A Holtec International Company

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4.1 INTRODUCTION

The Fundamental Purpose of the Generic Design Assessment (GDA) Safety, Security[1] and Environment Case (SSEC) is to demonstrate that the generic Small Modular Reactor (SMR)-300 can be constructed, commissioned, operated, and decommissioned on a generic site in the United Kingdom (UK) to fulfil the future licensee's legal duties to be safe, secure and protect people and the environment, as defined in Part A Chapter 1 [1].

This is achieved through the Fundamental Objective of the SSEC, which is to summarise the standards and criteria, management and organisation, Claims, Arguments and intended Evidence (CAE) to demonstrate that the generic SMR-300 design risks to people are likely to be tolerable and As Low as Reasonably Practicable (ALARP) and ensure a suitably high standard of environmental protection, demonstrating Best Available Techniques (BAT).

Part A Chapter 4 of the Preliminary Safety Report (PSR) presents the CAE for the Lifecycle Management of Safety and Quality Assurance (MSQA) topic. The lifecycle MSQA arrangements are a set of quality arrangements that allow safety, security, safeguards and environmental protection matters to be managed throughout the lifecycle.

4.1.1 Purpose and Scope

The Overarching SSEC Claims are presented in Part A Chapter 3 [2].

This chapter (Part A Chapter 4) links to the overarching claims through Claim 1.4:

Claim 1.4: Holtec has appropriate integrated project, quality, design and safety management arrangements to deliver a UK SMR-300 which is demonstrably safe and secure, protecting people and environment throughout its lifecycle.

Claim 1.4 is further broken down in this chapter into Level 3 claims, which highlight key MSQA aspects related to the lifecycle of the generic SMR-300. This chapter directly supports Level 3 Claims 1.4.1 – 1.4.5 listed in Table 1. Further discussion on how the Level 2 claim is broken down and how the Level 3 claims are met is provided in sub-chapter 4.3.

This chapter is structured as follows in support of the claim:

- Sub-chapter 4.2 provides an overview of Holtec's approach to MSQA.
- Sub-chapter 4.3 presents the detailed structure of the CAE, mapping where supporting arguments for the Level 3 claims are developed and discussed.
- Sub-chapter 4.4 outlines the relevant codes, standards and methodologies pertinent to MSQA.
- Sub-chapters 4.5 – 4.9 address in detail the arguments and evidence for the Level 3 claims, covering the below elements:
    - Holtec overarching MSQA arrangements.
    - Holtec SMR-300 project MSQA arrangements for design development.

[1] Security is considered to include safeguards throughout this chapter.

- Arrangements in place for managing the GDA process and the post-GDA arrangements.
- Processes for management of the SSEC.
- Arrangements for future SMR-300 lifecycle phases.

- Sub-chapter 4.10 provides a technical summary of how the claims for this chapter have been substantiated, along with key contributions of this chapter to the overall ALARP justification. Sub-chapter 4.10.3 also discusses any GDA commitments that have arisen.

Chapter A4 (this chapter) provides a description of all the processes and procedures undertaken for the SMR-300 Lifecycle MSQA, including the management of risks and design changes. Chapter A4 therefore supports the lifecycle elements of the ALARP demonstration, with respect to the management of safety and quality assurance for the construction, commissioning, operation and decommissioning of the SMR-300. Chapter A4 also describes the specific MSQA processes applied during the GDA for the development of the nuclear, conventional safety and environment and security cases.

A master list of definitions and abbreviations relevant to all PSR Chapters can be found in Part A Chapter 2 [3].

4.1.2 Assumptions

Assumptions which relate to this topic have been formally captured through the Commitments, Assumptions and Requirements (CARs) Procedure [4]. Further details of this process are provided in sub-chapter 4.8. The CAR Register [5] is also recorded on the Holtec document management system.

Fundamental to this chapter, and the wider Holtec SMR-300 GDA Project, is the assumption that Holtec does not intend to progress to GDA Step 3, as declared in Holtec's early strategy discussions with the Office for Nuclear Regulation (ONR). The chapter assumes that the current focus, on demonstrating the fundamental adequacy of the generic SMR-300 design, will transition into a focus on further developing a UK site-specific SMR-300. This is described in detail in the Through-Life Safety, Security and Environment Case [6] which describes the initial post-GDA focus on a Generic Pre-Construction SSEC which will progress into a Site-Specific Pre-Construction SSEC. Further information on future arrangements for SSEC development is explained in Section 4.9.1.

