment is provided in the main sections of this report. Our assessment confirms that the RP has adequate resources, management and quality assurance arrangements in place to support its development of the UK HPR1000 design, to ensure that high standards of environmental protection can be achieved. The arrangements are sufficient to ensure that the associated GDA document submission

OFFICIAL

demonstrates that the design uses best available techniques (BAT) for protecting the environment, and that those documents are in a suitable form to hand over to a future licensee.

In developing its MSQA arrangements, the RP has considered relevant Environment Agency Radioactive Substances Regulation (RSR) Environmental Principles (REPs) (Environment Agency, 2010). The arrangements include adequate capture and use of operating experience (OPEX), and adequate arrangements for handover of GDA information to a future licensee.

Some aspects of the design relating to environmental control are site-specific and cannot be developed fully at generic design stage. Commitments for a future licensee to carry out this work, plus underpinning design requirements and assumptions, and our GDA assessment findings, will be identified in GDA documentation to ensure that the future licensee is aware of them. We have identified one Assessment Finding which relates to the arrangements for developing the design that need to be addressed at the site licensing phase.

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

Our overall conclusion is that the Requesting Party's (RP's) management and quality arrangements are sufficient to support the development of the generic design for the UK HPR1000 reactor.

Contents

Executive summary	3
Contents	5
1. Introduction	6
2. Assessment	6
2.1 Assessment method	6
2.2 Requesting Party's responses to initial assessment conclusions	7
2.3 Assessment of management system documents	7
2.4 Inspections	9
2.5 Regulatory Queries, Regulatory Observations and Regulatory Issues	15
2.6 Transition arrangements	17
2.7 Compliance with Environment Agency requirements for GDA	18
3. Public comments	19
3.1 GNSL public comments process	19
3.2 Environment Agency public consultation	20
4. Conclusion	23
References	25
List of abbreviations	30

1. Introduction

This report covers our assessment of the Requesting Party's (RP'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 have used a 2-stage process to carry out generic design assessment: initial assessment, followed by detailed assessment. The initial assessment was completed in 2018 and reported 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](#)'. This stage of assessment focused on the implementation of arrangements as described in the RP's 'Preliminary Safety Report, Chapter 20 - MSQA and Safety Case Management' (document reference HPR/GDA/PSR/0020), and included inspections of arrangements at GNSL's offices in England and at GNSL's service providers (CGN in China and EDF in France).

Our stage 2 detailed assessment began in November 2018 and is reported in this document. During stage 2, we have looked to confirm that any issues identified during stage 1 have been addressed, that the management system and quality arrangements have been fully developed and implemented, and that they are effective in meeting the requirements set out in the P&ID.

The methods used in our assessment work, and our findings and conclusions, are presented in the following sections.

2. Assessment

2.1 Assessment method

We have carried out our assessment of the RP's management and quality arrangements against the requirements set out in our P&ID document, and 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

The detailed assessment process has entailed the following activities:

OFFICIAL

- review of responses to initial assessment findings
- assessment of management system documents and records
- inspections and workshops at GNSL and its service providers
- raising Regulatory Queries (RQs) to clarify our understanding of the information presented
- raising Regulatory Issues (RIs) or Regulatory Observations (ROs) where we believed the RP did not provide enough information
- an approximately monthly programme of technical and regulatory meetings with the RP

For the management and quality topic area, we work closely with ONR. We have carried out all inspections, workshops and meetings jointly with ONR, and we have issued a number of RQs and ROs jointly.

Since March 2019, all of our engagements with the RP have been carried out remotely using 'virtual' meetings, in line with Covid-19 pandemic restrictions. We do not believe that these constraints have impacted significantly on the quality of our assessment.

2.2 Requesting Party's responses to initial assessment conclusions

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

Overall, we were satisfied that the RP had made good and adequate progress in addressing issues that we identified in the initial assessment. We noted particular progress 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 the environment.

2.3 Assessment of management system documents

The RP has developed and implemented a formal documented management system in line with relevant standards and guidance identified in section 2.1. Management system documents are structured according to an established hierarchy of top-level policies; manuals, plans and organisation system; and procedures. All management system documents, and documents produced to support the UK HPR1000 design and GDA submission are quality controlled and subject to formal review, approval and version control.

OFFICIAL

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 below, assessing their implementation and effectiveness in inspections at GNSL, CGN and EDF.

