



**New Reactor Division – Generic Design Assessment**

**Step 2 Assessment of the Management for Safety and  
Quality Assurance of the UK HPR1000 Reactor**

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## EXECUTIVE SUMMARY

This report presents the results of my Management for Safety and Quality Assurance (MSQA) assessment of the UK HPR1000 undertaken as part of Step 2 of the Office for Nuclear Regulation's (ONR) Generic Design Assessment (GDA).

The GDA process calls for a step-wise assessment of the Requesting Party's (RP) safety submission with the assessments increasing in detail as the project progresses. Step 2 of GDA is an overview of the acceptability, in accordance with the regulatory regime of Great Britain, of the design fundamentals, including ONR's review of key nuclear safety and nuclear security claims (or assertions). The aim is to identify any fundamental safety or security shortfalls that could prevent ONR from permitting the construction of a power station based on the design.

During GDA Step 2 my work has focused on the assessment of the MSQA aspects within the UK HPR1000 Preliminary Safety Report (PSR), and a number of supporting references and supplementary documents submitted by the RP, focusing on design concepts and claims.

The standards I have used to judge the adequacy of the RP's submissions in the area of MSQA have been primarily ONR's Safety Assessment Principles (SAPs), in particular FP.2 - Leadership and Management for Safety, FP.4 - Safety Assessment and ONR's Technical Assessment Guides (TAGs) (Ref. 5) and Technical Inspection Guides (TIGs) (Ref. 6) that relate to MSQA, safety case management and design control. I have also made use of other relevant standards and guidance.

My GDA Step 2 assessment work has involved regular engagement with the RP in the form of technical exchange workshops and progress meetings, including meetings with the plant designers.

The UK HPR1000 PSR is primarily based on the Reference Design, Fangchenggang Unit 3 (FCG3), which is currently under construction in China. Key aspects of the UK HPR1000 preliminary safety case related to MSQA, as presented in the PSR, its supporting references and the supplementary documents submitted by the RP, describe GNS's GDA MSQA arrangements, its Service Providers' MSQA arrangements and the GNS's GDA Project Management arrangements.

In addition to assessing this documentation, I have also undertaken MSQA inspections at the headquarters of the RP and its Service Providers to ensure that the documented systems are applied in practice. During my GDA Step 2 MSQA assessment I have identified the following areas of strength:

- The RP with its Service Providers have developed specific management system arrangements for the GDA project, to provide control for the development, verification, validation and review of the safety, security and environmental submissions.
- Project arrangements are in place to allow each entity to perform their identified responsibilities.
- Regular project interfacing occurs between all three entities used for overall project co-ordination.
- Escalation routes are available at all three parties for the resolution of technical concerns.
- There is the reinforcing and building of the GDA competency within the Service Providers by using in-house staff that had prior GDA experience and /or were gaining the understanding to satisfy GDA requirements via training and GDA specialist support.
- The development of a 'Common Working Platform' between the RP and Service Providers to aid organisational cooperation.

- A strong culture exists with respect to Safety and Learning from Experience.

From the evidence sampled at the RP and Service Providers, the MSQA arrangements appeared to broadly satisfy regulatory expectations for this stage of the project

During my GDA Step 2 MSQA assessment I have identified the following areas that I will target during my Step 3 assessment:

- Practical application of the process for making fundamental safety decisions and plant modification decisions.
- Arrangements for developing and controlling the Master Document Submission List (MSDL) and the Document List.
- Resource planning and technical competency implementation.
- Arrangements for design change control, configuration management and design training deliverables.
- Safety Case management including work planning coordination and the application of approved ALARP methodologies.

During my GDA Step 2 assessment, I have not identified any fundamental safety shortfalls in the area of MSQA that might prevent the issue of a Design Acceptance Confirmation (DAC) for the UK HPR1000 design.

## LIST OF ABBREVIATIONS

ALARP	As Low As Reasonably Practicable
BAT	Best Available Technique
CGN	China General Nuclear Power Corporation
DAC	Design Acceptance Confirmation
EA	Environment Agency
EDF	Électricité de France
GNI	General Nuclear International
GNS	Generic Nuclear System Ltd
GSR	Generic Security Report
IAEA	International Atomic Energy Agency
ISO	International Organization for Standardization
JPO	(Regulators') Joint Programme Office
MSDL	Master Document Submission List
MSQA	Management for Safety and Quality Assurance
NPP	Nuclear Power Plant
ONR	Office for Nuclear Regulation
PCSR	Pre-construction Safety Report
PCER	Pre-construction Environmental Report
PSR	Preliminary Safety Report (includes security and environment)
PTI	Project Technical Inspector
QA	Quality Assurance
QMS	Quality Management System
RGP	Relevant Good Practice
RI	Regulatory Issue
RIA	Regulatory Issue Action
RO	Regulatory Observation
ROA	Regulatory Observation Action
RP	Requesting Party

RQ	Regulatory Query
SAP(s)	Safety Assessment Principle(s)
SSER	Safety, Security and Environmental Report
SFAIRP	So far as is reasonably practicable
SQEP	Suitably Qualified and Experienced Person
TAG	Technical Assessment Guide(s)
TIG	Technical Inspection Guide(s)
WENRA	Western European Nuclear Regulators' Association

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Table 1: Relevant Safety Assessment Principles Considered During the Assessment

