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UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 1 / 35

TABLE OF CONTENTS

20.1 List of Abbreviations and Acronyms.....	3
20.2 Introduction.....	4
20.2.1 Chapter Structure	5
20.2.2 Interfaces with other Chapters	6
20.3 Applicable Codes and Standards.....	6
20.4 Management of Safety and Quality Assurance (MSQA).....	7
20.4.1 Requesting Party Organisational Arrangements	7
20.4.2 General Nuclear System Limited’s MSQA.....	9
20.4.2.1 Classification of the Management System Documents	9
20.4.2.2 Culture, Policies and Principles	10
20.4.2.3 Leadership and Management for Safety	11
20.4.3 Supporting Organisations’ MSQA.....	13
20.4.3.1 CGN’s MSQA	13
20.4.3.2 EDF’s MSQA	18
20.4.3.3 Other Supporting Organisations’ MSQA.....	21
20.4.4 Project Management	21
20.4.4.1 Business Management	21
20.4.4.2 Project & Technical Management	21
20.4.4.3 Resource Management	22
20.4.4.4 Information Management	23
20.4.4.5 Security Management.....	24
20.4.4.6 Interface Management	24
20.4.4.7 Interface with Bradwell B GenCo	24
20.5 Safety Case and Design Control Management.....	25
20.5.1 Safety Case Development Strategy.....	25

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 2 / 35

20.5.2 Safety Case Management Organisation	25
20.5.3 Safety Case & Design Management	26
20.5.4 Production and Technical Review of SSER Submissions.....	27
20.5.5 ALARP & BAT Arrangements.....	27
20.5.6 Safety Case Configuration Management	28
20.5.7 Design Reference Configuration Management.....	30
20.6 Concluding Remarks	31
20.7 References	31

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 3 / 35

20.1 List of Abbreviations and Acronyms

ALARP	As Low As Reasonably Practicable
BAT	Best Available Technique
BRB	Bradwell B GenCo
CGN	China General Nuclear Power Corporation
CNPEC	China Nuclear Power Engineering Co., Ltd
CTO	Chief Technical Officer
DAC	Design Acceptance Confirmation
DL	Document List
EA	Environment Agency
EDF S.A.	Electricité de France S.A.
FCG3	Fangchenggang Nuclear Power Plant Unit 3
FOI	Freedom of Information
GDA	Generic Design Assessment
GNI	General Nuclear International
GSR	Generic Security Report
IAEA	International Atomic Energy Agency
IPR	Intellectual Property Rights
IT	Information Technique
KPIs	Key Performance Indicators
MDSL	Master Document Submission List
MSQA	Management of Safety and Quality Assurance
ONR	Office for Nuclear Regulation(UK)
PCER	Pre-Construction Environmental Report
PCSR	Pre-Construction Safety Report
P&ID	Process and Information Document for Generic Assessment of Candidate Nuclear Power Plant Designs
PWR	Pressurised Water Reactor

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 4 / 35

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
SQEP	Suitably Qualified and Experienced Person
SSER	Safety, Security and Environmental Report
TCN	Technical Change Notice
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 the International Atomic Energy Agency (IAEA) General Safety Requirements Part 2 *Leadership and Management for Safety*, Reference [1], the UK HPR1000 GDA project management system has been established with the aim, by effective arrangements, to ensure safety requirements and other requirements (e.g. quality, environment, and security) are managed in an integrated manner and a strong safety culture is fostered in the project and adopted by the supporting organisations. Hence, “safety” in the MSQA context refers to nuclear safety, conventional safety, environment and security. GDA documents are 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*

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 5 / 35

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 PCSR 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 a robust design process, 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 a brief introduction of PCSR Chapter 20, including chapter structure introduction and 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, and provides justification of the applicability of these codes and standards.

d) Sub-chapter 20.4 Management of Safety and Quality Assurance

This section presents the Requesting Party's MSQA and project management arrangements that have been established and implemented. This includes leadership, organisation capability, risk management, decision making, learning, safety culture, business management and resource management.

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

This section describes safety case and design control management arrangements for the UK HPR1000 GDA project. The section describes how the Requesting Party (RP) implements arrangements to achieve a high level of safety. This includes safety case management, As Low As Reasonably Practicable (ALARP) and Best Available Technique (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 to within this chapter.

20.2.2 Interfaces with other Chapters

In terms of claim supporting and standards selection, this chapter interfaces with PCSR Chapter 1 and PCSR Chapter 4 as listed in the Table T-20.2-1.

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

PCSR Chapter	Interface
Chapter 1 Introduction	Chapter 20 provides information and evidences to support the Level 2 Claim 2.2 presented in Chapter 1. Chapter 1 introduces the links between the present version of PCSR chapters and the Design Reference which are relevant to Design Reference Configuration Management in PCSR Chapter 20.
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 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], ISO 45001, 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). Therefore, the fact that these codes and standards are applied in the 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, ISO 45001 and ISO 14001, are also adopted in the management system establishment and implementation. The configuration management arrangements follow the requirements of IAEA TECDOC 1335, Reference [6]. The applicable codes and standards relating to the MSQA area are listed in Table T-20.3-1.