- Project Definition Document (HPR/GDA/REPO/0003)
- Preliminary Safety Report, Chapter 20 - MSQA and Safety Case Management (HPR/GDA/PSR/0020)
- Quality Management Manual (HPR/GDA/REPO/0004)
- Document List and Master Document Submission List Arrangements (HPR/GDA/PROC/0006)
- SSER V2 Guidance Note (HPR/GDA/REPO/0087)
- GDA Project Quality Plan (HPR/GDA/REPO/0024)
- Pre-Construction Environmental Report (PCER) Delivery Quality Plan (HPR/GDA/REPO/0038)
- Design Control Strategy (HPR/GDA/REPO/0006)
- Suitably Trained, Competent & Experienced Personnel - a Framework for GDA HPR-(GDA-PROC-0029)
- Management of Commitments for Safety Case Updates (HPR/GDA/PROC/0046)
- Design Reference Configuration Management Procedure (HPR/GDA/PROC/0054)
- Modification Categorisation Procedure (HPR/GDA/PROC/0033)
- Modification Control Procedure (HPR/GDA/PROC/0053)
- Summary of General Nuclear System Limited to BRB transition arrangements: as understood at end of Step 3 (HPR/GDA/REPO/0125)
- GNSL Management for Safety and Quality Assurance Audit Report for CGN (HPR/GDA/REPO/0152)
- CGN Organisation and Operating Rules of UK HPR1000 GDA Project (GH-40M-004)
- CGN Quality Assurance Programme for GDA of UK HPR1000 GH-20Q-001
- CGN Design and Development Control Procedure PJ-30E-001
- CGN Provisions on technical decision-making system for UK HPR1000 GDA project GH-30E-007
- CGN Submission Document List Management (GH-30E-008)
- CGN Management of Commitments for UK HPR1000 (GH-40M-020)
- Post-GDA Commitment List (GHX00100084KPGB03GN)
- CGN Requirements Management Summary Report (GHX00100127DOZJ03GN)
- CGN Requirements Management Provisions for UK HPR1000 GDA Project (GH-40M-026)
- CGN Safety Case Consolidation Summary Report (GHX00100090KPGB03GN)
- CGN Position Training Program and Management Rules on Authorization and Job Taking (ED-EDE-060)

OFFICIAL

- Provisions on Configuration Change Management for UK HPR1000 Generic Design Assessment (GDA) Project (GH-40M-012)
- CGN Management Rules on Experience Feedback of UK HPR1000 GDA project (GH-40M-001)
- Methodology for Use of OPEX in UK HPR1000 (GHX00100059DOZJ03GN)

These documents have mainly been assessed as part of one or more inspections (see section 2.4), or as and when documents have been produced or modified, for example, as a result of responses to Regulatory Queries and/or Regulatory Observations (section 2.5). Overall, we are satisfied that the management and quality framework that the RP has used is suitable for the production of the GDA design and associated documentation, and that the production and use of both management system and GDA documents have been subject to sufficient formal control.

2.4 Inspections

With ONR we carried out inspections and workshops at GNSL and its service providers, CGN and EDF. The aim of these interactions was to evaluate the degree and effectiveness of implementation of the GDA arrangements. In the case of workshops, the aim was also to provide the RP with more detail on regulatory expectations for specific topic areas. The main summary findings from these inspections are as follows.

2.4.1 GNSL inspection - April 2019

Our focus for this inspection was the implementation of 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 assessed GNSL's processes and procedures governing design modification and control. We found these to be logical and comprehensive.

We considered the function of the technical committee by reviewing procedures, records of meetings, and discussion with committee members. While noting that these arrangements were broadly in order at that time, we highlighted to GNSL the importance of it maintaining the capacity and focus of the committee 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.

We provided advice on a number of areas where we believed that improvements could be made, including:

- management system document change approval
- guidance on aspects of the GNSL modification control procedure

OFFICIAL

- 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.

2.4.2 CGN inspection - July 2019

Our focus for this 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 regulatory expectations in England, and environmental protection requirements

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 regulatory expectations in England (FCG3 is the baseline design for the UK HPR1000). 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 the 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 log of commitments (actions to be completed by the RP within GDA, or by a future site operator, to further develop the design)

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.

2.4.3 CGN workshop - October 2019

Our focus for this workshop was to follow up on our observations from the July 2019 inspection, and also to review in greater detail CGN's design and safety case management arrangements. This included 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)
- 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 regulatory requirements that apply in England. With ONR we raised Regulatory Observation RO-UKHPR1000-0024 on this matter.

We identified potential for improvement 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 GNSL and CGN 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 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 our inspection at EDF during the initial assessment stage in 2018, 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.

OFFICIAL

The workshop allowed us to gain confidence in EDF's ability to access 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.

Similarly, discussion and evidence reviewed during the workshop (principally discussion with relevant staff and scrutiny of meeting records) gave us confidence 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.

2.4.5 GNSL inspection – July 2020

Our focus for this inspection was to follow up on findings from the 2019 GNSL inspection, including specific consideration of quality control; design management; safety case development; and handover of the final safety case to a future licensee.

We noted that GNSL had completed actions on 15 improvement areas identified following the Step 3 MSQA inspections, including putting in place arrangements to improve communication with its service providers, and to improve quality control in the delivery of GDA submissions. Evidence reviewed during the inspection and via other engagements (notably 'Level 4' meetings) suggests that the improvement activities had been effective.

Procedures for design modification categorisation and control had been updated since the previous inspection, in line with commitments made under RO-UKHPR1000-0024. We considered these procedures to be appropriate.

Outline arrangements for revising OPEX arrangements were set out, in line with actions identified in the RO-UKHPR1000-0044 resolution plan. While these arrangements appeared to be appropriate, we did observe that the proposed process needed to address best available techniques (BAT) explicitly, in addition to as low as reasonably practicable (ALARP) requirements.

Transition arrangements for transfer of information to a future licensee remained in development at the time of the inspection. We considered this to be appropriate for that stage of the project.

Other areas of progress noted during the inspection included:

- the development of arrangements for management of commitments
- work on further developing requirements and assumptions management arrangements

OFFICIAL

- implementation of a holistic design review (a high-level review of all elements of the design to confirm that, taken together, they are consistent with BAT and ALARP)

Although CGN and EDF have management arrangements that are independently certified to the ISO9001 and ISO14001 standards, GNSL as a relatively short-lived project organisation has not sought independent certification of its quality management system. Nevertheless, GNSL commissioned an independent audit of its arrangements against the ISO9001 and ISO14001 requirements in 2019. Overall, this confirmed that GNSL's arrangements were sufficient to carry out GDA. A number of non-conformances that were identified during the audit were subsequently addressed by improvement actions. We consider this to be appropriate.