## 1 INTRODUCTION

1. The Office for Nuclear Regulation's (ONR) Generic Design Assessment (GDA) process calls for a step-wise assessment of the Requesting Party's (RP) safety submission with the assessments increasing in detail as the project progresses. General Nuclear System Ltd (GNS) has been established to act on behalf of the three joint requesting parties (China General Nuclear Power Corporation (CGN), Électricité de France (EDF) and General Nuclear International (GNI)) to implement the GDA of the UK HPR1000 reactor. For practical purposes GNS is referred to as the 'UK HPR1000 GDA Requesting Party'.
2. During Step 1 of GDA, which is the preparatory part of the design assessment process, the RP established its project management and technical teams and made arrangements for the GDA of the UK HPR1000 reactor. Also, during Step 1 the RP prepared submissions to be assessed by ONR and the Environment Agency (EA) during Step 2.
3. Step 2 commenced in November 2017. Step 2 of GDA is an overview of the acceptability, in accordance with the regulatory regime of Great Britain, of the design fundamentals, including ONR's assessment of key nuclear safety and nuclear security claims (or assertions). The aim is to identify any fundamental safety or security shortfalls that could prevent ONR permitting the construction of a power station based on the design.
4. My assessment has followed my GDA Step 2 Assessment Plan for Management for Safety and Quality Assurance (MSQA) (Ref. 11) prepared in October 2017 and shared with GNS to maximise openness and transparency.
5. This report presents the results of my MSQA assessment of the UK HPR1000 as presented in the UK HPR1000 Preliminary Safety Report (PSR) (Ref. 13) and its supporting documentation (Refs 15, 16 and 17).



## 2 ASSESSMENT STRATEGY

6. This section presents my strategy for the GDA Step 2 assessment of the MSQA aspects of the UK HPR1000 (Ref. 11). It also includes the scope of the assessment and the standards and criteria I have applied.

### 2.1 Scope of the Step 2 MSQA Assessment

7. The objective of my GDA Step 2 assessment was to assess the RP's, and its supporting Service Providers' MSQA arrangements for producing and delivering the safety, security, environmental and design documentation for the UK HPR1000.
8. In particular, my assessment has focused on the following:
- Organisation, Leadership and Governance.
  - Capacity and Capability.
  - GDA management including Project and Quality Management arrangements.
  - Design management.
  - Safety Case management.
  - Learning Organisation.
9. During GDA Step 2 I have also evaluated whether the claims related to MSQA are supported by a body of technical documentation sufficient to allow me to proceed with GDA work beyond Step 2.
10. Finally, during Step 2, I have undertaken the following preparatory work for my Step 3 assessment:
- Engaging with the RP via progress teleconferences and face-to-face technical meetings and workshops.
  - Raising Regulatory Queries (RQ) based on the findings of this report.
  - Coordination with the EA to determine relevant topics that should be assessed.

### 2.2 Standards and Criteria

11. For ONR, the primary goal of the GDA Step 2 assessment is to reach an independent and informed judgment on the adequacy of a preliminary nuclear safety and security case for the reactor technology being assessed. Assessment was undertaken in accordance with the requirements of the Office for Nuclear Regulation (ONR) How2 Business Management System (BMS) guide NS-PER-GD-014 (Ref. 1).
12. In addition, the Safety Assessment Principles (SAPs) (Ref. 2) constitute the regulatory principles against which duty holders' and RP's safety cases are judged. Consequently the SAPs are the basis for ONR's nuclear safety assessment and have therefore been used for the GDA Step 2 assessment of the UK HPR1000. The SAPs 2014 Edition is aligned with the International Atomic Energy Agency (IAEA) standards and guidance.
13. Furthermore, ONR is a member of the Western European Nuclear Regulators' Association (WENRA). WENRA has developed Reference Levels, which represent good practices for existing nuclear power plants, and Safety Objectives for new reactors.
14. The relevant SAPs, IAEA standards and WENRA reference levels are embodied and expanded on in the Technical Assessment Guides (TAGs) (Ref. 5) and Technical Inspection Guides (TIGS) (Ref. 6). These guides provide the principal means for assessing the MSQA aspects in practice.

### 2.2.1 Safety Assessment Principles

15. The key SAPs (Ref. 2) applied within my assessment are SAPs FP. 2 and FP. 4 (see also Table 1 for further details).

### 2.2.2 Technical Assessment Guides

16. The following Technical Assessment Guides have been used as part of this assessment (Ref. 5):
- NS-TAST-GD-027 - Training and Assuring Personnel Competence.
  - NS-TAST-GD-004 - Fundamental Principles.
  - NS-TAST-GD-049 - Licensee Core & Intelligent Customer Capabilities.
  - NS-TAST-GD-051 - The Purpose, Scope and Content of Nuclear Safety Cases.
  - NS-TAST-GD-057 - Design Safety Assurance.
  - NS-TAST-GD-065 - Function and Content of the Nuclear Baseline.
  - NS-TAST-GD-072 - Function and Content of Safety Management Prospectus.
  - NS-TAST-GD-077 - Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services.
  - NS-TAST-GD-080 - Challenge Culture, Independent Challenge Capability (including an Internal Regulation function), and the provision of Nuclear Safety Advice.
  - NS-TAST-GD-093 - Guidance for undertaking Leadership and Management for Safety Reviews.

### 2.2.3 Technical Assessment Guides

17. The following Technical Inspection Guides have been used as part of this assessment (Ref. 6):
- NS-INSP-GD-014 - Safety Documentation.
  - NS-INSP-GD-017 - Management Systems.