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 7 / 35

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

Codes and Standards	Title	Issued date
IAEA General Safety Requirements Part 2	Leadership and Management for Safety	2016
ISO 9001	Quality Management System-Requirement	2015
ISO 45001	Occupational Health and Safety Management System	2018
ISO 14001	Environmental Management System Requirement	2015
IAEA TECDOC 1335	Configuration Management in Nuclear Facilities	2003

20.4 Management of Safety and Quality Assurance (MSQA)

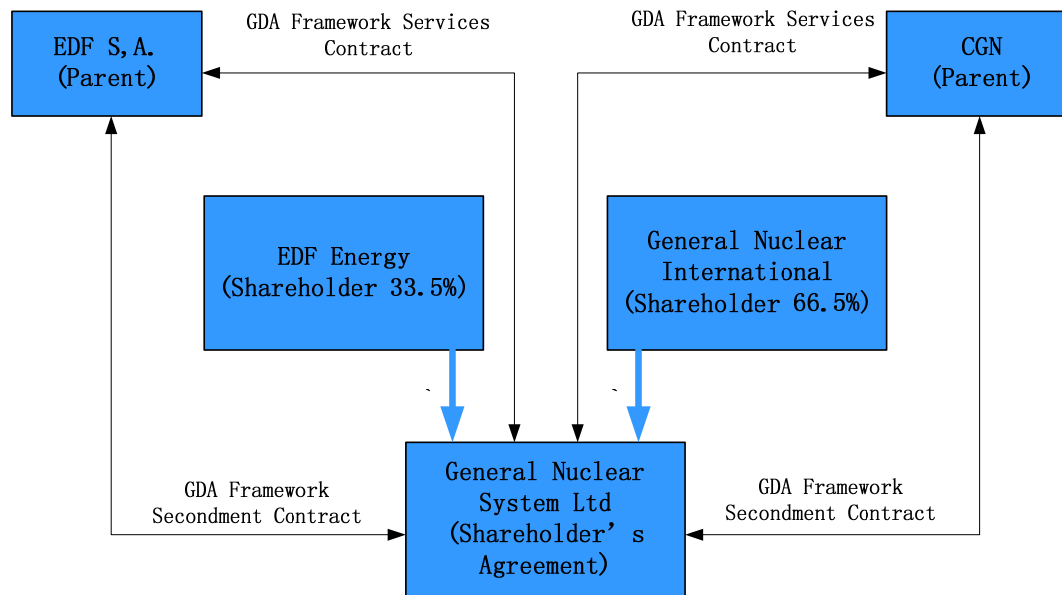
20.4.1 Requesting Party Organisational Arrangements

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

General Nuclear System Limited is appointed by the above shareholders to act on behalf of the RPs. The General Nuclear System Limited Shareholder Agreement (SHA) sets out the full specification of the governance arrangements and decision making processes for GDA. Notably, General Nuclear System Limited is authorised to manage and make key decisions for the purpose of GDA.

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 service contracts between General Nuclear System Limited-CGN and General Nuclear System Limited-EDF. The services are paid for by General Nuclear System Limited under the framework service contracts and delivered against an integrated work plan which is owned and managed by General Nuclear System Limited. As such, General Nuclear System Limited 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 Figure F-20.4-1 .



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

General Nuclear System Limited is supported by two key agreements: (1) a Secondment Agreement whereby staff from CGN and EDF are seconded into General Nuclear System Limited to deliver GDA, and (2) a Framework Service Contract 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 General Nuclear System Limited SHA and explained further in the *Project Definition Document*, Reference [7], and in the General Nuclear System Limited *Quality Management Manual*, Reference [8]. General Nuclear System Limited 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 from France and the UK, knowledge of international good practice applied to its existing nuclear fleet, past GDA experience (i.e. UK EPR) and current experience on its new build projects.
- 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, the RP will be supported by third party contract partners, based on their technical competencies relevant to the project.

