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## 20.1 List of Abbreviations and Acronyms

ALARP	As Low As Reasonably Practicable
BAT	Best Available Technique
CGN	China General Nuclear Power Corporation
CNPEC	China Nuclear Power Engineering Co., Ltd
CNI	China Nuclear Power Technology Research Institute
CNOC	China Nuclear Power Operations Co., Ltd
CTO	Chief Technical Officer
DAC	Design Acceptance Confirmation
DTS	Data Transformation Services
EA	Environment Agency
EDF	Électricité de France
EDF S. A.	Électricité de France S. A.
FCG3	Fangchenggang Nuclear Power Plant Unit3
FOI	Freedom of Information
GDA	Generic Design Assessment
GNI	General Nuclear International
GNS	General Nuclear System Limited
GSR	Generic Security Report
IAEA	International Atomic Energy Agency
I&C	Instrumentation and Control
IPR	Intellectual Property Rights
IT	Information Technique
KPIs	Key Performance Indicators
MSQA	Management of Safety and Quality Assurance
ONR	Office for Nuclear Regulation(UK)
PCER	Pre-Construction Environmental Report

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PCSR	Pre-Construction Safety Report
P&ID	Process and Information Document for Generic Assessment of Candidate Nuclear Power Plant Designs
PSR	Preliminary Safety Report
PWR	Pressurised Water Reactor
QA	Quality Assurance
RGP	Relevant Good Practice
RI	Regulatory Issue
RO	Regulatory Observation
RQ	Regulatory Query
RP	Requesting Party
SHA	Shareholder Agreement
SoDA	Statement of Design Acceptability
SNPI	Suzhou Nuclear Power Research Institute
SQEP	Suitably Qualified and Experienced Person
SSER	Safety, Security and Environmental Report
TCN	Technical Change Notice
TQ	Technical Query
UK HPR1000	UK Version of the Hua-long Pressurised Reactor

## 20.2 Introduction

This chapter describes the Management of Safety and Quality Assurance (MSQA) and safety case management arrangements that have been put in place for the delivery of the UK Version of Hua-long Pressurised Reactor (UK HPR1000) Generic Design Assessment (GDA) project. This chapter aims to demonstrate that the management system and safety case management implemented for the UK HPR1000 GDA submission and design production are appropriate and will meet UK regulatory expectations.

Following International Atomic Energy Agency (IAEA) General Safety Requirements Part 2 *Leadership and Management for Safety*, Reference[1], UK HPR1000 GDA project management systems has been established with the aim to be effective in its arrangements to ensure safety requirements and other requirements (for instance, quality, environment, and security.) are managed in an integrated manner and a strong

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safety culture is fostered in the project including the supporting organisations. Hence, “safety” in the MSQA context refers to nuclear safety, conventional safety, environment and security. GDA documentation is produced to cover these aspects and when requirements are specific to one aspect, this will be explicitly stated in the chapter (e.g. Pre-Construction Safety Report (PCSR) covers nuclear and conventional safety, Pre-Construction Environmental Report (PCER) covers environment impact, Generic Security Report (GSR) covers security).

The ***Fundamental Objective*** of the UK HPR1000 is that: *The Generic UK HPR1000 could be constructed, operated, and decommissioned in the UK on a site bounded by the generic site envelope in a way that is safe, secure and that protects people and the environment.*

To underpin this objective, five high level claims (Level 1 claims) and a number of Level 2 claims are developed and presented in Chapter 1. This chapter supports the ***Claim 2.2*** derived from the high level ***Claim 2***.

***Claim 2: The UK HPR1000 design will be developed in an evolutionary manner, using robust design processes, building on relevant good international practice, to achieve a strong safety and environmental performance.***

***Claim 2.2: Suitable organisational arrangements are in place for the development & substantiation of the UK HPR1000.***

### **20.2.1 Chapter Structure**

This Chapter is structured as follows:

- a) Sub-chapter 20.1 List of Abbreviations and Acronyms:

This section lists abbreviations and acronyms that are used in PCSR Chapter 20.

- b) Sub-chapter 20.2 Introduction

This section gives the brief introduction of the PCSR Chapter 20, including chapter structure introduction and the Chapter 20 interface description with other chapters.

- c) Sub-chapter 20.3 Applicable Codes and Standards

This section lists the codes and standards applied in MSQA area.

- d) Sub-chapter 20.4 MSQA

This section presents that the RPs’ MSQA and project management arrangements have been effectively established and will be efficiently implemented. This includes leadership, organisational capability, decision making, learning, safety culture, business management and resource management.

- e) Sub-chapter 20.5 Safety Case and Design Control Management

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This section describes safety case and design control management arrangements for the UK HPR1000 GDA project. The section describes how the RP carries out arrangements to achieve a high level of safety. This includes safety case management, ALARP and BAT arrangements, and design control.

f) Sub-chapter 20.6 Concluding Remarks

This section provides a summary of the main aspects of this chapter.

g) Sub-chapter 20.7 References

This section lists the supporting documents referred within this Chapter.

### 20.2.2 Interfaces with other Chapters

The organisational arrangements and quality assurance (QA) arrangements set out in this chapter are implemented in the production of GDA Submission and in design process. Consequently, this chapter is related with all other PCSR, PCER and GSR chapters. The interfaces with other PCSR chapters are listed in the following table.

T-20.2-1 Interfaces Between Chapter 20 and Other Chapters

<b>PCSR Chapter</b>	<b>Interface</b>
Chapter 1~Chapter 33	The organisational arrangements and quality assurance arrangements set out in Chapter 20 are implemented in the design process and production of all PCSR.
Chapter 1 Introduction	Chapter 20 provides information and evidences to support the Level 2 Claim 2.2 presented in Chapter 1.
Chapter 4 General Safety and Design Principles	Chapter 20 presents codes and standards applied in MSQA which is based on the selection principles of codes and standards in Chapter 4.

### 20.3 Applicable Codes and Standards

The applicable codes and standards of the principles presented in Chapter 20 are selected and determined based on the requirements presented in Chapter 4 Section 4.4.7 and the selection principles and the process presented in *General Principles for Application of Laws, Regulations, Codes and Standards*, Reference [2]. UK context specific expectations and Relevant Good Practice (RGP) have been taken into account in the codes and standards selection process.

The IAEA General Safety Requirements Part 2, Reference [1], ISO 9001, Reference [3], OHSAS 18001, Reference [4], and ISO 14001, Reference [5] are widely recognised as RGP. These standards are accepted in the nuclear industry and were applied in the reference plant Fangchenggang Nuclear Power Plant Unit 3 (FCG3).