Our inspection findings were summarised in contact record ONR-NR-CR-20-407.

2.4.6 CGN inspection – October 2020

Our focus for this inspection was to follow up on findings from the 2019 CGN inspection, including specifically focusing on arrangements for design and safety case management.

We reviewed improvements introduced to the design modification control process in response to RO-UKHPR1000-0024. The inspection included sampling examples of design modification documentation, which indicated the improvements had been implemented and were effective.

We noted that additional or modified quality assurance and quality control measures introduced since the move into the detailed assessment stage appeared to be effective. This was demonstrated by Environment Agency and ONR assessors reporting fewer quality issues. We reviewed the outputs of internal quality audits, noting these to be thorough.

We considered the role of the modification committee in confirming modification categorisation, and reviewed recent copies of the modification committee minutes. These were in order and consistent with the revised arrangements for design modification control.

We observed that the holistic design review has provided regulators with additional assurance as to the overall BAT and ALARP status of the design, taking into account the cumulative effect of design changes up to mid-2020.

The development of OPEX arrangements was noted to have progressed in response to RO-UKHPR1000-0044. During this inspection, we considered the training provision for OPEX, and noted that the original training provision did not address the role of OPEX in identifying and demonstrating BAT. While recognising that the new OPEX methodology does explicitly address BAT, and that BAT training is provided elsewhere to designers, we considered the apparent absence of any reference to BAT in the OPEX training to be a potential shortcoming in arrangements. Also, considering our observation on OPEX and BAT during the previous inspection at GNSL (section 2.4.5), we subsequently raised RQ-

OFFICIAL

UKHPR1000-1387 to request more information on GNSL's and CGN's intentions to address this point.

The commitments log was sampled and appeared to be comprehensive and adequate for its purpose.

Overall, we considered the CGN management and quality arrangements to be established and effective. We noted opportunities for improvement related to capturing and tracking actions and recommendations arising from quality audits, modification committee meetings, and commitments within the safety case (including post-GDA commitments).

Our inspection findings were summarised in contact record ONR-NR-CR-20-724.

2.4.7 EDF inspection – March 2021

Our focus for this workshop was to follow up on findings from the 2020 EDF workshop.

It was evident that there were improvements in communications between GNSL, EDF and its service providers compared to the situation in January 2020. It was apparent that EDF had better access to information in carrying out its technical review role, although we did note further opportunity for improvement in this area.

We noted that EDF continued to make good use of internal audit and assurance to continually improve its arrangements.

EDF's role in assuring the final Safety, Security and Environment Reports (SSER) in terms of holistic ALARP and BAT was recognised, but it was not entirely clear how EDF and GNSL would approach this as part of the PCER/PCSR/GSR V2 reviews later in the year. We raised RQ-UKHPR100-1685 in relation to this observation.

Our inspection findings were summarised in contact record ONR-NR-CR-20-1115.

2.4.8 GNSL and CGN workshop – July 2021

Our focus for this workshop was to consider consolidation and assurance of GDA documents in the RP's development of the final form safety case submissions within the SSER.

We established that the RP has adequate arrangements in place to ensure that the Design Reference, PCER and supporting documentation take into account all the additional information that has been provided in response to regulators' technical questions, and to any design (and safety case) changes that regulators have agreed can be included in the GDA scope. Our sampling of those arrangements during the workshop indicated that they are being implemented effectively.

We noted that the consolidation work is supported by a number of quality control activities, including independent sampling checks, project reviews, and final confirmatory checks

carried out by GNSL's GDA Project Office. Again, sampling of these arrangements indicated that they were suitable and effective.

During the workshop, we also took the opportunity to consider application of EDF's review role in assuring the quality of the final safety case documentation, and also considered the implementation of revised OPEX arrangements following from GNSL's responses to RO-UKHPR1000-0044. For both areas, we were satisfied with GNSL's approach.

Our inspection findings were summarised in contact record ONR-NR-CR-21-203.

2.5 Regulatory Queries, Regulatory Observations and Regulatory Issues

During the MSQA detailed assessment stage we issued, or worked with ONR in issuing, the following ROs and RQs. We did not raise any RIs.

Regulatory Observations (ROs)

- RO-UKHPR1000-0004 Development of a suitable and sufficient safety case
- RO-UKHPR1000-0024 Control of changes to the UK HPR1000 design
- RO-UKHPR1000-0044 Identification and use of operational experience (OPEX) in the UK HPR1000 generic design and safety case

Regulatory Queries (RQs)

- RQ-UKHPR1000-0147 Formal accreditation of management system arrangements in GNSL and EDF
- RQ-UKHPR1000-0196 Application of learning from RO-UKHPR1000-0004 to the Environmental Case
- RQ-UKHPR1000-0216 Request for GNSL MSQA documentation
- RQ-UKHPR1000-0217 Request for 12 CGN and GNSL MSQA documents
- RQ-UKHPR1000-0929 Environment Agency comments on GHX00100127DOZJ03GN Rev A GDA for UK HPR1000 - Requirements management summary report
- RQ-UKHPR1000-0982 Post-inspection information request
- RQ-UKHPR1000-1084 AFIs from MSQA Inspection, Report No.: NR-NR-CR-20-407 Revision 0, cm9 Ref.:2020/252767
- RQ-UKHPR1000-1103 Inclusion of Modification Details on Submissions Revision Status Pages
- RQ-UKHPR1000-1164 Management System Arrangements for the Control of the UK HPR1000 Electronic 3D Design Model
- RQ-UKHPR1000-1218 Queries on Deliverables Received in Response to ROA1 of RO-UKHPR1000-0044
- RQ-UKHPR1000-1387 Development of training to ensure that the OPEX process addresses the concept of Best Available Techniques (BAT)