### 2.2.4 National and International Standards and Guidance

18. The following national and international standards and guidance have been considered as part of this assessment:
- Relevant IAEA standards (Ref. 7)
    - Leadership and Management for Safety, General Safety Requirements, GSR Part 2, 2016.
    - Configuration Management in Nuclear Power Plants, IAEA-TECDOC-1335, 2003.
  - WENRA references (Ref. 8)
    - Safety Reference Levels for existing reactors, WENRA. September 2014.
  - Other international standards (Ref. 9)
    - ISO 9001:2015: Quality management systems – Requirements.

- ISO 10005:2005: Quality management systems - Guidelines for Quality Plans
- BS ISO 10007:2003: Guidelines for Configuration Management.

### **2.3 Use of Technical Support Contractors**

19. During Step 2, I have not engaged Technical Support Contractors (TSCs) to support the assessment of the MSQA for the UK HPR1000.

### **2.4 Integration with Other Assessment Topics**

20. Early in GDA, I recognised the importance of working closely with other inspectors (including Environment Agency's inspectors) as part of the MSQA assessment process. Similarly, other inspectors sought input from my assessment of the MSQA for the UK HPR1000. I consider these interactions are key to the success of the project in order to prevent or mitigate any gaps, duplications or inconsistencies in ONR's assessment. From the start of the project, I have endeavoured to identify potential interactions between the MSQA and other technical areas, with the understanding that this position will evolve throughout the UK HPR1000 GDA.
21. To undertake my assessment effectively I have had close interactions with the Project Technical Inspector (PTI), who leads on the assessment of cross-cutting matters which directly relate to MSQA including safety case development, design control and the application of ALARP. Project wide assessment of the cross-cutting topics is reported in the Summary of the Step 2 Assessment of the UK HPR1000 Reactor (Ref. 24).
22. I have also coordinated my assessment with the EA MSQA Inspector in order to ensure consideration of environmental management matters that impact on matters of safety and security, such as the development of Best Available Technique (BAT) methodologies and their interaction with ALARP.
23. I have liaised with inspectors from other topics in order to obtain information of relevance to my MSQA assessment.

### 3 REQUESTING PARTY'S MANAGEMENT SYSTEM ARRANGEMENTS

24. This section presents a summary of the RP's Management for Safety and Quality Assurance (MSQA) arrangements for the UK HPR1000 as described in the RP's Preliminary Safety Report (PSR) submission for Step 2 (Ref. 13). It also identifies the supporting documentation submitted by the RP and their Service Providers which form the basis of my MSQA assessment.

#### 3.1 Summary of the RP's Management System Arrangements

25. ONR expects the RP to have adequate management system arrangements to deliver the Safety, Security and Environmental Report (SSER) submissions and to meet Regulators expectations as recorded in ONR and EA guidance documents (Refs 3 and 4).

26. To meet these requirements, GNS has employed the services of the other parties of the UK HPR1000 Shareholder Agreement (i.e. CGN and EDF) as two Service Providers along with their management arrangements, to support the production of the SSER submissions. As per the PSR (Ref. 13), which outlines this arrangement, each entity has the following responsibility:

- GNS to provide project management oversight and governance for the project.
- CGN is responsible for production of the safety case submissions for the UK HPR 1000 design.
- EDF is responsible for technically reviewing CGN's safety case output.

This assessment reviews both the holistic GDA project and organisation specific aspects of the management arrangements of the RP (i.e. GNS) and its Service Providers (i.e. CGN and EDF) as described in the PSR, for the delivery of the SSER.

27. The RP and their Service Providers submitted a suite of MSQA Management System documentation supporting their roles in the GDA process. A description of the submitted MSQA documentation is outlined below and was the focus of my MSQA assessment.

- **Organisation, Leadership and Governance:** These arrangements are intended to ensure that adequate Leadership and Organisational arrangements are in place to direct, manage, supervise, account for and assure the effectiveness by which the RP delivers the SSERs.
- **Capacity and Capability:** These arrangements are intended to ensure that the persons developing, reviewing and approving the safety case submission are competent to do so and that there is sufficient resource available to fulfil the required roles and responsibilities.
- **GDA Management including Project and Quality Management arrangements:** Project arrangements to plan, organise and control activities so that the project is successfully completed while managing the risks. Quality Management arrangements provide required key and supporting processes, helping to ensure that the production of the SSER documentation is performed 'right the first time'. These arrangements include competency requirements, document control, supplier selection process, quality control process and auditing.
- **Design Management:** MSQA arrangements to ensure that the GDA project adheres to the required design process and that they are clearly integrated into the safety case process, considering all aspects of Safety. The process addresses elements such as verification, validation, independent review, design change control and intelligent customer oversight.
- **Safety Case management:** Arrangements for the effective delivery of the UK HPR1000 Safety Case. This includes having interface arrangements between

the Design and Safety case process as well as the provision of competent and experienced resource used for the production, review and approval of the relevant submissions.

- **Learning Organisation.** RP and Service Provider arrangements to learn from GDA experiences from previous GDA applicants as well as learning from their direct experience during the GDA process.

### 3.2 Basis of Assessment: RP's Documentation

28. The RP's and Service Providers' documentation that has formed the basis for my GDA Step 2 assessment of the safety claims related to the MSQA aspects of the UK HPR1000 is presented in Refs 15, 16 and 17.
29. In addition, during April 2018 GNS submitted to ONR, for information, an advance copy of the UK HPR1000 Pre-Construction Safety Report (PCSR) Chapter 20 (Ref. 14) which addresses MSQA. Having early visibility of the scope and content of this chapter/s has been useful in the planning and preparation of my GDA Step 3 assessment work.