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Therefore, the fact that these codes and standards are applied in UK HPR1000 GDA project MSQA arrangements is deemed appropriate.

The IAEA General Safety Requirements Part 2 is applied in management system establishment and implementation. Meanwhile the requirements of ISO 9001, OHSAS 18001 and ISO 14001, are also adopted in the management system establishment and implementation. The configuration management arrangements follow the requirements in IAEA TECDOC 1335, Reference [6]. Applicable codes and standards in the MSQA area are listed in T-20.3-1.

#### T-20.3-1 Applicable Codes and Standards for Chapter 20

<b>Codes and Standards</b>	<b>Title</b>	<b>Issued date</b>
IAEA General Safety Requirements Part 2	Leadership and Management for Safety	2016
ISO 9001	Quality Management System-Requirement	2015
OHSAS 18001	Occupational Health and Safety Management System	2007
ISO 14001	Environmental Management System Requirement	2015
IAEA TECDOC 1335	Configuration Management in Nuclear Facilities	2003

## **20.4 MSQA**

### **20.4.1 Requesting Party Organisational Arrangements**

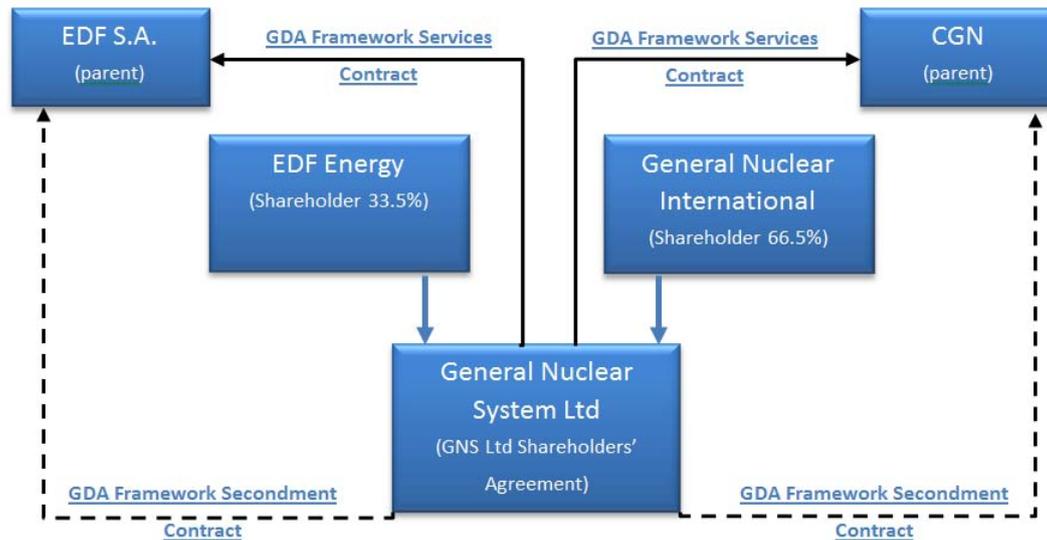
The Requesting Party (RP), for the purposes of the GDA process in respect of UK HPR1000, is constituted jointly by China General Nuclear Power Corporation (CGN), Électricité de France S. A. (EDF S. A.) and General Nuclear International Limited (GNI). GNI is a UK registered subsidiary of CGN which is currently owned by CGN.

GNS is appointed by the above shareholders to act on behalf of the RPs. The GNS Shareholder Agreement (SHA) sets out the full specification of the governance arrangements and decision making processes for GDA. Notably, GNS is authorised to manage and make key decisions for the purpose of GDA irrespective of the makeup of the shareholdings in GNI. Such arrangements provide safeguards against future changes in ownership structure.

In the SHA, technical support and resource are guaranteed by the parent organisations CGN and EDF S. A.. The specific types of service are defined in the framework agreements between GNS-CGN and GNS-EDF. The services are paid for by GNS under the framework agreements and delivered against an integrated work plan which is owned and managed by GNS. As such, GNS is the GDA delivery and project

management organisation supported by two parent organisations with design, construction, and operational experience.

The makeup of the shareholding and arrangements is shown in F-20.4-1 .



F-20.4-1 UK HPR1000 GDA RP Organisation Structure (shareholders)

GNS is supported by two key agreements: (1) a Secondment Agreement whereby staffs from CGN and EDF are seconded into GNS to deliver GDA, and (2) a Framework Service Agreement where CGN and EDF are also the supporting organisations.

The governance arrangement, roles and responsibilities of the organisations involved in the GDA project are mandated in the GNS SHA and explained further in the *Project Definition Document*, Reference [7], and in the *GNS Quality Management Manual*, Reference [8]. GNS is supported by CGN and EDF, and the roles of CGN and EDF are as follows:

- a) CGN as the ‘designer’ is responsible for undertaking technical aspects of the design and adaptation of the Hua-long technology into the UK HPR1000 whilst considering UK context;
- b) EDF provides technical expertise to support the UK HPR1000 project. This includes reviewing technical documentation, providing operating plant experience in France and the UK, as well as the knowledge of international good practice applied to existing nuclear fleet, past GDA experience (i.e. UK EPR) and current experience on its new build project;
- c) Production of GDA submissions are primarily performed by CGN with support from EDF. In instances where the UK context is particularly relevant, wider collaborative effort will be required;
- d) Where appropriate, GNS will be supported by third party contract partners, based

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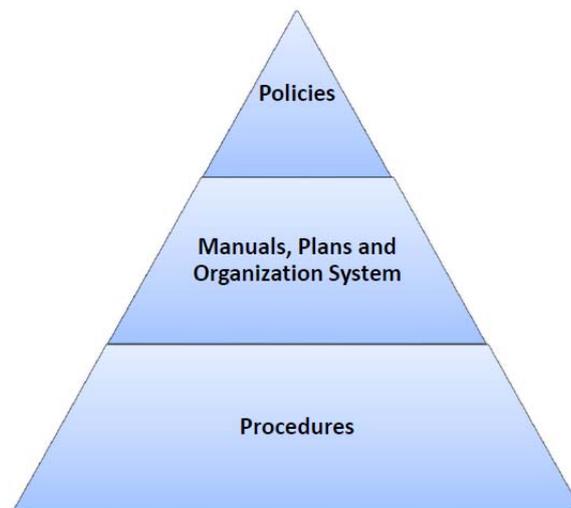
on their technical competencies relevant to the project.