OFFICIAL

- RQ-UKHPR1000-1490 UK HPR1000 – GDA - Safety Case Consolidation
- RQ-UKHPR1000-1661 UK HPR1000 – GDA - Safety Case – Post GDA Commitments criteria
- RQ-UKHPR1000-1655 Environment Limiting Conditions for Operations
- RQ-UKHPR1000-1685 EDF SSER Review - Approach and Limitations
- RQ-UKHPR1000-1741 Management System Procedures referenced in the Safety Case Chapter 20, MSQA, not referenced in the MDSL
- RQ-UKHPR1000-1753 Control of documents impacted by design modifications

The RQs were raised before or after inspections to request supporting information, or for the purpose of clarification.

Three ROs were issued following inspection and assessment of GNSL's arrangements to highlight potential shortcomings in MSQA arrangements and secure GNSL's commitment to address those shortcomings. Relevant outcomes from the resolution plans GNSL put in place to address the ROs are summarised below.

RO-UKHPR1000-0004 (and RQ-UKHPR1000-0196, RQ-UKHPR1000-0929)

ONR raised RO-UKHPR1000-0004 in relation to the development of a suitable and sufficient safety case. We considered that there were significant aspects of the resolution of RO-UKHPR1000-0004 that would be applicable to the development of the PCER, including how the RP will manage requirements and assumptions relating to environmental protection functionality. RQ-UKHPR1000-0196 was subsequently raised to establish how the RP intended to address environmental aspects as part of its response to RO-UKHPR1000-0004. RQ-UKHPR1000-0929 was raised seeking further clarification of arrangements, including those for the transfer of commitments, requirements and assumptions to a future site operator.

In its response, GNSL has confirmed that some aspects of the management of requirements and commitments relating to environmental aspects of the design will be directed at the future licensee to resolve. This is because these aspects are site-specific in their nature. The RP has put arrangements in place to ensure that commitments that are directed at a future licensee to carry out this work, plus underpinning design requirements and assumptions, and our GDA assessment findings, will be identified in GDA documentation to ensure that the future licensee is aware of them. We accept these arrangements, and have noted a corresponding Assessment Finding relating to the arrangements for developing the design that need to be addressed at the site licensing phase.

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

RO-UKHPR1000-0024

OFFICIAL

This RO relates to the control of changes to the UK HPR1000 design during GDA, and follows on from our visits to CGN in China in July and October 2019. The RP 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 section 2.3, and implementing those modified procedures. We have confirmed, by assessing the revised procedures and inspecting arrangements, that the changes are appropriate, and have been implemented effectively. RO-UKHPR1000-0024 was confirmed as closed by ONR letter REG-GNS-0081N, Closure of Regulatory Observation RO-UKHPR1000-0024 - Control of Changes to the UK HPR1000 Design, 14 January 2021.

RO-UKHPR1000-0044 (and RQ-UKHPR1000-1387)

This RO relates to identifying relevant operating experience (OPEX) during the GDA process and using it in developing the UK HPR1000 design. Considering relevant OPEX is important when the designer is identifying and implementing best available techniques (BAT).

We highlighted shortcomings in the RP's OPEX arrangements during our stage 2 assessment work, and noted this as a potential GDA Issue at the time of our public consultation. RO-UKHPR1000-0044 was issued to identify these shortcomings and seek the RP's commitment to improvement. The RP subsequently established a resolution plan entailing modifying OPEX procedures, training, and developing a number of case studies to show how OPEX has been identified and used.

The RP set out its arrangements for ensuring that BAT is taken into account in delivering OPEX training in its response to us on RQ-UKHPR1000-1387, thereby addressing points raised during inspections at GNSL and CGN in 2020 (see sections 2.4.5 and 2.4.6).

We have confirmed, by assessing the revised procedures and inspecting arrangements, that the RP has introduced appropriate changes to its OPEX procedures and training, and that these have been implemented effectively (reference ONR Assessment Note ONR-NR-AN-21-012, Assessment of the Response to RO-UKHPR1000-0044 – Identification and Use of OPEX in the UK HPR1000 Generic Design and Safety Case, 20 May 2021). Consequently, we consider that the potential GDA Issue on OPEX identified in our consultation document is now closed.

2.6 Transition arrangements

Throughout the detailed assessment stage of GDA, we have reviewed the development of The RP's arrangements for transferring the design to a future site operator, and the implementation of those arrangements. Effective transition to a future site operator relies on the RP's production of a clear and coherent safety case, supported by suitably referenced underpinning documents, and clearly documented commitments, requirements and assumptions.

These aspects of the RP's arrangements have been scrutinised as part of scheduled inspections and other engagements during detailed assessment. Additional focus on improving those arrangements has been applied by issuing Regulatory Observation RO-UKHPR1000-0004 and associated Regulatory Queries as detailed earlier in this report. The RP's resolution plan for RO-UKHPR1000-0004 is now complete and the RO has now been closed. We are satisfied that the RP's arrangements for transfer of the GDA design are adequate.