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 9 / 35

20.4.2 General Nuclear System Limited's MSQA

20.4.2.1 Classification of the Management System Documents

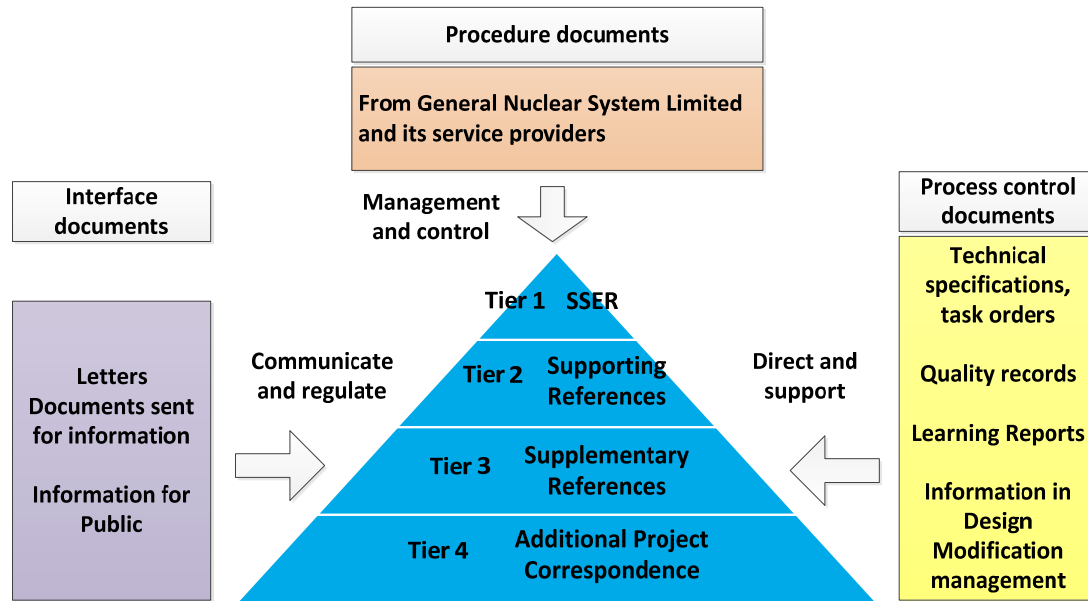
The management system is designed to ensure General Nuclear System Limited's capability to control quality, content and accuracy of delivered output for GDA. The aim is to provide confidence that all outputs consistently meets regulatory requirements and that the management system helps to improve performance. The MSQA arrangements of General Nuclear System Limited 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 General Nuclear System Limited. All the management system documents are classified as shown in Figure F-20.4-2. Hierarchy of General Nuclear System Limited management system documentation is divided into the following three levels:

- a) Level 1 consists of General Nuclear System Limited's Policies; the key policies are described in section 20.4.2.2.
- b) Level 2 consists of manuals, management system plans 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 the management system.



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

All official documents shall be produced under the document control system. This system ensures control of document 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 Figure F-20.4-3.



F-20.4-3 GDA Document Hierarchy

The GDA submissions are divided into four tiers. They are respectively Safety, Security and Environmental Report (SSER), 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, Reference [9]. The Master Document Submission List (MDSL) is the live totality of the GDA submission at tier 1-3 showing only the latest revision. The Document List (DL) 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

General Nuclear System Limited 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:

- The *Nuclear Safety Culture Principles*, Reference [10], sets out expectations of the leadership team and to all employees to exercise conservative decision making in day to day operations of General Nuclear System Limited and to be a learning organisation.
- The Quality Policy sets out expectations on prioritising safety in the drive for excellence and aspiring to achieve zero harm to people and environment.
- The 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.

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 11 / 35

- d) The Sustainability Business Policy sets out the company ambitions in being a sustainable business.
- e) The Business Continuity Management Policy sets out the business continuity management arrangements to protect the interest of its stakeholders and staff.
- f) The Security Policy describes the arrangements for security to meet legislative and regulatory security requirements and names all key security related stakeholders.

20.4.2.3 Leadership and Management for Safety

20.4.2.3.1 Leadership

The General Nuclear System Limited Executive Committee is accountable to the General Nuclear System Limited Board for the performance of the GDA project. The General Nuclear System Limited 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 a 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 General Nuclear System Limited Board. Details of the arrangements are further described in the General Nuclear System Limited's *Quality Management Manual*, Reference [8].

20.4.2.3.2 Organisational Capability

General Nuclear System Limited is a joint venture between CGN and EDF, two competent, international utility companies with a strong nuclear safety culture and capability.

For the GDA project, General Nuclear System Limited 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 their responsibility.

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 12 / 35

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 General Nuclear System Limited Chief Technical Officer (CTO). Active challenge is part of the decision making process, with a questioning attitude cultivated and promoted amongst the team.

The General Nuclear System Limited Executive Committee is responsible for the day to day management of General Nuclear System Limited's GDA activities. For technical matters, General Nuclear System Limited has established a Technical Committee that operates under the General Nuclear System Limited procedure *Technical Committee Operation Guidance*, Reference [11], which sets out the protocols, interfaces and escalation routes for technical decision making. General Nuclear System Limited, CGN or EDF representatives can propose topics at the Technical Committee meetings. The Technical Committee will make decisions on safety significant related issues. For less significant aspects, the Technical Committee recommendations can be provided by the Technical Committee members. The decision making processes within General Nuclear System Limited and CGN are being developed to ensure that the Technical Committee has sufficient input and visibility of the technical decision making process.

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 other 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).
- d) Experience from previous GDA steps, for example lessons learnt from the SSER production process, Reference [12].

A method for documenting organisational learning within General Nuclear System

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 13 / 35

Limited 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.

20.4.2.3.5 Monitoring and Improvement

Arrangements are in place to improve the effectiveness and efficiency of operations in General Nuclear System Limited. 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 General Nuclear System Limited 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 [13], 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 once during each GDA step. In addition, *Self-Assessments Procedure*, Reference [14], 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. Where areas for improvement are identified, improvement actions will be raised and tracked through to completion. These form the basis of the project's continuous improvement plan.