## 20.4.2 GNS' MSQA

### 20.4.2.1 Classification of the Management System Documents

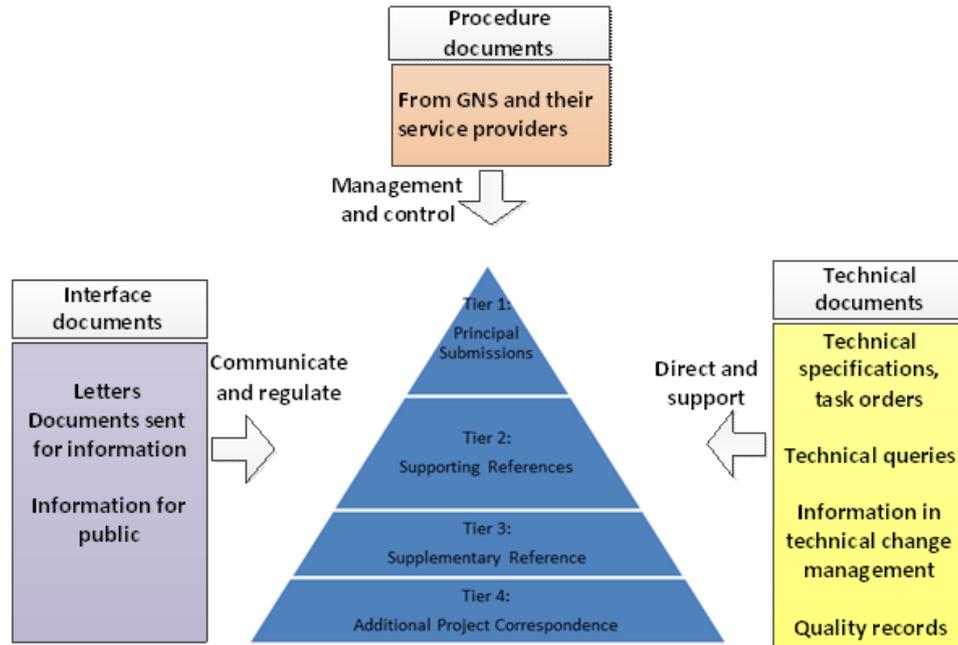
The management system is designed to ensure GNS's capability to control quality, content and accuracy of delivered output for GDA. The aim is to provide confidence that all outputs consistently meets regulatory requirements and that the management system helps improve performance. The MSQA arrangements of GNS are compliant with the principles of IAEA General Safety Requirements Part 2 and ISO9001, Reference [1] and [3]. The management system applies to activities carried out by GNS. All the management system documents are classified as shown in F-20.4-2. Hierarchy of GNS management system documentation is divided into the following three levels:

- a) Level 1 consists of GNS' Policies, the key policies are described in section 20.4.2.2;
- b) Level 2 consists of manuals, management system plan and organisational arrangements to support policies;
- c) Level 3 consists of specific work procedures which are used for guiding the process and detailing requirements to support management system.



F-20.4-2 Hierarchy of Documents in the Quality Management System

All official documents shall be produced under the document control system. This control entails their preparation, review, verification, approval, issuing, distribution, modifications, updating, superseding, withdrawal, cancelling, and archiving. The scope of document control and the relationship of documents are showed as shown in F-20.4-3.



F-20.4-3 GDA Document Hierarchy

The GDA submissions are divided into four tiers. They are respectively principal submissions, supporting references, supplementary references and additional project correspondence. The detailed definition and scope of the Master Document Submission List and Document List have been identified in procedure, reference [9]. The Master Document Submission List is the totality of the GDA submission at tier 1-3. Document list is the totality of the information submitted to the Regulators during GDA, including information sent for information purposes only and responses to Regulatory Query (RQ), Regulatory Observation (RO) and Regulatory Issue (RI).

#### 20.4.2.2 Culture, Policies and Principles

GNS has developed a set of principles and standards under which it shall operate. This is to ensure the purpose and context of the organisation is set out and provides a framework for setting safety objectives. The key policies are described as follows:

- a) The GNS document *Nuclear Safety Culture*, Reference [10], sets out expectations of the leadership team and to all employees to exercise conservative decision making in day to day operations of GNS and to be a learning organisation;
- b) The GNS Quality Policy sets out expectations on prioritising safety in the drive for excellence and aspiring to achieve zero harm to people and environment;
- c) The GNS Health, Safety & Environmental Policy sets out the standards and expectations for employees and contractors alike, to work safely and adhere to the safety and environment regulations and work procedures;
- d) The GNS Sustainability Business Policy sets out the company ambitions in being

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a sustainable business;

- e) The GNS Business Continuity Management Policy sets out the business continuity management arrangements to protect the interest of its stakeholders and staff;
- f) The GNS Security Policy describes the arrangements for security to meet legislative and regulatory security requirements and all key security related stakeholders. This includes having the appropriate security arrangements, processes and contingencies in place to effectively and economically mitigate the risks associated from identified security threats.

#### 20.4.2.3 Leadership and Management for Safety

##### 20.4.2.3.1 Leadership

The GNS Executive Committee is accountable to the GNS Board for the performance of the GDA project. The GNS Executive Committee will demonstrate leadership for safety and a commitment to safety by adopting the following:

- a) establishing policies and goals for safety ;
- b) providing direction and governance on safety culture, giving a visible commitment to safety and encouraging safe behaviour;
- c) providing adequate resources for safety activities;
- d) making an conservative decision when facing conflict between safety and other goals (e.g. conflict between safety and production or commercial pressures);
- e) reviewing safety performance and culture on a regular basis.

The implementation and performance of these activities will be overseen by the GNS Board. Details of the arrangements are further described in the GNS *Quality Management Manual*, Reference [8].

##### 20.4.2.3.2 Organisational Capability

GNS is formed from CGN and EDF, two competent, international utility companies with a strong nuclear safety culture and capability.

For the GDA project, GNS has competence arrangements in place to ensure that all personnel, including third-party contracting partners, are suitably qualified and experienced to carry out their roles in the GDA project. For all GDA submissions, these arrangements are to ensure the personnel developing, reviewing, verifying and approving have the appropriate technical competence and experience commensurate with the responsibility.

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#### 20.4.2.3.3 Decision Making

Decision making is undertaken in a manner to prioritise safety over other business goals, with the chief advocate being the GNS Chief Technical Officer (CTO). Active challenge is part of the decision making process, with a questioning attitude cultivated and promoted amongst the team. Where significant decisions are being made, one of the team is specifically requested to be the ‘voice of challenge’, to initiate and encourage a challenge. This does not prevent others from making a challenge, it is intended to ensure that a challenge is raised, heard, and suitably respected.