2.7 Compliance with Environment Agency requirements for GDA

We consider that the RP has complied with the requirements set out in the P&ID document and our REPs as follows.

MLDP1 – Establishing and sustaining leadership and management

The RP has developed effective management and quality arrangements that recognise and address environmental requirements. The arrangements are equivalent (but not formally certified) to the ISO9001 and 14001 standards. These arrangements include provisions for the handover of the generic design and safety case to a future licensee.

MLDP 2 – High standards of environment protection

The RP's design development arrangements draw on well-established processes in its service provider organisations, 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

The RP can draw on substantial suitably qualified and experienced (SQEP) resources in its service provider organisations. Training has been given to design engineers and safety case authors on BAT and the regulatory context in England. The RP has supplemented its resources by using specialist contractors to provide specific advice and support on radioactive waste, BAT and environmental permitting requirements in England.

MLDP4 – Decision making

The RP'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 approving decisions, and for assessing the implementation and effectiveness of GDA governance and decision-making arrangements.

MLDP5 – Learning from experience

The RP has management system arrangements in place to identify and consider OPEX in the development of the UK HPR1000 design. Following the issue of a Regulatory Observation (RO-UKHPR1000-0044) on OPEX, the RP has modified and supplemented these arrangements, and we now consider its OPEX arrangements to be adequate.

3. Public comments

3.1 GNSL public comments process

GNSL received 2 public comments up to 17 September 2021 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 England 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. GNSL has completed its responses to these actions, as described in section 2. With ONR, we reviewed the effectiveness of these responses as part of our 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 site operator. Our assessment has taken into account these and other quality issues. We are satisfied that the GDA documents are of adequate quality.

3.2 Environment Agency public consultation

We received 5 responses relating to MSQA following our public consultation, which ran from 11 January to 04 April 2021:

- Response reference UKHPR1000-011. The responder requested that all resolution plans are published so that stakeholders can see how Potential GDA Issues will be addressed, prior to any statement of design acceptability (SoDA) being issued.

Our response: All resolution plans for ROs have been published at <https://www.onr.org.uk/new-reactors/uk-hpr1000/ro-res-plan.htm>. Additionally, the full set of GDA Assessment Reports will describe how any potential GDA Issues have been closed out (for example, reference to the close-out of the potential GDA Issue on OPEX described in section 2.5 of this document).

- Response reference UKHPR1000-018. The responder questioned the use of the term "appear to be adequate" in relation to our assessment of the management arrangements.

Our response: Our assessment is carried out against the standards and guidance referred to in section 2.1 of this report, with the aim of determining whether the RP's MSQA arrangements meet those specifications, and so would enable us to proceed with issuing a statement of design acceptability (SoDA). The outcome from the GDA process is therefore a decision as to whether the arrangements are or are not adequate in this respect. Beyond this, no other quality judgement is made. Regarding using the term "appear to", our assessment process is of necessity a sampling process. We do not examine every element of the RP's arrangements in full detail, and therefore the outcome of the process must be qualified to reflect that we have used a sampling approach to form a broad judgement on the adequacy of the full arrangements. If the arrangements were not acceptable we would say so, take appropriate action and would reflect this in the decisions we make.

- Response reference UKHPR1000-032. The responder commented: "the document does not make it clear how management systems will progress over [the timescales for construction, operation, waste storage and decommissioning]", and requested that "It should be made clear how permitting may change over the lifetime of the site that is over several 100 years."

Our response: Our assessment is of the RP's management systems that are used to produce the UK HPR1000 generic design only. The assessment scope does not extend beyond the GDA process, to the construction, operation and decommissioning of the facility. While we do look to see at the generic design development stage that design development considers the functional requirements that these phases of the future facility will need to address, post-GDA management and quality arrangements are for a future operator to develop and demonstrate. Regulatory scrutiny of these phases would be carried out as part of a future operator's application for relevant permits, as part of ongoing compliance inspection

OFFICIAL

and assessment against relevant conditions within those permits, and ultimately at site closure as part of the final permit surrender process.

- Response reference UKHPR1000-043. The responder commented: "It is unclear if the organisational capacity and capability is considered 'adequate' after investigation by the Environment Agency/ONR or just a report from GNSL. On the design management aspect, this is an assurance given by GNSL and, as yet, unverified. This point is too substantial to assume it would be completed during the remainder of the GDA process. The transfer information to future licensee arrangements are, again, assumed that they will be completed, 'adequate progress' is vague."

Our response: Organisational capacity and capability has been assessed as part of our inspection of GNSL, CGN and EDF at each stage of the GDA process. To do this, we reviewed the RP's plans and procedures, and sampled a range of management system documents and records covering staff numbers, skills, training, and the use of supply chain resources (contractors). It is on this basis that we have determined organisational capacity and capability to be adequate.

Since the issues relating to design management were identified, we have issued RO-UK HPR1000-0024, to which the RP has now responded in full. We have also further inspected CGN's arrangements, including sampling of design management records, to verify that the shortcomings that were identified in step 3 of GDA have been addressed satisfactorily. We are satisfied that this is the case, and RO-UKHPR1000-0024 has now been closed.