Independent assessments are 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 is evaluated with necessary actions put in place to implement identified improvements.

Collectively, these activities help General Nuclear System Limited 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 the UK HPR1000 GDA Project. China Nuclear Power Engineering Co., Ltd (CNPEC) is the leading member of several CGN subsidiaries involved in the GDA project. CNPEC is a leading nuclear power plant system integrator and nuclear power technology provider in China,

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 14 / 35

capable of efficient resource allocation, competent project organisation and management along with 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.
- b) Preparation of comprehensive reports to be submitted to the Office for Nuclear Regulation (ONR) and Environment Agency (EA) for assessment along with relevant supporting documents.
- c) Answering the regulatory questions including RQ, RO and RI.
- d) Design of improvements to be implemented for the UK HPR1000.

CNPEC has established the GDA Project Department to manage, guide and implement the quality assurance program, Reference [15], and to ensure smooth progress of various tasks related to GDA. The GDA Project Department is supported by CNPEC's business centres including 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 support to the GDA Project Department. The detailed organisation and operation rules can be found in Reference [16]. Safety Case Control Group, UK HPR1000 Design Control Group, Cross-cutting Working Groups and Design Modification Working Groups were established during GDA step 3 to strengthen the management of GDA project.

CNPEC is supported by other CGN subsidiaries through subcontracts. CNPEC and the other CGN subsidiaries which provide support to the UK HPR1000 GDA project have management systems certified to ISO 9001/ISO 14001 and are 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.

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 15 / 35

20.4.3.1.3 Safety Culture

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

- a) Issue and advocate the safety policy statements and safety culture manuals to ensure all personnel have a comprehensive understanding and consensus of safety.
- b) Provide the 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, evaluation and improvement of safety culture level.

20.4.3.1.4 Decision Making

The CGN GDA project decision making procedure, Reference [17], describes the principles, processes 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) Minimisation of the short-term and long-term risks.
- e) ALARP and BAT.

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 16 / 35

f) Laws, regulations, standards and technical requirements.

20.4.3.1.5 Personnel Allocation and Training

The CNPEC procedure, Reference [18], describes the process for qualifying personnel and task assignment for a nuclear power plant project. Qualification management mainly comprises 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 of personnel can be classed as a Suitably Qualified and Experienced Person (SQEP). It also ensures that personnel understand and are familiar with the work basis, can achieve and maintain professional ability and have the necessary nuclear safety awareness to carry out tasks that may affect the safety.

Based on reference [18], CNPEC produced two supplementary procedures for GDA project personnel qualification management and job responsibilities, Reference [19] and [20]. CNPEC analysed the role of GDA tasks, identified the associated competencies that personnel require, established training plans, carried out training and evaluated personnel capability. These activities ensure all personnel engaged in the GDA project have received the 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 research and development, siting, construction, commissioning, operation and decommissioning. CGN puts emphasis on continuous knowledge acquirement, sharing and application.

CGN ensures that the personnel participating in the GDA project 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 processes/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 thereby

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 17 / 35

continuously improving quality management. CGN's GDA project experience feedback procedure, Reference [21], has been developed to promote the effectiveness of experience feedback.

20.4.3.1.7 Document and Record Control

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. In accordance with General Nuclear System Limited's DL and MDSL control procedure, CNPEC established a dedicated document control procedure, Reference [22], to identify and control submission of documents, within CGN's workscope, required for GDA.

20.4.3.1.8 Design Control and Configuration Management

The existing CNPEC design control procedure, Reference [23], describes how the design process is controlled (e.g. design planning, design inputs, design analysis, design interfaces, design review, design verification, design outputs, design validation 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 and 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 sheets, design reviews and design verification records.

To ensure design consistency and control design changes, the 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 [24] and [25], are in compliance with IAEA configuration management standards TECDOC 1335, Reference [6]. Configuration change management for any design change is administered through Reference [25]. 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 [26], stipulates management and control of the

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 18 / 35

subcontracting process in the CGN GDA project. The supplier is evaluated and selected on the basis of their ability in provision of items or services as per the 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, schedule, applicable regulations and standards, design basis, technical specification and SQEP requirements. CNPEC carries out various purchasing process control measures based on safety importance and complexity. A final acceptance process is carried out to ensure the quality of products/services is compliant with the 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 Safety Management and Quality Assurance Department is responsible for selecting the auditor and organising the audit team. CNPEC carries out management system reviews at least once a year to ensure the management system remains suitable, adequate and effective. The results of the 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 General Nuclear System Limited on the work that CGN carried out for them. CNPEC supports the MSQA inspection carried out by the regulators and seeks opportunity to implement continuous improvement.