The GNS Executive Committee is responsible for the day to day management of GNS’ GDA activities. For technical matters, GNS has established a Technical Committee that operates under the GNS procedure *Technical Committee Operation Guidance*, Reference [11] which, sets out the protocols, interfaces and escalation routes for technical decision making. GNS, CGN or EDF representatives can propose topics at the Technical Committee meetings. The GNS Technical Committee will make decisions on safety significant related issues. For less significant aspects, the Technical Committee recommendations will be provided by the Technical Committee members.

Decisions made are recorded, endorsed, and cascaded appropriately through the organisation.

#### 20.4.2.3.4 Learning

Throughout the GDA process, there are appropriate arrangements in place to apply learning from CGN's experience in the construction and operation of the predecessor reactor designs as well as the reference plant FCG3. Learning will also be drawn from EDF’s existing nuclear fleet in UK and France, its past GDA project as well as the current new build project. External sources such as previous GDA projects will also be considered where this is relevant and appropriate to the UK HPR1000 project.

In summary, there are a number of sources of learning being considered:

- a) Feedback from the design, construction and operation of Pressurised Water Reactor (PWR) in China, including the reference plant FCG3;
- b) Experience from new build and operating nuclear power plants worldwide, including operating experience from the EDF UK and France fleet and experience from the current Hinkley Point C new build project;
- c) Experience from other GDA projects (e.g. UK AP1000, UK ABWR, UK EPR).

A method for documenting organisational learning within GNS has been developed, and lessons learned are shared through both face-to-face and written briefings. Issues arising will be routinely monitored by the Executive Committee, and, where appropriate, training is provided to address the identified requirements.

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#### 20.4.2.3.5 Audits and Self-Assessments

Initial arrangements are in place to improve the effectiveness and efficiency of operations in GNS. The overall aim is to identify and fix performance gaps in the organisation, behaviour, processes as well as finding improved ways of working.

Performance monitoring and management reviews are carried out to continually improve performance. These include Key Performance Indicators (KPIs) set by the GNS Executive Committee, which through accountability reporting from the respective discipline areas provide a measure of performance and identification of areas for improvement or requiring further attention.

Using the corporation quality assurance (QA) audit process, Reference [12], quality management audits are carried out to assess in a systematic manner, whether key activities have been carried out to the required performance standards. Audits will be carried out regularly and at least before the end of each GDA step. In addition, *Self-Assessments Procedure*, Reference [13], are also carried out regularly to review the adequacy of the processes in place to ensure they remain fit for purpose and are being consistently applied. Similar to audits, where areas for improvement are identified, improvement actions will be raised and tracked through completion. These form the basis of the project's continuous improvement plan.

Independent assessments are to be carried out based on a risk-informed approach, taking into consideration the adequacy of GDA submissions in terms of quality, technical content or effectiveness of the management processes applied. The output from the independent assessments will be evaluated with necessary actions put in place to implement improvements identified.

Collectively, these activities help GNS prepare for its readiness review at each GDA Step Entry with the UK regulators.

### **20.4.3 Supporting Organisations' MSQA**

#### 20.4.3.1 CGN's MSQA

##### 20.4.3.1.1 Organisation

CGN is the main party undertaking the technical work of UK HPR1000 GDA Project. China Nuclear Power Engineering Co., Ltd (CNPEC) is the leading member of several CGN's subsidiaries involved in the GDA project. CNPEC is a leading nuclear power plant system integrator and nuclear power technology provider in China, capable of efficient resources allocation, competent project organisation and management, continuous scientific and technological innovation. CNPEC is responsible for:

- a) Undertaking technical aspects of the design and adaptation of the Hua-long technology into the UK HPR1000;

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- b) Preparation of comprehensive reports to be submitted to Office for Nuclear Regulation (ONR) and Environment Agency (EA) for assessment and relevant supporting documents;
- c) Answering the regulatory questions including RQ, RO and RI; and
- d) Design of improvements to be implemented for UK HPR1000.

CNPEC has established the GDA Project Department to manage, guide and implement the quality assurance program, Reference [14], and to ensure smooth progress of various tasks related to GDA. The GDA Project Department is supported by CNPEC's business centres include Design Institute, Equipment Procurement and Supply Division, Construction Management Division and Start-up & Commissioning Division. In addition, functional departments in CNPEC such as Planning and Business Department, Project Management Department, Safety Management and Quality Assurance Department also provide supports to GDA Project Department. The detailed organisation and operation rules can be found in Reference [15].

CNPEC is supported by other CGN's subsidiaries through subcontracts. China Nuclear Power Operations Co., Ltd (CNOC) is responsible for providing operation data (e.g. source item and radioactive waste emission) and other operation experience feedback. Suzhou Nuclear Power Research Institute (SNPI) is responsible for providing support for environmental impact assessments. China Nuclear Power Technology Research Institute (CNI) the reactor core and fuel designer is responsible for providing comprehensive thermal-hydraulic and safety test facilities. China Techenergy Co., Ltd (CTEC) is responsible for the work related to the Instrumentation and Control (I&C) platform. CNPEC and the above mentioned subsidiaries have management system accredited by ISO9001 and in line with IAEA General Safety Requirements Part 2.

#### 20.4.3.1.2 Management System Document

CGN's GDA project management system has been established according to the duty of CGN in the UK HPR1000 GDA project. The hierarchy of management system documents is divided into the following three levels:

- a) Level 1: documents of GDA project overall arrangement, project planning documents, quality assurance program, project technical and organisational measures, which describe the project policies, overall plan, general principles of management system and general technical arrangements;
- b) Level 2: management procedures applicable to GDA project;
- c) Level 3: specific working procedures, rules, work plan, technical instructions applicable to GDA specific activities;

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#### 20.4.3.1.3 Safety Culture

CGN GDA project promotes and strengthens the safety culture of the organisation by the following means:

- a) Release policy statements, publish the safety culture manuals and perform the publicity to ensure all personnel have a comprehensive understanding and consensus of safety;
- b) Provide necessary methods and sufficient resources to promote and support a strong safety culture;
- c) Establish an organisational culture of transparency, cooperation and communication. Provide the necessary incentive mechanisms and support to encourage all personnel to cultivate the attitude of questioning and reporting problems and risks related to safety in a timely manner and come up with improvement suggestions;
- d) React to any defects influencing safety, and take actions in a timely manner;
- e) Continuously promote the positive safety culture by periodic training and education for personnel, performing special activities to improve procedure quality and human behaviours, periodically implementing and organising the monitoring and evaluation and improvement of safety culture level.