The RP developed and put in place arrangements for transferring information to a future licensee during the detailed assessment stage of GDA. These arrangements centre on producing suitable and sufficient GDA documentation, including demonstrating that the design represents BAT, identifying GDA design changes compared to the baseline design, and identifying commitments that fall on a future licensee relating to site-specific design development and site-specific operational requirements and assumptions. We are satisfied that these arrangements are adequate to ensure that the documented GDA output is suitable for a future licensee to use.

- Response reference UKHPR1000-047. The responder commented: "Without seen [sic] examples of the evidence collected or the number of documents and references to the same, it is somewhat difficult to ascertain exactly what you looked at and comment on it. That said, from the comments you do provide, a robust management system and understanding of what that looks like does not seem to be present. Particularly concerning is the design change management process, corrective actions (that is, on assessment findings), closeouts etc, there is no mention of responsibilities in terms of whether the system is robust in notifying responsible persons of action needed to be taken, on what and when, or any system for notifying of and escalating when actions are overdue. One would expect, on a project of this scale and cost to have some form of a robust electronic system

OFFICIAL

for capturing the above and sending a notification, escalating when overdue, and providing both a top-level and detailed overview of the status of the overall management system and its various elements, however, there is no mention of such. There is also a lack of comment in respect to overall responsibilities, how these are documented and enforced.

As a qualified lead auditor for both ISO9001 and ISO14001, I found the consultation documentation less than helpful in providing any evidence of robust systems or indeed any confidence that such is either in place or being worked upon. I am left feeling rather concerned that the management system is made up of add hock [sic] arrangements, is poorly thought out, is not clearly defined and fails to meet the standards one would expect for such a high-risk project.

I found the statement that the management systems are broadly equivalent to (ISO14000 and 14001 standards) rather ambiguous in light of the importance of excellent management systems that such a high-risk project should necessitate. Surely one would expect the management system to at least meet the exact requirements of these standards and anything less for such a potentially catastrophic [sic] has to be unacceptable within the UK framework. Of particular note is the lack of information in respect to management control (of which there seems to be very little on the evidence provided) and the effectiveness of the PDCA cycle, which is not specifically mentioned at all."

Our response: The findings of our assessment of the RP's management systems and quality arrangements are reported in summary form in our Assessment Report. This topic area has been subject to ongoing assessment and inspection throughout the UK HPR1000 GDA process by a specific Environment Agency MSQA topic lead, working jointly with MSQA specialist leads within ONR. Arrangements have been assessed and inspected in detail at each step of the GDA process, within GNSL and its service providers (CGN, and EDF). Our overall finding is that the RP's management system and quality arrangements are adequate for the purpose of GDA and are consistent with applicable guidance and standards, including IAEA GSR Part 2, current Environment Agency and ONR guidance on management systems, and relevant environmental and quality standards ISO9001 and ISO14001. This includes our judgement that the arrangements are systematic and integrated, and are supported by effective governance arrangements and assurance activities (including independent audit). Regarding design management, we did identify some shortcomings in these arrangements earlier in the detailed assessment stage. As a result, and as described earlier in this report, we issued RO-UKHPR1000-0024, to which the RP has now responded in full. We have further inspected CGN's arrangements, including sampling of design management records, to verify that the shortcomings that we identified have been addressed satisfactorily. We are satisfied that this is the case, and RO-UKHPR1000-0024 has now been closed. On arrangements for corrective actions, the RP uses an electronic system for capturing, sentencing for action and tracking completion of corrective actions,

and we have sampled the effectiveness of this system as part of our inspections. We are satisfied that the RP's arrangements on corrective action are adequate.

4. Conclusion

The assessment detailed in this report relates to the RP'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. Through the GDA process, working with ONR, we have confirmed by assessment and inspection that the RP's GDA management and quality assurance arrangements are adequately developed and implemented, and meet the requirements of the P&ID as follows.

Developing the design

The RP has employed adequate numbers of suitably qualified, trained and experienced people to support the development of the UK HPR1000 design and the associated GDA submissions. This includes using specialist contract organisations to provide support on ensuring that the design and safety case meet regulatory expectations in England. We are satisfied that the capacity and capability of the organisation for developing the design are adequate.

Managing the generic design assessment (GDA) project

The RP has a formal management system in place which meets the specifications set out in relevant guidance and standards, including IAEA GSR Part 2, relevant Environment Agency and ONR guidance, and the ISO9001 and 14001 standards (albeit, for GNSL, without formal accreditation to the latter given their limited organisational lifespan). There is an appropriate organisational structure in place, including governance and internal assurance arrangements. Management procedures and associated documentation are fully developed and implemented. We are satisfied that management system and quality assurance arrangements are adequate for the UK HPR1000 GDA project.

Establishing the method for identifying the best available techniques (BAT) and making sure they are used in the design

The RP has addressed BAT explicitly in developing the design. Formal procedures for carrying out BAT assessment are in place, implemented by suitably qualified and experienced people (both suitably trained people within the RP and specialists from the supply chain). Similarly, arrangements for OPEX have been developed and implemented to support the identification of BAT. BAT decisions have been used in developing the design, and are recorded. We are satisfied that an appropriate BAT methodology has been developed and implemented in the development of the UK HPR1000 design.

Producing and maintaining the submission

OFFICIAL

The RP has formal arrangements in place for development and quality assurance of the safety case, such that the final Pre-Construction Environmental Report submissions present a suitable and sufficient demonstration that the UK HPR1000 design could meet environmental permitting requirements in England, subject to submission of suitable site-specific permit applications.