## 4 ONR ASSESSMENT

30. This assessment has been carried out in accordance with HOW2 guide NS-PER-GD-014, "Purpose and Scope of Permissioning" (Ref. 1).
31. My Step 2 assessment work has involved regular engagement with the RP's MSQA specialists and the Service Providers and has included three inspections undertaken at the UK, Chinese and French offices of GNS, CGN and EDF respectively. Eleven other progress meetings have also been held.
32. During my GDA Step 2 assessment, I have identified some gaps in the documentation formally submitted to ONR. Consistent with ONR's Guidance to Requesting Parties (Ref. 3), these normally lead to Regulatory Queries (RQs) being issued. At the time of writing my assessment report, in MSQA, during Step 2, I have raised three RQs to facilitate my assessment.
33. Similarly, and again consistent with ONR's Guidance to Requesting Parties (Ref. 3), more significant shortfalls against regulatory expectations in the generic safety case are captured by issuing Regulatory Observations (ROs). At the time of writing my assessment report in MSQA, during Step 2, I have not raised any ROs.

Details of my GDA Step 2 assessment of the UK HPR1000 preliminary safety case in the area of MSQA, including the conclusions I have reached, are presented in the following sub-sections of the report. This includes the areas of strength I have identified, as well as the items that require follow-up during subsequent stages.

### 4.1 Overarching assessment approach

34. The inspections assessed the MSQA arrangements for the UK HPR1000 as described in the Preliminary Safety Report (Ref. 13) and supported by the RP's (i.e. GNS) and Service Providers' (i.e. CGN and EDF) MSQA documentation (Refs 15, 16 and 17).
35. The ONR and the EA carried out these assessments as joint inspections, on each of the three organisations at their head offices.
36. Inspection plans for GNS (Ref. 18), CGN (Ref. 20) and EDF (Ref. 22) were developed. Similar topics were assessed during each inspection allowing the ONR and the EA to apply a consistent approach to the inspection strategy. It also allowed the ONR and EA to gain both a holistic project and organisation specific understanding of the implementation of the RP's MSQA arrangements.
37. The topics covered by the inspection plans were:
  - Organisation, Leadership and Governance.
  - Capacity and Capability.
  - GDA management including Project and Quality Management arrangements.
  - Design management.
  - Safety Case management.
  - Learning Organisation.
38. The findings from each inspection were recorded in three separate inspection reports, highlighting strengths / areas of good practice and areas for improvement for GNS (Ref. 19), CGN (Ref. 21) and EDF (Ref. 23). The assessment, key areas of strength and areas for improvement/follow up are discussed in the following sub sections.

## 4.2 Organisation, Leadership and Governance

### 4.2.1 Assessment

39. GNS, CGN and EDF have organisational arrangements in place for the delivery of Design and Safety Case requirements and to satisfy their 'Framework Service Agreement', which is used to support the production of the SSER submissions. The sampled arrangements appear to be well developed across all three entities and satisfy fundamental Regulatory expectations for this stage of the project (Refs 19, 21 and 23).
40. Detailed planning activities are conducted by each entity to address their area of responsibility and arrangements are in place to allow regular project interfacing. These arrangements have elements of an integrated approach to work planning, incorporating Service Provider considerations into the RP's planning schedules. Within GNS, Lead Project Correspondents (LPC) and Project Correspondents are also individually assigned to various portfolios of work such as Design, Safety Case to oversee their delivery (Ref. 19).
41. GNS's governance arrangements include engagement with their Service Provider with control provided by GNS top management, though these arrangements were primarily focused on project management concerns.
42. Arrangements are in place for the resolution of technical issues within each of the entities. These include an escalation and resolution route to the GNS Technical Committee, whose main function is to address fundamental safety and physical modification decisions, which can be described as significant technical decisions that could affect the robustness of the Safety Case submissions (Refs 19, 21 and 23).
43. Although Intellectual Property (IP) arrangements were not assessed during the inspections, during the CGN inspection, it was stated that arrangements are in place to manage IP concerns. This included the establishment of a GNS IP Committee, which can be used for the resolution of related issues. It was also stated that a process is also in place to gain permission to share certain types of information between the three organisations. It is recognised that this issue requires appropriate management to ensure that the respective entities gain sufficient understanding of the design in order to effectively undertake their roles (Ref. 21)

### 4.2.2 Strengths

44. To aid organisational cooperation, a 'Common Working Platform' has also been established in China where a small number of EDF personnel are based, facilitating the resolution of any matters that arise (Ref. 23),

### 4.2.3 Items that Require Follow-up

45. During my GDA Step 2 assessment of "Organisation, Leadership and Governance" I have identified the following potential shortfalls that I will follow-up during Step 3 of GDA:
  - Although GNS does engage with CGN on areas of Design and Safety Case management, there is uncertainty of the role of GNS with regard to providing technical input to GDA submissions, and the subsequent level of technical capability that it requires for managing their delivery (Refs 19 and 23).
  - Though there was a strong understanding of the term 'Nuclear Safety Culture' across all three entities, it was noted that there is an inconsistency in the

definition and application of the term 'Safety' throughout various MSQA documentation. This application did not always match the description as given in GSR Part 2 (Ref. 7).