#### 20.4.3.1.4 Decision Making

CNPEC GDA project decision making procedure, Reference [16], describes the principles, process and requirements of decision making. The decision making escalating principle is defined in this procedure.

The decision making process ensures that relevant personnel are fully authorised to make decisions in a timely manner, that relevant information and opinions (including divergences) are fully collected and considered, that the decision making process adopts the methods giving priority to safety, and that safety decision making will not be delayed or influenced by schedule/cost or any other factors.

Safety is prioritised in the decision making process and the following factors are considered for decision making influencing safety:

- a) Adequacy and quality of intelligence and information;
- b) Importance of uncertainties;
- c) Questions related to assumptions and detection of all relevant content compromising safety;
- d) Minimise the short-term and long-term risks;
- e) As Low As Reasonably Practicable (ALARP) and Best Available Technique

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(BAT);

- f) Laws, regulations, standards and technical requirements.

#### 20.4.3.1.5 Personnel Allocation and Training

The CNPEC procedure, Reference [17], describes the process for qualifying personnel and task assignment for nuclear power plant project. The qualification management mainly comprises of the following steps, such as training, assessment, authorisation and task assignment (job taking). The authorisation considers academic background, experience and professional proficiency. These activities ensure that all levels personnel are suitably trained, qualified and experienced persons (SQEP), understand and are familiar with the work basis, can achieve and maintain professional ability and nuclear safety awareness to carry out tasks that may affect the safety.

Based on reference [17], CNPEC supplemented GDA project personnel qualification management procedure, Reference [18], to achieve SQEP. CNPEC analysed the role of GDA tasks, identified the associated competencies that personnel should have, established training plan and carried out training, and evaluated personnel capability and authorised. These activities ensure all personnel engaged in GDA are received necessary and targeted UK context training, such as ALARP/ BAT training.

#### 20.4.3.1.6 Knowledge Management and Experience Feedback

- a) Knowledge Management

CGN's knowledge management covers nuclear power plant development and research, siting, construction, commissioning, operation and decommissioning. CGN puts emphasis on knowledge acquirement, sharing and application, and continues to accumulate and inherit knowledge.

The personnel participating in GDA have the necessary knowledge for the smooth operation of safety related processes. Such knowledge includes:

- 1) Internal knowledge: company's procedures and business processes, scientific and technological achievements, Intellectual Property Rights (IPR), training materials, experience summary and feedback and improvement of process/products and services;
- 2) External knowledge: laws, codes, regulations, standards, scientific and technical literature, academic documents, external communications and collected information and intelligence.

- b) Experience Feedback

CGN has established an experience feedback and improvement mechanism to summarise experience and prevent recurrence of non-conformances, continuously improving the quality management.

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#### 20.4.3.1.7 Document and Record Control

CNPEC identifies and controls documents and records required for GDA, according to GNS's procedure, Reference [9]. CNPEC's procedures for document control have been formulated and implemented, including coding, preparation, checking, approval, issuing, distribution and modification. CNPEC implements record procedures for records management, including the preparation, collection, marking, indexing, lookup, storage, custody, storage life, archiving and handling of records related to the GDA project.

#### 20.4.3.1.8 Design Control and Configuration Management

The existing CNPEC design control procedure, Reference [19], describes the control of the design process (e.g. design planning, design inputs, design analysis, design interfaces, design review, design verification, design outputs and design changes) so as to ensure that the design is in full compliance with all relevant principles, codes and standards and that the required design quality is realised. CNPEC has a well-developed design management Information Technique (IT) platform to manage the design process. Design process activities and quality control activities are always documented ensuring traceable auditable records. Such records include design documents (e.g. calculations, specifications, reports, etc.), design planning documents (e.g. Project Planning Report, Technical and Organisational Measures etc.), design analysis documents, design input sheet, design review and design verification records.

To ensure design consistency and control design change, GDA project uses a configuration management approach to carry out design change control. The configuration management procedure identifies requirements of the configuration baseline, configuration change and configuration identification. CNPEC GDA project configuration management procedures, Reference [20], Reference [21], are in compliance with IAEA configuration management standards TECDOC 1335, Reference [6]. Configuration change management for any design change is administered through Reference [21]. This procedure describes the process and requirements for the initiation, handling and closure of a design change and specifies the responsibilities and authorities of relevant personnel through the Technical Change Notice (TCN) process.

#### 20.4.3.1.9 Procurement Control

The CNPEC procedure, reference [22], stipulates management and control of the subcontracting process in CGN GDA project. The suppliers are evaluated and selected on the basis of their ability in provision of items or services as per requirements of the purchasing documents. Purchasing documents include contracts, agreements and other forms which specify the detailed requirements, such as quality requirements of design services, completion time, applicable regulations and standards, design basis, technical specification and SQEP requirements. CNPEC carries out various

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purchasing process controls measures based on its safety importance and complexity. The final acceptance must be carried out to ensure the quality of products/services are compliant with requirements of the purchasing document.

#### 20.4.3.1.10 Evaluation and Improvement

To ensure effectiveness and efficiency of the CGN GDA project management system, CNPEC periodically perform audits and surveillance on all the departments participating in GDA project work. The quality department is responsible for selecting the auditor and composing audit team. CNPEC carries out management reviews at least once a year to ensure the management system remains suitable, adequate and effective. The results of GDA quality assurance program implementation are assessed during the management review to continually improve project management systems.

CNPEC will also support the audit conducted by GNS on the work that CGN carried out for them. CNPEC accepts the inspection carried out by the regulator and seeks opportunity to implement continuous improvement.

#### 20.4.3.2 EDF's MSQA

##### 20.4.3.2.1 Organisation

According to SHA, EDF provides technical expertise to support the UK HPR1000 GDA project through the Framework Service Contract with GNS. The Framework Service Contract provides arrangements and scope for provision of services. Contribution to the main GDA submissions, particularly regarding UK context, will form the main part of EDF's role. Provision of services are requested by GNS through Work Orders which provide all relevant information required to undertake works by main work streams as technical review of GDA submissions, support to regulatory correspondence, review of technical documents or call off technical support. Where specific technical tasks are required, task sheets supplement the Work Order providing more detailed specification and guidance. As such, EDF have produced a Quality Management Plan, Reference [23], for GDA project which details the management system and QA arrangements that have been put in place to support GNS. For the production of the Safety, Security and Environmental Report (SSER), EDF has detailed arrangements and approach to manage their delivery of technical work, and which will be demonstrably acceptable to GNS.