20.4.3.2 EDF's MSQA

20.4.3.2.1 Organisation

According to the SHA, EDF provides technical expertise to support the UK HPR1000 GDA project through the Framework Service Contract with General Nuclear System Limited. 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. Provisions of services are requested by General Nuclear System Limited through Work Orders. Work Orders provide all the relevant information required to undertake activities such as technical reviews of GDA submissions, support to regulatory correspondence, review of technical documents or technical support on specific technical topics requested by General Nuclear System Limited. Where specific technical tasks are required, task sheets supplement the Work Order providing more detailed specification on the scope and to agree on the inputs and outputs. As such, EDF have produced a *Quality Management Plan*, Reference [27], for the GDA project which details the management system and QA arrangements that have been put in place to support General Nuclear System Limited. For the review of the Safety, Security and

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 19 / 35

Environmental Report (SSER), EDF has detailed arrangements and approach to manage their delivery of technical work which will be demonstrably acceptable to General Nuclear System Limited.

Quality assurance of the work delivered by EDF on behalf of General Nuclear System Limited 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 quality, cost and time. As the EDF Group is comprised of EDF S.A., EDF Energy Nuclear Generation, Nuclear New Build and other EDF affiliates and entities, the entities shall apply their own QA arrangements that are considered to be acceptable to General Nuclear System Limited 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.

The information of these Affiliates and Entities is described below:

- a) EDF S.A. and affiliates have extensive technical 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 issue throughout the whole GDA project. Utilising these expertise is achieved through involvement of resources from the EDF Group engineering centres.
- 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 great experience in safely operating 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 (Hinkley Point C) and site development (Sizewell C) projects in UK.
- e) EDF Energy Limited has longstanding UK experience in corporate support (IT and legal).

20.4.3.2.2 Quality Management System

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

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 20 / 35

- a) Level 0: General Nuclear System Limited quality management manual, processes and procedures. These provide the description of the client's quality management plan, the description on how the project is delivered and how General Nuclear System Limited interfaces with regulator, shareholders and service providers.
- b) Level 1: EDF Group *Quality Management Plan*, Reference [27], and organisation documents. These are applicable to the overall EDF affiliate and entity for this project.
- 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 Group entities specific quality plans, processes and procedures.

20.4.3.2.3 Safety Culture

EDF Group implements a strong safety culture in terms of nuclear safety as well as 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 entity management systems. Each of the affiliates management of resources relies on:

- a) Capacity

All affiliates perform periodic update of their mid-term plan to enable the EDF Group to align resources with the General Nuclear System Limited 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 processes. They indicate, to the engineering departments, the expected type and volume of resources needed in the project time line by establishing an annual update of project mid-term plan assumptions.

- b) Capability:

Along with the update of the mid-term plan, each of the affiliates carries out a management review of competencies forecast in the framework of the relevant

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 21 / 35

EDF Group policy. This enables the required expertise to be identified, appropriate training to be planned and succession management to be undertaken.

20.4.3.2.5 Measurement, Assessment and Improvement

Project performance is maintained through the application of the EDF *Quality Management Plan*, Reference [27], and via implementation of the project procedures by all persons working on the project. Improvement actions issued from General Nuclear System Limited audits or requests through outcomes of project learning (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 non-compliant areas, are initiated where required.

20.4.3.2.6 Document Control

EDF Group has set up specific document control processes for the project. These processes are formalised in an appropriate manner.

20.4.3.3 Other Supporting Organisations' MSQA

All potential external support organisations are required to go through a pre-qualification review. For specific technical activities, the *Control of Service Provider Technical Work* procedure, Reference [28], 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.

20.4.4 Project Management

20.4.4.1 Business Management

The General Nuclear System Limited Board is responsible for the strategic oversight of the GDA process. As such strategies are set and resourced for delivery through the General Nuclear System Limited Executive Committee. Progress with the implementation of the plan is checked throughout the year. The Quality Management Manual sets out the 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 General Nuclear System Limited.

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 22 / 35

20.4.4.2.1 Project Controls

Project control requirements for the management of technical work in General Nuclear System Limited are contained within Reference [29]. 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. Compliance with the overall project requirements is managed and controlled via the use of an approved *Generic Task Project Quality Plan*, Reference [30].

Project planning requirements include detailed planning of activities underpinned by tangible deliverables. Changes to plans are governed by arrangements defined in the *GDA Schedule Management Mechanism*, Reference [31].

20.4.4.2.2 Risk Management

Risk management is separated into Project Risks and Technical Risks. Project Risks take into consideration costs, resource and time constraints. They are logged in a Project Risk Log and tracked against the overall GDA work schedule.

Technical Risks are managed under arrangements in the *Technical Risk Register Management Procedure*, Reference [32]. 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 [33] and the Environment Agency's Process and Information Document Guidance, Reference [34].

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 to 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 General Nuclear System Limited, as well as the parent support organisations (CGN and EDF) and third party suppliers utilised in the project.

Within General Nuclear System Limited, a framework has been established,

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 23 / 35

Reference [35], to ensure personnel have received suitable training and are demonstrably competent to perform their role in the GDA phase of the project.

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 [36].

The IT system enables General Nuclear System Limited to operate effectively with information being transferred through a secure Document Transfer System on an ISO27001 information security management 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 [37]. All changes to controlled documents are reviewed and approved via a Document Query Process, Reference [38].