- In reviewing the RP's Technical Decision Making process, I noted that there was a lack of clarity on what constitutes a 'Fundamental Safety Decisions and Physical Modification Decisions' and what was the process used by:
  - GNS's Service Providers to provide visibility of how they sentence design decisions so that GNS can assure itself that all significant matters are being correctly referred to the GNS Technical Committee for consideration (Ref. 19).
  - GNS to manage technical related issues sent to the GNS Technical Committee (Ref.19).

#### **4.2.4 Conclusions**

46. Based on the outcome of my Step 2 assessment of "Organisation, Leadership and Governance", I have concluded that the current arrangement is appropriate for this stage of the GDA project. Arrangements are in place for project oversight, assigned RP personnel to oversee the delivery of the SSER submissions, and engagement between all three entities focusing on planning requirements and the resolution of significant technical issues. However, the Regulators will be addressing the Items that require follow up during Step 3 of GDA as these elements add robustness to the RP's governance arrangements and the Technical Decision Making process.

### **4.3 Capacity and Capability**

#### **4.3.1 Assessment**

##### **4.3.1.1 Capacity**

47. Across the three organisations, resource planning arrangements are in place, supported by the available financial resource to achieve their projected capacity. Work planning and the associated resource requirements are reviewed at monthly meetings held between all three parties (Refs 19, 21 and 23).
48. Within GNS, arrangements are in place to provide resource via secondments from their parent organisations with their resource modelling defined and fixed by the 'Framework Service Agreements'. GNS's resource arrangement is supported by their flexibility to provide for short, medium or long term commitments via external recruiting, to address shortfalls is personnel availability (Ref. 19).
49. Within CGN, there appears to be adequate capacity to support the GDA project given CGN's size, the priority given to the GDA project within the organisation and the nature of its core activities which focuses on design, nuclear new build expertise and operational arrangements (Ref. 21).
50. EDF's arrangement to provide GDA resource utilises standardised company arrangements whose effectiveness has been tested on other EDF projects. They have also assigned a contract manager who acts as the main point of contact with GNS. Planning arrangements include the use of GNS Level 3 plans for the development of annual, semester and weekly resource profiles, which is resourced by the wider EDF (Ref. 23).



#### 4.3.1.2 Capability

51. The RP's and their Service Providers' competency arrangements are in place and appeared fit for purpose, addressing the need for roles profiles for safety significant positions supported by records of training and experience for personnel fulfilling those roles.
52. Training arrangements were also in place across the Service Providers for the development of BAT and ALARP competencies, with EDF subject matter experts providing support and oversight to its EDF GDA colleagues and CGN initially obtaining specialist support from the UK supply chain (Refs 21 and 23).

#### 4.3.2 Strengths

53. Across the three entities, I noted that the organisations are reinforcing and building their GDA competency by using in-house staff that had prior GDA experience and /or were gaining the understanding to satisfy GDA requirements via training and GDA specialist support. Currently, there is no technical work being carried out by external subcontractors, although there are embedded contractors who are working closely within the project's technical scope.

#### 4.3.3 Items that Require Follow-up

54. During my GDA Step 2 assessment of "Capacity and Capability" I have identified the following potential shortfalls that I will follow-up during Step 3 of GDA:
  - Although monthly meetings are held with all three entities to discuss work planning, EDF's service provider arrangements to plan for resource for technical review are challenged due to the lack of full visibility of planned submissions throughout GDA and the demand from the wider EDF for the same resource type (Ref. 23). In addition, there are concerns that the GNS's current resource management arrangements might not be flexible enough to deal with foreseeable fluctuations in workload and forthcoming rotations in secondees (Ref. 19).
  - It was unclear how CGN GDA personnel, trained in BAT and ALARP approaches, developed sufficient experience to be considered company experts in these fields. Full competence in BAT and ALARP will take some time to achieve, primarily by practical experience of undertaking such assessments and substantiating the relevant arguments in the safety case (Ref. 21). For EDF, there was a lack of clarity as to whether or not all the EDF affiliates assigned to GDA had received initial BAT /ALARP training so that they are better able to recognise associated issues (Ref. 23).

#### 4.3.4 Conclusions

55. Overall, I consider that the RP and their Service Providers have used a reasonable approach to set out arrangements to secure the capacity and capability requirements for the project. My assessment in this topic area concludes that the current arrangements are satisfactory for this stage of the project. Arrangements were place to provide resource based on the specific organisation's internal arrangements. GDA competency within the Service Providers was reinforced and increased by using in-house staff that had prior GDA experience or were gaining the understanding of GDA requirements via training and GDA specialist support. However, both the ability of assigned CGN personnel to gain sufficient BAT and ALARP experience for the project

as well as the RP and Service providers flexibility to deploy competent resource in short timescales, will be critical determining factors to produce adequate submissions during Step 3 and will be key aspects of my assessment.

#### **4.4 GDA management including Project and Quality Management arrangements**

##### **4.4.1 Assessment**

##### **4.4.1.1 Project Management Arrangements**

56. Formalised project management arrangements are in place at the RP and their Service Providers, with particular areas being more prominent depending on the roles of the organisations (Ref. 19, 21 and 23).
57. The RP provided project management oversight and governance via a defined set of processes used to support their key portfolio of work (Ref. 19). These defined their key processes and the Service Provider interfaces required for Safety Case production. This includes arrangements for the RP to receive SSER documentation from CGN so that they undergo GNS 'gate keeper reviews'. GNS also determines which supporting reference documentation requires review by EDF and if any additional supporting references require technical review (Ref. 23).
58. Established project management arrangements were in place at each of the Service provider addressing task management, schedule control, cost control and risk management. Service Providers' alignment of work planning activities is managed using schedules based on the work planning schedules from the RP and regular project interfacing at monthly meetings. Risk registers were in place recording project and /or technical risk which were shared with the RP (Refs 21 and 23).
59. The processes and arrangements that have been developed by CGN to manage RQs/ROs/RIs appear fit-for-purpose and are integrated with the RP's processes. EDF resolution arrangements to address any safety and technical issues are available.