Quality assurance of the work delivered by EDF on behalf of GNS is governed by an EDF Group organisation set up specifically for the UK HPR1000 GDA project. This is headed by an EDF Coordination Manager who is accountable for the delivery of work to time, cost and quality. As the EDF Group is comprised of EDF S. A., EDF Energy, Nuclear New Build and other EDF affiliates and entities, the entities shall apply their own QA arrangements that are considered to be acceptable to GNS and appropriate for the UK HPR1000 GDA. The size and structure of the EDF Group organisation shall adapt to the demands of the GDA project.

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The information of these Affiliates and Entities is below:

- a) EDF S. A. has extensive technical expertise in GDA expertise through successful completion of the GDA process for the UK EPR Technology. The wide range of competencies within the EDF Group provides expertise on any design and licensing issues throughout the whole GDA project. This is achieved by involvement of expertise and resources EDF Group engineering centres and entities belonging to;
- b) EDF China Holding is an EDF S. A. affiliate based in China which brings to the project its unique understanding of both French and Chinese context. It also has the ability to mobilise technical resources with considerable experience in design and licensing on certain specific areas;
- c) EDF Energy Nuclear Generation has extensive knowledge of UK context and of licensing aspects thanks to their large experience in safely running a fleet of nuclear power plants in UK;
- d) Nuclear New Build has experience in nuclear new build and site development issues thanks to the current construction and licensing (HPC) and site development (SZC) business in UK;
- e) EDF Energy has longstanding UK experience in corporate support (IT, legal).

#### 20.4.3.2.2 Quality Management System

Supporting the GDA processes as a service provider to GNS, the EDF Group performs its duties according to the GNS technical specifications which are supplemented by internal arrangements. EDF management system documentation for the project is composed of four level of documentation:

- a) Level 0: GNS quality management manual, process and procedures. These provide the description of the client's quality management plan, the description on how the project is delivered and how GNS interfaces with regulator, shareholders and service providers;
- b) Level 1: EDF Group Quality Management Plan, Reference [23], and organisation documents. These are applicable to the overall EDF affiliate and entity for this project. Quality Management Systems of each EDF affiliate and entity are applicable individually to each entity and affiliate;
- c) Level 2: EDF Group project manuals and associated processes and procedures. These are applicable to the overall EDF affiliate and entity for this Project;
- d) Level 3: EDF S. A. entities specific quality plans, processes and procedures.

#### 20.4.3.2.3 Safety Culture

EDF Group implements a strong safety culture in term of nuclear safety as well as

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conventional and environmental safety and security. Each of the EDF entities involved in the UK HPR1000 GDA activities have a 'Robust Safety Culture' that has been demonstrated through many years of successful performance as nuclear plant designers and operators. Work is performed by the EDF entities according to established arrangements for technical reviews. Pre-job briefs performed before technical reviews have a requirement that an appropriate and proportionate level of challenge should be applied within the reviews.

#### 20.4.3.2.4 Human Resources Management

EDF affiliates and entities ensure that suitably skilled and experienced people are allocated to the project to deliver the specific task requested by the client. EDF affiliates and entities rely on existing individual management systems. Each of the affiliates management of resources relies both on:

##### a) Capacity

All affiliates perform periodic update of their mid-term plan to enable the EDF Group to align resources with the GNS plan. This exercise aims at identifying needs in term of human resources for the forthcoming years. This process is simultaneously deployed across the whole EDF Group.

The Contract Manager and the Service Provider Lead Representatives play a key role within such process by indicating to the engineering departments the expected type and volume of resources needed in the project time line by establishing and annual update of project mid-term plan assumptions.

##### b) Capability:

Along with the update of mid-term plan, each of the affiliates carries out a management review of competencies forecast in the framework of the relevant EDF Group policy. This enables to recognise expertise, to forecast training and to manage successions while internal job mobility.

#### 20.4.3.2.5 Measurement, Assessment and Improvement

Project performance is maintained through the application of Reference [23] and via implementation of the project procedures by all persons working on the project. Improvement actions issued from GNS audits or requests and as outcomes of project learning organisation notably through post job briefs are submitted internally for improvement actions.

Internal audits are managed within each organisation in accordance with the requirements of its own management system. Internal audits are planned and performed by qualified auditors who have no direct responsibility in the areas being audited. Follow-up actions, including re-audits of the deficient areas, are initiated where required.

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#### 20.4.3.2.6 Document Control

EDF Group has set up specific document control processes for the project. These processes will be formalised in an appropriate manner in accordance with the outcome of the EDF MSQA inspection from the ONR.

#### 20.4.3.3 Other Supporting Organisations' MSQA

All potential external support organisations are required to go through a pre-qualification review. Each organisation will produce a QA Plan when providing support to GNS during the GDA process. This will detail MSQA arrangements that have been put in place to support GNS.

For specific technical activities, Reference [24] describes the step by step process on how the technical work is being controlled. This covers the lifecycle of the activity (i.e. from the production of the technical specification, pre-job brief, execution of task and post-job debrief) and sets down the requirements to control the activity, documented by a detailed work plan/quality plan.

### **20.4.4 Project Management**

#### 20.4.4.1 Business Management

The GNS Board is responsible for the strategic oversight of the GDA process. As such strategies are set and resourced for delivery through the GNS Executive Committee. Progress with the implementation of the plan is checked throughout the year. The Quality Management Manual sets out arrangements to ensure the company policies are complied with. Within the context of GDA, the *GDA Project Definition Document*, Reference [7], sets the direction, scope, strategy and approach for the GDA project.

#### 20.4.4.2 Project & Technical Management

The project management process ensures tasks are consistently delivered to the correct quality, time and cost in satisfying the business need of GNS.

##### 20.4.4.2.1 Project Controls

Project control requirements for the management of technical work in GNS are set down in Reference [25]. These requirements are aimed at ensuring consistent guidance is applied and followed when taking into consideration resource, budget and time constraints as well as the management of change. Project Risks are logged in a Project Risk Log and tracked against the overall GDA work schedule. This takes into consideration costs, resource and time constraints and has been established as required by Reference [25]. Compliance with the overall project requirements is managed and controlled via the use of an approved GNS Project Quality Plan – guidance is provided in Reference [26].

A project, in the context of GDA, shall refer to the delivery of GDA submissions such

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as the PCSR, PCER, GSR and Design Reference documentation. Project planning requirements include detailed planning of activities underpinned by tangible deliverables. Changes to plans are governed by arrangements defined in Reference [27].

#### 20.4.4.2.2 Technical Risk Management

Risk management is separated into Project Risks and Technical Risks. Project Risks are logged and assessed against the GDA plan with consideration of costs and resource taken into account. The Project Risk log has been established.