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 General Nuclear System Limited controlled documents are kept as General Nuclear System Limited records, Reference [39]. All the records are kept in General Nuclear System Limited's General Document Archive System to ensure such documents are preserved and retrievable when required.

All records, including superseded records, will be kept for at least 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 General Nuclear System Limited staff with the appropriate permission to access them. All records also have clearly marked and appropriate UK security classification.

20.4.4.4.3 Export Control

The transfer of controlled items out of the United Kingdom are managed to ensure compliance with the export control legislation. This is achieved through a standardised process for determining the export control status of items, managing exports under existing licences, obtaining new licences, and maintaining and monitoring compliance with any conditions of extant licences, Reference [40].

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 24 / 35

20.4.4.5 Security Management

All General Nuclear System Limited security policies 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 HPR1000 GDA, General Nuclear System Limited 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 General Nuclear System Limited and the UK regulators, Reference [41], set out the interaction requirements. Internally within General Nuclear System Limited, several companion procedures and protocol documents have been produced to ensure these requirements are met.

Consequently, interface arrangements between General Nuclear System Limited and its parent organisations (CGN and EDF), Reference [42] and [43] respectively, have been established to ensure that the parent organisations have the appropriate arrangements in place to support General Nuclear System Limited. Third party suppliers are managed via their respective framework service agreements.

General Nuclear System Limited 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.

20.4.4.7 Interface with Bradwell B GenCo

Bradwell B GenCo (BRB) is the future licensee for the planned UK HPR1000 power plant at Bradwell-on-Sea. A BRB Project Technical Committee has been established to provide a multidisciplinary review forum to inform decisions by the BRB CEO on technical issues affecting the project. The BRB Project Technical Committee has a key focus on managing the interface between General Nuclear System Limited and BRB to ensure that technical decisions in each organisation are taken in the best interest of the BRB project through design, construction, operation and decommissioning. The BRB Project Framework Agreement is being produced to set out arrangements by which General Nuclear System Limited and BRB will deliver safe designs, underpinned by robust safety cases, for the GDA generic site and BRB site specific UK HPR1000 plant, Reference [44] . The Project Framework Agreement provides a high level framework enabling General Nuclear System Limited and BRB to effectively plan, coordinate and work collaboratively to facilitate the transfer of the GDA design and safety case information to BRB. The Project Framework Agreement also covers the integration plan of GDA and BRB site specific design reference and

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 25 / 35

change processes, jointly developed by the General Nuclear System Limited Chief Technology Officer and BRB Engineering Management Office Deputy Director. A resource plan and a transition plan will be developed in accordance with the Project Framework Agreement to manage the transition and migration of assets between GDA and BRB.

20.5 Safety Case and Design Control Management

20.5.1 Safety Case Development Strategy

An over-arching Safety Case Development Strategy, Reference [45], and arrangements are in place to ensure the delivery of safety case submissions are properly managed in terms of consistency, quality, budget and timeliness of delivery.

The General Nuclear System Limited Safety Case Development Strategy which covers the development and delivery of SSER V1 submitted for the Step 4 assessment is supported by topic level production strategies for Safety, Security and Environmental Topics. The supporting production strategies provide detailed information on the expected structure, hierarchy and interfaces of the topic level safety cases to ensure the planned work will result in a fit-for-purpose UK HPR1000 safety case for GDA at each step.

The structure and content presented in SSER V1 shall follow the general requirements set down in the Safety Case strategy documents. Control of work is managed by the respective PSCR, PCER and GSR quality plans, References [46], [47], and [48]. The *Design Control Strategy*, Reference [49], 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.

To provide set expectations on how to produce safety case documentation within the UK context and provide guidance to authors on how to present safety case information a Safety Case Development Manual has been developed, Reference [50].