##### **4.4.1.2 Quality Management Arrangements**

60. The Quality Management arrangements in place across all the three entities appeared fit for purpose for this stage of the project with CGN holding valid ISO 9001 and 14001 certification which included 'Design' in their certification scope (Refs 19, 21 and 23).
61. The RP's Quality Management framework has been established with document control implementation at an advanced stage. Regulatory Queries (RQ), Regulatory Observations (RO) and Regulatory Issues (RI) management arrangements are defined and an operational commitments log is used to track actions. There was evidence to show that GNS were in the process of continually improving some of their Quality Management arrangements (Ref. 19).
62. Quality Plans were in place at the RP and EDF, while CGN had produced a Quality Assurance Programme (Ref. 21) used to give guidance as to how Quality was to be established and controlled in the production of the Safety Case and design.
63. Defined Quality Assurance roles and responsibilities within the RP and CGN have been established to oversee the functioning of the GDA QA system in their respective organisations.
64. Supply Chain arrangements are in place across the RP and their Service Providers. GNS subcontracts work on behalf of CGN in order to accommodate the UK context /

requirements. However, with permission from GNS, EDF may subcontract out directly to the supply chain as it has prior experience of working with UK requirements.

#### 4.4.2 Items that Require Follow-up

65. During my GDA Step 2 assessment of “GDA management including Project and Quality Management arrangements ” I have identified the following potential shortfalls that I will follow-up during Step 3 of GDA:
- It is unclear what technical competency arrangements GNS had in place to determine which of the supporting reference documents they required EDF to review. This technical role of GNS does not align with GNS’s current role which is to manage project related activities (Refs 19 and 23).
  - Within CGN, there was a lack of clarity on the process for developing RO/RI Resolution Plan (plans used to address an RO/RI), specifically what level of interaction occurs between GNS and CGN during the development of the plans. Moreover, it was observed that the current process’s timescales for producing these plans are unlikely to be achievable based upon demonstrated performance and should be reviewed to ensure process adherence (Ref. 21).
  - Within CGN, there was no defined process and approach for the management of the MDSL and Document List between GNS and CGN. The MDSL is a ‘live’ document that allows the ONR to understand and reference exactly what constitutes the latest versions of the GDA submissions. The Document List is the totality of the information submitted to the Regulators during GDA, including information sent for information purposes only and responses to RQs (Ref. 21).

#### 4.4.3 Conclusions

66. Based on my assessment, I consider that the current, Project Management and Quality Management arrangements that were sampled, satisfy the fundamental Regulatory requirements for this stage of the project. Arrangements were in place to allow each entity to perform their identified responsibilities and there was regular project interfacing between all three entities used for overall project co-ordination. Although GNS and EDF were in the process determining possible areas for improvement, their Quality Management arrangements were ‘fit for purpose’ for this stage of the process. The Regulators understand that both the Project and Quality Management arrangements may need to develop further to address future GDA demands where necessary. This continual improvement and the highlighted items that require follow up will be reviewed during Step 3 of GDA.

### 4.5 Design management

#### 4.5.1 Assessment

67. Fundamental Design management arrangements for the Project have been established at the RP and the Service Provider organisations, tailored to the role that they serve in the GDA process (Ref. 19, 21 and 23).
68. Control of the design process was evident by a ‘GNS Design Control Strategy’ documenting the key GDA deliverables to be produced by their Service Providers with a method to track the status of the deliverables. Service Provider design processes were also defined and supported by procedures, setting out the specifics of their design arrangements such as design scope, objectives, risk assessment and quality assurance, design inputs, design review, verification and validation.

69. Arrangements for conducting technical reviews were also clearly defined by the assigned Service Provider and evidence from inspections indicated that they have been applied in the GDA process.

#### **4.5.2 Items that Require Follow-up**

70. During my GDA Step 2 assessment of “Design Management ” I have identified the following potential shortfalls that I will follow-up during Step 3 of GDA:
- Engagement initiated by CGN with GNS in design change management appeared subjective where decisions are below the level warranting escalation to the GNS Technical Committee or have not yet been confirmed as matters for escalation. CGN should, in conjunction with GNS, further develop its procedures for escalating relevant design decisions to GNS’s Technical Committee (Ref. 21).
  - Within the GNS Design Control Strategy, various training deliverables were required to help fulfil the said strategy. At the time of the GNS inspection, these deliverables were not recorded and tracked on the Design Level 3 plan. As such, oversight of their delivery could be reduced or lost (Ref. 19). I consider that both the document and associated training deliverables, as stated in the Design Control Strategy, are of importance for the effective implementation of the Design Management process and will be reviewing their development during Step 3.
  - As stated during the CGN inspection, both the Configuration Change Control and the UK HPR1000 Design Change Control processes are currently under development. The current list of design modifications associated with the FCG3-UK HPR1000 gap analysis will need to be put through these processes retrospectively. Engagement by GNS in design change management appears subjective where decisions are below the level warranting escalation to the GNS Technical Committee or have not yet been confirmed as matters for escalation (Ref. 21).