Technical Risks are managed under arrangements in Reference [28]. The technical risk review has been undertaken and the technical risk log has been established.

#### 20.4.4.2.3 Readiness Review

At the end of each GDA step, the RP's readiness is assessed for transition to the next step. This assessment is against criteria in the ONR's Guidance to Requesting Parties, Reference [29] and the Environment Agency's Process and Information Document Guidance, Reference [30].

A Step Entry Evidence pack is submitted prior to each step entry to demonstrate the RP's readiness in terms of having fulfilled the current step requirements as well as the ability to proceed into the next step.

#### 20.4.4.3 Resource Management

Resource management covers a broad range of processes including recruitment and selection, performance management, training and development as well as reward and recognition. In the context of GDA, the focus shall be on training and development to ensure GDA work is competently managed and demonstrating the organisation's capability to manage resource and knowledge retention for the UK HPR1000 project.

All personnel involved in the safety case and design development are to be suitably qualified and experienced to perform their role. This includes GNS, as well as the parent support organisations (CGN and EDF) and third party suppliers utilised in the project.

Within GNS, a framework has been established, Reference [31], to ensure personnel have received suitable training and are demonstrably competent to perform their role in GDA.

A key element in maintaining knowledge is being aware of operational experience within GNS, the parent organisations as well as the wider nuclear and non-nuclear industries. This is managed under the theme of Organisational Learning and will develop into a mature process as the project progresses. Currently, GNS produces Learning Reports on a regular basis to ensure continued awareness of developments within and outside of the nuclear industry.

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#### 20.4.4.4 Information Management

Information management involves the operating and maintenance of the management system and infrastructure that support the company's processes. Protocols are in place to ensure rules for handling protectively marked information are followed, Reference [32].

The GNS IT system enables GNS to operate effectively with information being transferred securely through a secure Data Transformation Services (DTS) SharePoint system on an ISO27001 accredited corporate network.

##### 20.4.4.4.1 Document Control

Documents which describe processes and/or specify requirements are controlled. Such documents are controlled to ensure they are up to date, fit for purpose and readily identifiable and available for use, Reference [33]. All changes to controlled documents are reviewed and approved via a Document Query Process, Reference [34].

##### 20.4.4.4.2 Records Control

Establishing and maintaining a good record keeping system forms an essential part of the UK HPR1000 GDA project. GDA documents that are relevant to the project but are not GNS controlled documents are kept as GNS records, Reference [35]. This is to ensure such documents are preserved and retrievable when required.

All records, including superseded records, will be kept at least for the length of time the Design Acceptance Confirmation (DAC) and the Statement of Design Acceptability (SoDA) are valid. They are kept on the Records Management System so that they are easily accessible to GNS staff with the appropriate permission to access them. All records also have clearly marked and appropriate UK security classification.

##### 20.4.4.5 Security Management

All GNS security policy and procedures have been established to ensure security requirements, namely Regulation 22 and Project Security are satisfied. The security measures in place include control of access, vetting, physical and procedural deterrents as well as information security.

##### 20.4.4.6 Interface Management

As part of the UK HPR100 GDA, GNS interfaces with the UK regulators, the public, its parent organisations as well as third party service providers. Separate interface arrangements have been established to manage these interfaces.

GDA interface arrangements between GNS and the UK regulators, Reference [36], set out the interaction requirements. Internally within GNS, several companion procedures and protocol documents have been produced to ensure these requirements

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are met.

Consequently, interface arrangements between GNS and its parent organisations (CGN and EDF), Reference [37] and Reference [38], have been established to ensure, in turn, that the parent organisations have the appropriate arrangements in place to support GNS. Third party suppliers are managed via their respective framework service agreements.

GNS has also established arrangements to interface with the public and handle public communication of information either through the GDA website and/or Freedom of Information (FOI) requests from the ONR/EA.

## 20.5 Safety Case and Design Control Management

The Preliminary Safety Report (PSR) submitted for Step 2 assessment had its own bespoke set of production and review arrangements. For the subsequent GDA Tier 1 SSER submissions, these are of a more substantive undertaking. Hence an over-arching SSER strategy and arrangement is in place to ensure the delivery of these submissions is properly managed in terms consistency, quality, budget and timeliness of delivery.

Each PCSR, PCER and GSR submission has its own submission delivery strategy, Reference [39], Reference [40], and Reference [41], and shall work within the general requirements set down in the SSER strategy document. Control of work is managed by their own respective quality plans. The *Design Control Strategy*, Reference [42], sets the requirements necessary to ensure the design reference and safety case development are consistent from the beginning and subsequent design changes are reflected in the submissions.

In order to effectively manage the safety case, a Safety Case Manual will be developed during GDA Step 3.

A Safety Case Working Group has been established with the intention of ensuring the delivery strategies remain aligned. This feeds into a wider Cross-Cutting Forum sponsored by the Chief Technical Officer to ensure the interactions between the various disciplines are active and maintained and includes the review of regulatory matters that can potentially affect one or multiple disciplines.

### 20.5.1 Safety Case & Design Management

The objective in safety case and design management is to ensure the UK HPR1000 design and safety requirements are met. Where changes are made to the design or its justification, these are to be carried out in a controlled and systematic manner to ensure configuration control is maintained in the design and safety case documentation.

In terms of the principles to be applied, the design and safety principles are detailed in

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PCSR Chapter 4. These principles are to be applied when reviewing the adequacy of nuclear safety arising from design modifications.

As part of GNS's risk assessment arrangements, the principles to be applied to ensure that risks are reduced to ALARP are briefly described in section 20.5.3 where the 'holistic' ALARP review process for the UK HPR1000 reactor design is considered. For design and safety modifications, the 'specific' ALARP & BAT decision making process is considered. These are supported by the UK HPR1000 modification categorisation and control procedures necessary to implement design changes.

The principles to be applied to the production and technical review of work are documented within Reference [24]. Briefly, the principles are:

- a) Work will be performed by suitably qualified and experienced personnel in accordance with an approved QA process;
- b) Use of verified data;
- c) Use of justified assumptions;
- d) Use of verified and validated computer codes and models (if any);
- e) Contain a degree of conservatism;
- f) Use of engineering judgements must be clearly stated.

These are to help ensure a high standard is maintained for all GDA submissions.

### **20.5.2 Production and Technical Review of SSER Submissions**

The step by step approach in the production and technical review process for each of the submissions will be detailed in their respective guidance document. The *Control of Service Providers Technical Work*, Reference [24], is the mainstay of the production and review process, covering the technical management aspects as well as the production, verification and technical review general requirements. More submission-specific requirements are detailed in their respective technical specifications.