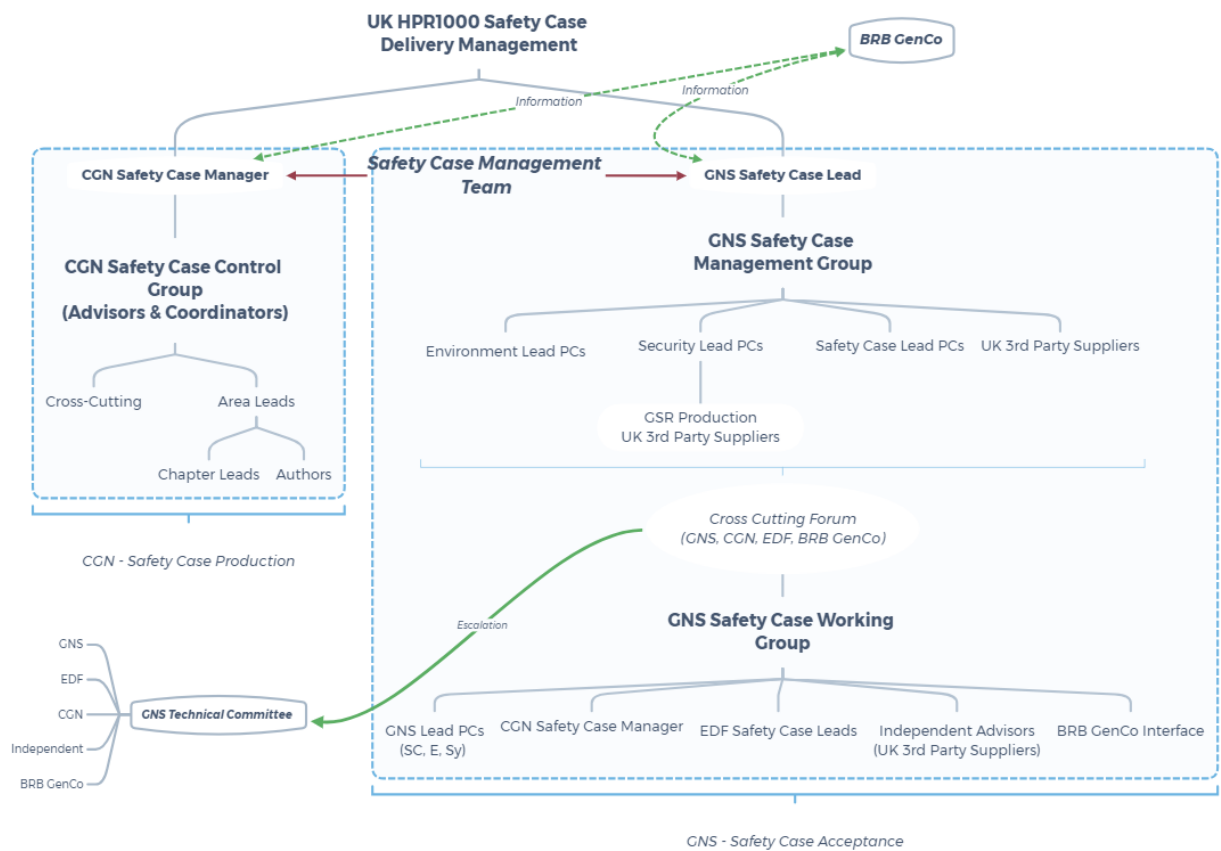
An Integrated Delivery Tool has been implemented in order to provide a single source of information to monitor the production, review and submission of GDA documentation at tiers 1 to 3, and also record all the GDA submissions at tier 4, Reference [51]. The integrated tool can export outputs for the MDSL, DL and integrated delivery plan.

20.5.2 Safety Case Management Organisation

A Safety Case Manager within CGN has been appointed who leads Safety Cases within CGN as the responsible designer. The Safety Case Manager closely interfaces with the General Nuclear System Limited Safety Case Lead PC to provide leadership and set strategic direction of safety case activities. Within CGN and General Nuclear System Limited, a Safety Case Working Group provides the coverage of safety case activities within the organisation and interacts between the organisations to coordinate,

control and deliver safety case tasks. Where required, third party suppliers supplement the teams to deliver specific tasks and provide UK context guidance and experience.

A Safety Case Working Group includes representatives from the RP, potential future licensee and third party suppliers with a brief to agree strategic decisions and resolve safety case issues raised within the RP and by the regulators, Reference [52]. An overview of the organisation is shown in Figure F-20.5-1. This feeds into a wider Cross-Cutting Forum sponsored by the Chief Technical Officer (CTO) 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. Where a topic requires escalation, ultimately the General Nuclear System Limited Technical Committee is responsible for decision making.



F-20.5-1 Overview of Safety Case Management Organisation

20.5.3 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.

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 27 / 35

In terms of the principles to be applied, the design and safety principles are detailed in PCSR Chapter 4. These principles are to be applied when reviewing the adequacy of nuclear safety arising from design modifications.

As part of General Nuclear System Limited's risk assessment arrangements, the principles to be applied to ensure that risks are reduced to ALARP are briefly described in section 20.5.5 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, reference [53] and [54] .

20.5.4 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* procedure, Reference [28], 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 specific guidance has been provided for the production and review of SSER V1, Reference [55].

The principles to be applied to the production and technical review of work are documented within the *Control of Service Provider Technical Work* procedure, Reference [28]. 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.

20.5.5 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 [56], has been developed to be compliant with the

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 28 / 35

principles in Reference [57], in particular, Annex 02 (ALARP for proposed new civil nuclear reactors). This is a ‘holistic’ ALARP demonstration which addresses the following areas:

- 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 [56], has been developed to meet Environment Agency’s *Process and Information Document for Generic Assessment of Candidate Nuclear Power Plant Designs (P&ID)*. 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, reference [58] .

With respect to the optioneering activity, CGN has established ALARP and BAT, Reference [59] and [60], assessment processes 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.

20.5.6 Safety Case Configuration Management

Configuration control management is necessary 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.

It is recognised that throughout the GDA process, the RP will make commitments to update the safety case prior to formal submission at the end of the respective Step.