#### **4.5.3 Conclusions**

71. Based on my assessment, I consider that the sampled Design Management arrangements satisfy fundamental Regulatory requirements for this stage of the project. The fundamental process steps for Design managements, such as design inputs, design review, verification and validation, were in place (Ref. 21). However, the Regulators noted observations such as Design Change Control and Configuration Change Controls will require further addressing. These concerns were highlighted during the inspection and I will be considering how they have been addressed in Step 3.

### **4.6 Safety Case Management**

#### **4.6.1 Assessment**

72. The RP’s GDA Project Definition Document, Delivery Strategies and supporting procedures give direction for project management oversight and the development of specifications for the Safety Case submissions (Ref.19). SSER production Managers at CGN co-ordinate the development of the Safety Case via topic / chapter area in collaboration with the CGN Design departments (Ref. 21). EDF performs its ‘technical reviewer’ role for the CGN’s output (Ref. 23).

73. CGN's arrangements for verification and validation appeared appropriate for Safety Case production. GNS arrangements were in place to request technical reviews by EDF on selected Safety Case submissions against a defined specification. GNS determines which supporting reference documentation requires reviewing by EDF and if any additional supporting reference requires technical review.
74. Each Service Provider had internal control arrangements to monitor the progress and quality of work delivery. Independent reviews were performed by the RP on CGN's safety case outputs.
75. Suitably Qualified and Experienced Person (SQEP) records were available from the RP's and Service Providers' to demonstrate that personnel were assessed as competent for their roles (Refs 19, 21 and 23). These were also available for BAT and ALARP training for Safety Case authors and technical reviewers.
76. BAT and ALARP methodologies were being developed at the time of the inspections (Ref. 21).

#### **4.6.2 Items that Require Follow-up**

77. During my GDA Step 2 assessment of "Safety Case Management" I have identified the following potential shortfalls that I will follow-up during Step 3 of GDA:
  - The coordination for the updating of the PCSR/ PCER submission appeared to be out of sync, where the update of the said documents appeared to be done before they have received the latest technical review (Ref. 23). This misalignment in coordination may mean that the required submissions will not include the information from the reviews, thus negatively impacting the robustness of the Safety Case content.
  - It was unclear as to whether or not any additional supporting references will be required to be reviewed by EDF. Currently EDF's remit does not appear to extend to reviewing such additional supporting documents. It is expected that the supporting references (current or additional) will contain relevant technical information used to substantiate the SSER submissions (Ref. 23).
  - The RP's ALARP/BAT methodology documents had not been issued at the time of the inspections and I was informed that any identified design changes will be worked up but not implemented (i.e. formally change-controlled into the design) until the new ALARP/BAT methodology is fully implemented, and until a suitable change control methodology is available to retrospectively assess the proposed changes (Refs 19 and 21). I will assess the effectiveness of this approach during Step 3. ALARP is identified as a Cross-Cutting matter and further information is presented in the Summary of the Step 2 Assessment of the UK HPR1000 Reactor (Ref. 24).
  - Although my MSQA assessment included a high level sampling of written arrangements for delivering the PCSR, it did not include a detailed assessment of the effectiveness of the RP's arrangements for developing the safety case in order to ensure that the final PCSR at the end of GDA will be complete, cogent, coherent and consistent. This work is undertaken by the PTI as part of the Cross-Cutting topic area and reported on in the Summary of the Step 2 Assessment of the UK HPR1000 Reactor (Ref. 24). It should be noted that the PTI has identified potential shortfalls with the RP's approach to safety case development and at the time of writing this report was preparing to issue an RO. I will continue to coordinate my assessment with the PTI to ensure consistency.

### 4.6.3 Conclusions

78. Overall, I conclude that the sampled arrangements for safety case management satisfy fundamental requirements for this stage of the project. Each organisation has defined, key roles where GNS produced the specification for the safety case, CGN produced the safety case in accordance to the specification with EDF performing as the technical reviewer of CGN's output. Learning from the production of earlier safety documentation, was incorporated into to the current Safety Case management arrangements. Production managers were also assigned to coordinate the development of the safety cases via topic/ chapter. However, the follow up areas highlighted under this topic area will undergo further review in Step 3 of GDA.

## 4.7 Learning Organisation

### 4.7.1 Assessment

79. GNS's approach to GDA placed significant emphasis on obtaining 'learning from experience' from CGN and EDF, and more widely from other GDA projects. Some of this learning has been captured in a draft GNS Improvement Plan. Audits and Quality Management document reviews are specified within the GNS management system (Ref. 19).
80. CGN appears to have several characteristics of a learning organisation that have been displayed throughout such as management support to create a learning organisation as evidenced by their policies that encourage a 'questioning attitude', established processes in place for identifying and addressing short falls and Safety Culture performance metrics based upon IAEA guidance (Ref. 21).
81. EDF appeared to have adequate arrangements in place to manage continual improvement of the GDA process. It conducted a 'lessons learnt' review of their GDA arrangements for the EPR design, incorporating them into the UK HPR1000 GDA project. The improvements addressed both technical and project related topics (ref. 23).

### 4.7.2 Strength

82. As evidenced from the assessments, all three organisations appeared to have robust arrangements for learning from experience / continual improvement and were actively engaged in implementing their improvement activities.

### 4.7.3 Items that Require Follow-up

83. During my GDA Step 2 assessment of "Learning Organisation" I have not identified any specific or potential shortfalls. However, during Step 3 I will be identifying whether the RP or its Service Providers have identified and acted upon any learning from Step 2.