Ongoing communications with the regulators and responding to matters they raised during GDA

The RP has formal procedures in place for engaging with regulators and for responding to matters raised during GDA. Throughout the project there have been frequent meetings and engagements (including workshops and inspections) to facilitate our assessment of the UK HPR1000 generic design. The RP has responded to all formal Regulatory Queries and Regulatory Observations raised as part of our assessment.

Maintaining records of design and construction

The RP has formal procedures in place for maintaining documents and records. We have inspected samples of these records and found them to be adequate.

Controlling and documenting design modifications, both during and after completion of GDA

The RP has formal arrangements in place for design development, configuration management and design change control. These arrangements are integrated with equivalent arrangements employed by CGN as the designer. We assessed the effectiveness of these arrangements and although most were satisfactory, we found some shortcomings in relation to the specified requirements for design change review, and the rigour of their application. Regulatory Observation RO-UKHPR1000-0024 was raised on this matter. The RP has fully responded to the RO, and we have subsequently confirmed (by inspection) that appropriate changes to the relevant procedures have been made, and that the changes are effective in addressing the previous shortcomings.

Transferring information to potential operators and providing ongoing support to them throughout the reactor's life cycle

The RP has developed and implemented processes for transferring the UK HPR1000 technology to a future operator. An important element of this is to ensure that the GDA documentation presents a clear and coherent description of the design, and sets out BAT claims, arguments and evidence clearly (including underpinning requirements and assumptions). On the basis of our assessment of the RP's documents and procedures, we are satisfied that this is the case. Some aspects of the design are intended to be completed by a future operator (for example, where the design is dependent on site-specific details). We have identified one Assessment Finding in relation to this, as follows.

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

References

China General Nuclear, 2021

CGN procedure GH-40M-012, Provisions on Configuration Change Management for UK HPR1000 Generic Design Assessment (GDA) Project. 29 June 2021.

China General Nuclear, 2021

CGN Organisation and Operating Rules of UK HPR1000 GDA Project. GH-40M-004, 11 March 2021.

China General Nuclear, 2021

CGN Quality Assurance Programme for GDA of UK HPR1000. GH-20Q-001, 29 March 2021.

China General Nuclear, 2018

CGN Design and Development Control Procedure. PJ-30E-001, 02 March 2018.

China General Nuclear, 2019

Provisions on Technical Decision-Making System for UK HPR1000 GDA Project. GH-30E-007, 27 November 2019.

China General Nuclear, 2019

CGN Submission Document List Management. GH-30E-008, 23 June 2020.

China General Nuclear, 2021

CGN Requirements Management Provisions for UK HPR1000 GDA Project. GH-40M-026, 28 May 2021.

China General Nuclear, 2020

CGN Management Rules on Experience Feedback of UK HPR1000 GDA project. GH-40M-001, 25 August 2020.

China General Nuclear, 2020

Methodology for Use of OPEX in UK HPR1000. GHX00100059DOZJ03GN, 26 August 2020.

China General Nuclear, 2019

CGN procedure GH-40M-020, Management of Commitments for UK HPR1000. 23 February 2021.

China General Nuclear, 2020

Requirements Management Summary Report, Revision D, GHX00100127DOZJ03GN, 28 July 2021.

China General Nuclear, 2021

Post-GDA Commitment List. GHX00100084KPGB03GN, Revision C, 26 August 2021.

China General Nuclear, 2021

Safety Case Consolidation Summary Report, GHX00100090KPGB03GN, 23 September 2021.

China General Nuclear, 2021

CGN Position Training Program and Management Rules on Authorization and Job Taking, ED-EDE-060, 05 August 2020.

Environment Agency, 2010

Radioactive Substances Regulation – Environmental Principles. Version 2, 2010.

Environment Agency, 2010

Radioactive Substances Regulation: Management Arrangements at Nuclear Sites. 01 April 2010.

Environment Agency, 2016

Process and Information Document for Generic Assessment of Candidate Nuclear Power Plant Designs. Version 2. Environment Agency, 2016.

Environment Agency, 2018

Initial assessment of General Nuclear System's UK HPR1000 design: Statement of findings. Version 1, 2018.

General Nuclear Systems Limited, 2020

Project Definition Document. HPR/GDA/REPO/0003, 02 October 2020.

General Nuclear Systems Limited, 2020

Pre-Construction Safety Report Chapter 20 - MSQA and Safety Case. HPR/GDA/PCSR/0020, Revision 002, 04 October 2021.

General Nuclear Systems Limited, 2020

Quality Management Manual. HPR/GDA/REPO/0004, 15 October 2018.

General Nuclear Systems Limited, 2018

GDA Project Quality Plan. HPR/GDA/REPO/0024, 14 October 2020.

General Nuclear Systems Limited, 2019

PCER Delivery Quality Plan. HPR/GDA/REPO/0038, 08 June 2021.

General Nuclear Systems Limited, 2019

Design Control Strategy. HPR/GDA/REPO/0006, 30 May 2019.

General Nuclear Systems Limited, 2018

Design Reference Configuration Management Procedure. HPR/GDA/PROC/0054, 08 November 2018.

General Nuclear Systems Limited, 2019

Management of Commitments for Safety Case Updates. HPR/GDA/PROC/0046, 30 September 2019.

General Nuclear Systems Limited, 2020

Modification Categorisation Procedure. HPR/GDA/PROC/0033, 03 January 2020.

General Nuclear Systems Limited, 2020

Modification Control Procedure. HPR/GDA/PROC/0053, 22 June 2020.