Any deviation from the technical specification (e.g. change in scope) is managed via a Technical Query(TQ) procedure which enables technical queries to be raised and systematically recorded, tracked and responded to in a timely manner by GNS.

### **20.5.3 ALARP & BAT Arrangements**

In GDA, there is a fundamental requirement that the RP sets out their process to reduce risks to ALARP (ONR requirement) or to minimise the environmental impact by the application of 'Best Available Techniques (BAT) (EA requirement).

With regards to managing risks to ALARP, a UK HPR1000 ALARP methodology application procedure, Reference [43], has been developed to be compliant with the

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principles in Reference [44], in particular, Annex 02 (ALARP for proposed new civil nuclear reactors). This is a ‘holistic’ ALARP demonstration which addresses the following areas, namely:

- a) Relevant Good Practice;
- b) Options;
- c) Risk Assessment;
- d) Clear conclusion that there are no further reasonably practicable improvements that could be implemented and therefore the risk has been reduced to ALARP.

With regards to BAT demonstration, a UK HPR1000 BAT methodology application procedure, reference [43], has been developed to meet Environment Agency’s Process and Information Document (P&ID) for Generic Assessment of Candidate Nuclear Power Plant Designs. Both methods will take cognisance of the other (e.g. ALARP process will consider BAT when minimising environmental impact) in the optioneering and decision making phase, when the two approaches will converge and integrate to ensure all reasonably practicable options are being considered - where potential design enhancements are identified, the ‘specific’ ALARP & BAT optioneering and decision making process is considered.

With respect to the optioneering activity, CGN has established ALARP and BAT, Reference [45] and Reference [46], assessment process to demonstrate the following:

- a) Collect and collate issues into a register of potential enhancements;
- b) Group the potential enhancements as appropriate to create a problem statement;
- c) Undertake optioneering, and identify option(s) that shall be recommended for implementation for a particular Problem Statement.

#### **20.5.4 Safety Case Configuration Management**

Configuration control management is to ensure any change to the UK HPR1000 design, is appropriately considered, authorised, and correctly implemented. This is to ensure the design of the plant, safety case and associated documentation are self-consistent and within the design intent.

Through the course of the project, commitments are logged and their delivery plans monitored to ensure these are systematically addressed.

It is recognised that throughout the GDA process, GNS will make commitments to update the safety case prior to formal submission at the end of the respective Step. To ensure that all updates are incorporated into the relevant documentation, GNS will implement arrangements for capturing and managing commitments for safety case updates throughout GDA.

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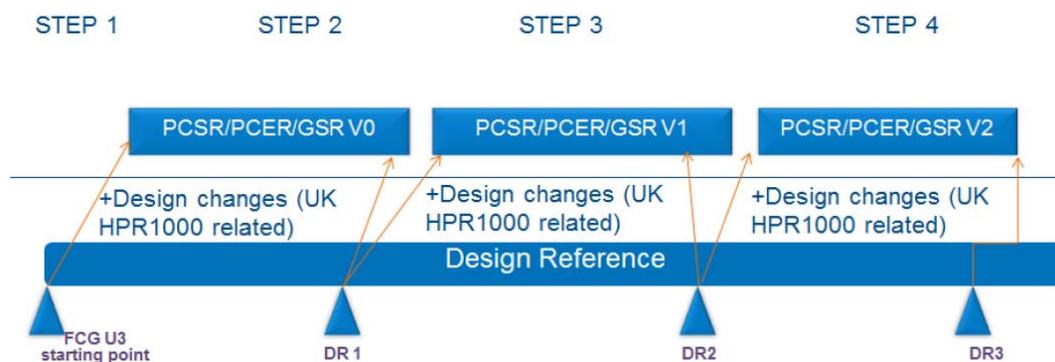
Throughout the GDA process, it is essential that the revision status and development of the SSER submissions is known. This shall enable GNS to formally submit the GDA submissions; including supporting documentation for regulatory assessment that accurately reflects the UK HPR1000 design reference. GNS procedure Reference [47] provides the configuration control of the SSER submissions for the UK HPR1000 GDA project. The requirements for configuration control of SSER submissions takes into consideration the influences from:

- a) Changes to the Design Reference;
- b) Changes to GDA Scope;
- c) Modification Changes;
- d) Regulatory feedback.

Arrangements for the management and tracking of documentation submitted to the UK regulators, including those for regulatory assessment, through use of a Document List and Master Document List is described in Reference [9].

### 20.5.5 Design Reference Configuration Management

Throughout the GDA project it will be necessary to update and revise the UK HPR1000 Design Reference and associated Design Reference Report. This is to ensure the latest available design information can be referenced by major GDA submissions, and as such the revised reference will need to be in place at a time that allows the submission(s) being supported to address the implications of the revised design. The proposed logic sequence is shown in F-20.5-1.



F-20.5-1 Relationship between GDA Submissions and Design Reference Revisions

The details are presented in the *Design Control Strategy*, Reference [42]. Briefly, the design reference for UK HPR1000 will initially be based on the reference plant FCG3 to support PCSR, PCER and GSR production. The Design Reference (i.e. DR1) has been established to support the development of this version of the PCSR, PCER and GSR. This version of Design Reference supports the development of the next version of the PCSR, PCER and GSR at the start of Step 3. This logic is shown illustratively

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in F-20.5-1. Through the course of the project, design modifications will be made and following a series of design reviews that ensure the design requirements are met and fulfil the design intent, the Design Reference will be updated accordingly and shall align with the safety documentation. The frequency of the design reviews will be dependent on the significance and volume of changes to be made.

## **20.6 Concluding Remarks**

An effective and efficient management system is important for the UK HPR1000 GDA project. This chapter presents the MSQA arrangements and safety case management of the UK HPR1000 GDA project.

This chapter describes management system of GNS which are proposed to ensure the required safety level will be delivered throughout the UK HPR1000 GDA project, including organisational arrangements, management system documents, safety culture, policies, decision making, experience feedback and continue improvement. Furthermore this chapter introduces the MSQA of CGN and EDF respectively.

Appropriate arrangements to support the GDA project management have been identified, established and implemented. This includes arrangements for control of documents and records, resource management and business management. This chapter gives an overview of these arrangements.

This chapter describes the safety case management arrangements which are established to ensure the UK HPR1000 design and safety requirements are met. This includes ALARP and BAT arrangement, safety case configuration management and design reference configuration management.

In summary, this chapter has described the current state of development regarding the arrangements of MSQA in UK HPR1000. Suitable organisational arrangements are in place for the development & substantiation of the UK HPR1000.

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