Through the course of the project, commitments shall be logged and their delivery plans monitored to ensure these are systematically addressed and that all updates are incorporated into the relevant documentation.

The management of commitments made during GDA is managed according to *Management of Commitments for Safety Case Updates* procedure, Reference [61] .

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 29 / 35

Commitments may be generated as part of SSER submissions which are produced by CGN (PCSR & PCER) and General Nuclear System Limited (GSR), formal responses to RQs, within safety case supporting reference documentation implicitly or explicitly or during formal Level 4 interactions with Regulators. Local procedures within CGN provide the formal process for commitment management, Reference [62].

Throughout the GDA process, it is essential that the revision status and development of the SSER submissions is known. This shall enable General Nuclear System Limited to formally submit the GDA submissions, including supporting documentation for regulatory assessment that accurately reflects the UK HPR1000 design reference. General Nuclear System Limited has developed guidance, Reference [63], to provide configuration control of the SSER submissions for the UK HPR1000 GDA project. The requirements for configuration control of SSER submissions takes into consideration:

- 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, is achieved through use of a Document List and Master Document Submission List, Reference [9].

Configuration control management has been put in place for the safety case, notably between SSER V0 and SSER V1, Reference [61], [62] and [64], to ensure that potential changes are identified in terms of:

- a) The source of the proposed change.
- b) The reason for the proposed change.
- c) The impact to interfacing SSER chapters and supporting references.

Adherence to this guidance will ensure improved traceability and control of the proposed SSER Chapter changes:

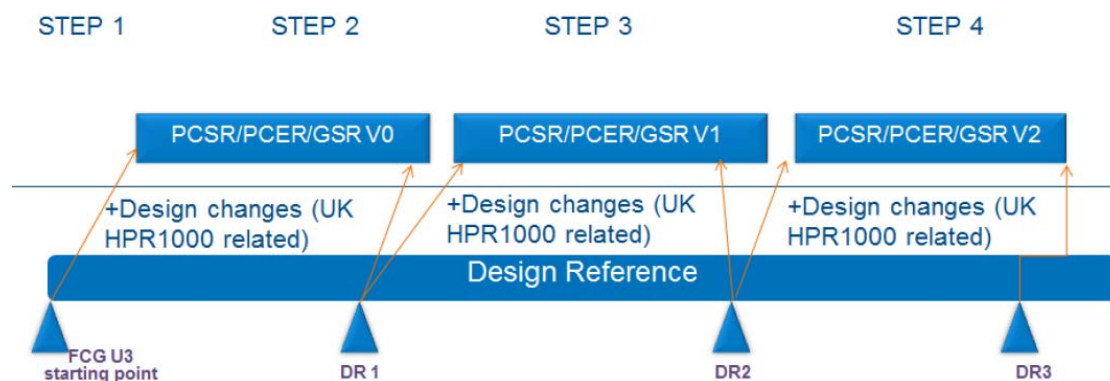
- a) Change can be agreed among RP's before the Chapter is updated.
- b) Analysis of the potential impact of the SSER changes.
- c) Provision of a QA record of the Chapter update, review and approval.

The management of requirements inside the UK HPR1000 project is based on CGN's overall design management process, and is undertaken using a bottom-up approach to define and propagate safety, engineering, and operational requirements throughout the design.

The internal information management system (for management of internal design interfaces between the different disciplines inside CGN) and interface management system (for management of external design interfaces to the supply chains) ensure that the bottom-up approach shares all data across the project as required. The above systems provide the mechanisms for the internal and external transfer of design and safety case information. The interface management process was investigated as part of the *UK HPR1000 Requirement Management Gap Analysis Report*, Reference [65], and was found to be an effective tool for the various design and study teams to transfer information between each other.

20.5.7 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, Reference [66]. 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 Figure F-20.5-2. The Design Reference is gradually frozen into DR1, DR2, and DR3 points at the end of Step 2, 3 and 4 of the GDA project. Between two design freezes, different internal state control points can be set according to progress of the design work, for example DR2.1, DR2.2, can be set between DR2 and DR3. The details are presented in *UK HPR1000 Design Control Strategy* and *UK HPR1000 Design Reference Report*, Reference [49] and [67]. The links between the present version of PCSR/PCER chapters and the Design Reference are presented in PCSR Chapter 1 section 1.5 and PCER Chapter 1 section 1.4.3.



F-20.5-2 Relationship between GDA Submissions and Design Reference Revisions

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, Reference [66]. The frequency of the design reviews will be dependent on the significance and volume of changes to be made.

UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 31 / 35

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 the management system of General Nuclear System Limited which is 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 continuous 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 arrangements, 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 the UK HPR1000. Suitable organisational arrangements are in place for the development & substantiation of the UK HPR1000.

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UK HPR1000 GDA	Pre-Construction Safety Report Chapter 20 MSQA and Safety Case Management	UK Protective Marking: Not Protectively Marked	
		Rev: 001	Page: 32 / 35

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		Rev: 001	Page: 33 / 35

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		Rev: 001	Page: 34 / 35

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		Rev: 001	Page: 35 / 35

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