### 4.7.4 Conclusions

84. I consider that RP and its Service Providers have the fundamental elements in place to demonstrate that they are a learning organisation and are seeking to improve their current arrangements where necessary.

#### **4.8 Out of Scope Items**

85. The following items have been left outside the scope of my GDA Step 2 assessment of the UK HPR1000 Management for Safety and Quality Assurance.
- Design Authority. The reason for leaving this matter out of the scope of my GDA Step 2 assessment is that this is a function of an approved licensee and is not applicable to the RP through the GDA project
86. It should be noted that the above omissions do not invalidate the conclusions from my GDA Step 2 assessment.

#### **4.9 Comparison with Standards, Guidance and Relevant Good Practice**

87. In Section 2.2, above, I have listed the standards and criteria I have used during my GDA Step 2 assessment of the UK UKHPR1000 MSQA, to judge the adequacy of the preliminary safety case. In this regard, my overall conclusions can be summarised as follows:
- SAPs: the expectations of SAP FP.2 - Leadership and Management for Safety and SAP FP.4 – Safety Assessment, have been fulfilled. Table 1 provides further details.
  - The fundamental expectation for management systems on ONR's TAGs (Ref. 5) and TIGs (Ref. 6) have been fulfilled by the RP's GDA management arrangements.
  - For this stage of the GDA project, the MSQA arrangements for the UK HPR1000 were also assessed against international QMS standards (Ref. 7 and 9) and were found to broadly fulfil those requirements.

#### **4.10 Interactions with Other Regulators**

88. The MSQA assessment and inspection was carried out jointly by ONR and EA. All assessment and inspection activities were planned, carried out and reported jointly. This included the joint MSQA implementation inspection carried out at the RP's Offices in the UK and at the Service Providers' offices in China and France.

## 5 CONCLUSIONS AND RECOMMENDATIONS

### 5.1 Conclusions

89. During Step 2 of GDA, the RP submitted a PSR and other supporting references, which outline a preliminary nuclear safety case for the UK HPR1000. These documents have been formally assessed by ONR. The PSR together with its supporting references present at a high level the claims in the area of Management for Safety and Quality Assurance that underpin the safety of the UK HPR1000.
90. During Step 2 of GDA I have targeted my assessment at the content of the PSR and its references that is of most relevance to the area of 'Management for Safety and Quality Assurance' against the expectations of ONR's SAPs and TAGs and other guidance which ONR regards as Relevant Good Practice. From the UK HPR1000 assessment done so far, I conclude the following:

- The RP and its supporting Service Providers have developed and implemented fundamental management arrangements to control the development and production of the SSERs for the GDA of the UK HPR100. These included:
  - Project arrangements that allow each entity to perform their identified responsibilities.
  - Regular project interfacing between all three entities used for overall project co-ordination.
  - Escalation routes available at all three parties for the resolution of technical concerns.
  - The reinforcing and building of the GDA competency within the Service Providers by using in-house staff that had prior GDA experience and /or were gaining the understanding to satisfy GDA requirements via training and GDA specialist support.
  - The development of a 'Common Working Platform' between the RP and Service Providers to aid organisational cooperation.
  - A strong culture with respect to Safety and Learning from Experience.

I believe that these current arrangements broadly satisfy regulatory expectations for this stage of the GDA project.

- The following matters will be followed up during Step 3: Technical Decision Making Process; Management of Resolution Plans, the Master Document Submission Lists (MSDL) and the Document List; Resource Planning and Technical Competency implementation; Design Change control, Configuration Management and Design Training deliverables; Work Planning coordination and the application of approved BAT and ALARP methodologies.
  - My understanding of the technology and management arrangements is high level at the moment and is commensurate with the level of detail required for Step 2, but it will be developed as GDA progresses.
  - I consider that the adequacy of the management arrangements GDA project for UK HPR1000 is likely to be more developed later in GDA.
91. Overall, during my GDA Step 2 assessment, I have not identified any fundamental safety shortfalls in the area of MSQA that might prevent the issue of a Design Acceptance Confirmation (DAC) for the UK HPR1000 design.



## 5.2 Recommendations

92. My recommendations are as follows.

- Recommendation 1: ONR should consider the findings of my assessment in deciding whether to proceed to Step 3 of GDA for the UK HPR1000.
- Recommendation 2: All the items identified in Step 2 as important to be followed up should be included in ONR's GDA Step 3 MSQA Assessment Plan for the UK HPR1000.

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**Table 1**

Relevant Safety Assessment Principles Considered During the Assessment

SAP No and Title	Description	Interpretation	Comment
<b>FP.2 – Leadership and Management for Safety</b>	Effective leadership and management for safety must be established and sustained in organisations concerned with, and facilities and activities that give rise to, radiation risk.	<p>This principle sets the foundation for the effective delivery of Safety which includes nuclear, environmental, conventional and security aspects.</p> <p>The delivery of this principle will address key element such as Leadership, the establishment of a capable organisation, decision making and learning as defined by the SAPs, underpinned by a management system that gives due regard to Safety and which is supported by a positive Safety culture.</p>	Addressed in Section 4 of this report.
<b>FP.4 – Safety Assessment</b>	Duty holders must demonstrate effective understanding and control of the hazards posed by a site or facility through a comprehensive and systematic process for safety assessment.	The principle takes into account the process used for producing safety cases ‘right first time’. The safety cases process needs to deliver consistently good quality fit for purpose cases. The process may include initial optioneering, writing the case and any means of verification/review.	Addressed in Section 4 of this report.