General Nuclear Systems Limited, 2020

Suitably Trained, Competent & Experienced Personnel – a Framework for GDA. HPR/GDA/PROC/0029, 11 June 2020.

General Nuclear Systems Limited, 2019

Document List and Master Document Submission List Arrangements. HPR/GDA/PROC/0006, 24 May 2019

General Nuclear Systems Limited, 2019

Summary of General Nuclear System Limited to BRB Transition Arrangements: as understood at end of Step 3. HPR/GDA/REPO/0125, 03 October 2019

General Nuclear Systems Limited, 2020

GNSL Management for Safety and Quality Assurance Audit Report for CGN. HPR/GDA/REPO/0152, 14 August 2020.

General Nuclear Systems Limited, 2021

SSER V2 Guidance Note. HPR/GDA/REPO/0087, 26 March 2021.

International Atomic Energy Agency, 2016

Leadership and Management for Safety, General Safety Requirements Part 2. 2016.

International Standards Organisation, 2015

Environmental Management System Requirement, ISO 14001:2015.

Office for Nuclear Regulation, 2019

Contact Record ONR-NR-CR-19-029, UK HPR1000 Generic Design Assessment (GDA) - Step 3 Inspection of GNS Arrangements for Management Systems for Quality Assurance (MSQA), 23 April 2019.

Office for Nuclear Regulation, 2019

Contact Record ONR-NR-CR-19-183, Step 3 MSQA Inspection of CGN Arrangements for the UK HPR1000 GDA, 15 August 2019.

Office for Nuclear Regulation, 2019

Contact Record ONR-NR-CR-19-312 Revision 1, MSQA and Safety Case Workshops in Shenzhen, China, 10 December 2019.

Office for Nuclear Regulation, 2020

Contact Record ONR-NR-CR-19-507, MSQA Workshops at EDF SA, France, 12 February 2020.

Office for Nuclear Regulation, 2020

Contact Record ONR-NR-CR-20-407, MSQA Workshop/ Inspection of GNSL, 27, 29, 30 July 2020 and 03 August 2020.

Office for Nuclear Regulation, 2020

Contact Record ONR-NR-CR-20-724, MSQA Workshop/ Inspection of CGN, 27 October 2020 – 5 November 2020.

Office for Nuclear Regulation, 2021

ONR letter REG-GNS-0081N, Closure of Regulatory Observation RO-UKHPR1000-0024 - Control of Changes to the UK HPR1000 Design, 14 January 2021.

Office for Nuclear Regulation, 2021

Contact Record ONR-NR-CR-20-1115, Inspection of GDA MSQA arrangements in EDF, 24 March 2021.

Office for Nuclear Regulation, 2021

Contact Record ONR-NR-CR-21-203, Safety Case & MSQA Workshop with GNSL, 07 July 2021.

Office for Nuclear Regulation, 2021

Assessment Note ONR-NR-AN-21-012, Assessment of the Response to RO-UKHPR1000-0044 – Identification and Use of OPEX in the UK HPR1000 Generic Design and Safety Case, 20 May 2021.

Office for Nuclear Regulation, 2018

Regulatory Observation RO-UKHPR1000-0004, Development of a Suitable and Sufficient Safety Case, 03 September 2018.

Office for Nuclear Regulation, 2019

Regulatory Observation RO-UKHPR1000-0024, Control of Changes to the UK HPR1000 Design, 21 October 2019.

Office for Nuclear Regulation, 2020

Regulatory Observation RO-UKHPR1000-0044, Identification and Use of Operational Experience (OPEX) in the UK HPR1000 Generic Design and Safety Case, 19 May 2020.

Office for Nuclear Regulation, 2013

Nuclear Safety Technical Assessment Guide NS-TAST-GD-072, Revision 2, Function and Content of a Safety Management Prospectus, April 2013.

Office for Nuclear Regulation, 2016

Nuclear Safety Technical Inspection Guide NS-INSP-GD-014 Revision 3, LC14 Safety Documentation, May 2016.

List of abbreviations

AF	Assessment Finding
AFI	Area for improvement
ALARP	As low as reasonably practicable
BAT	Best available techniques
CGN	China General Nuclear
EDF	Électricité 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
GSR	Generic security report
HPR	Hualong Pressurised Reactor
ONR	Office for Nuclear Regulation
OPEX	Operating experience
P&ID	Process and Information Document
PCER	Pre-Construction Environmental Report
PCSR	Pre-Construction Safety Report
REP	Regulatory Environmental Principles
RGP	Relevant good practice
RO	Regulatory Observation
RP	Requesting Party
RQ	Regulatory Query
RSMDP	Radioactive Substances Management Developed Principle
RSR	Radioactive Substances Regulation
SQEP	Suitably qualified and experienced person
SSER	Safety, Security and Environment Report (a collation of the PCER, PCSR and GSR)

Would you like to find out more about us or your environment?

Then call us on

03708 506 506 (Monday to Friday, 8am to 6pm)

Email: enquiries@environment-agency.gov.uk

Or visit our website

www.gov.uk/environment-agency

incident hotline

0800 807060 (24 hours)

floodline

0345 988 1188 (24 hours)

Find out about call charges (<https://www.gov.uk/call-charges>)

Environment first

Are you viewing this onscreen? Please consider the environment and only print if absolutely necessary. If you are reading a paper copy, please don't forget to reuse and recycle.