Relevant to this chapter and the future SMR-300 design is that Holtec do not intend to be the sole future licensee or operator of the plant in the UK. Holtec will likely perform the role of Responsible Designer for the scope of design.

It is assumed for the purposes of this PSR that Holtec will not be the licensee, and therefore Design Authority, for the SMR-300 in the UK. It is also assumed that Holtec will be a Responsible Designer for the UK SMR-300.

4.1.3 Interfaces with other SSEC Chapters

This sub-chapter discusses the Part A Chapter 4 interfaces with other parts of the SSEC.

4.1.3.1 Interfaces of MSQA topic within the SSEC - General

Due to the cross-cutting nature of MSQA, this chapter, where appropriate, points to key documentation and other SSEC chapters, rather than repeating information, with the overall aim of providing a comprehensive overview and allowing key aspects to be further explored as considered necessary by stakeholders.

The SSEC chapters may create GDA Commitments to capture any design changes that are deemed necessary by the process but that won't be implemented within GDA timescales. The Management of GDA Commitments arising from the SSEC chapters is outlined in this chapter, in sub-chapter 4.8.4.

4.1.3.2 Interfaces of MSQA topic with PSR Part A Chapters

The MSQA topic addressed in this chapter interfaces specifically with the following Part A chapters:

- Chapter A1 Introduction [1] provides an overview of the Holtec SMR-300 GDA project and presents the SSEC structure, summarising each chapter content.
- Chapter A2 General Design Aspects & Site Characteristics [3] presents an overview of the design evolution, the generic design of the SMR-300 presented for the GDA, the fundamental design and safety principles and the reference design for the generic SMR-300. This chapter addresses the lifecycle management of this reference design, the application of design changes through ongoing design development, and the interactions with the Palisades First-of-a-Kind (FOAK) SMR-300 reference plant.
- Chapter A3 Claims, Arguments & Evidence [2] presents the overarching SSEC claims, to which this chapter contributes to through Claim 1.4.
- Chapter A5 Summary of ALARP and the SSEC [7] summarises the outcomes from the PSR, Preliminary Environmental Report (PER), Generic Security Report (GSR) and Preliminary Safeguards Report (PSgR) to demonstrate that the SSEC Fundamental Purpose [1] has been met, and to provide an overarching demonstration that the risks associated with the design are likely to be tolerable and ALARP. By linking to the PER and GSR [8], Chapter A5 draws conclusions about the application of Best Available Techniques and management of security risks. Chapter A5 also describes the process adopted to options management which Holtec applies to all prospective design challenges to the GDA reference design.

4.1.3.3 Interfaces of MSQA with PSR Part B Chapters

This chapter interfaces specifically with the following PSR Part B Chapters. A full breakdown of Chapter contents and references can be found in PSR Part A Chapter 1 [1]:

- Chapters 1, 2, 4, 5 and 6 are related to the Design and Main Operating Systems and include Reactor Coolant System and Engineered Safety Features, Reactor Fuel & Core, Control & Instrumentation, Reactor Supporting Facilities, Electrical Engineering. This chapter describes the design processes that have been applied within those disciplines including those associated with reference design definition and change control.
- Chapter 9 Conduct of Operations [9] supports the claim that the operational control will be based upon identified good practice and that the operating and technical support organisation will be defined and adequately managed to enable and ensure safe operation of the plant. This MSQA chapter refers to the process [4] on the transfer of commitments

made within SSEC documentation into the intended operating regime. This chapter also provides an overview of the SSEC development strategy.

- Chapter 12 'Nuclear Site Health and Safety and Conventional Fire Safety' [10] references and summarises key GDA deliverables setting out the Construction (Design and Management) Regulations 2015 (CDM 2015) approach. The principal reference is the Holtec Britain CDM Strategy, Revision 1 [11], which describes CDM implementation, integration and compliance in design management, including conventional Health and Safety (H&S) management throughout the SMR-300 lifecycle. This chapter, which outlines the overarching quality management arrangements, references [10] for details on Conventional H&S and duty holders' responsibilities. This chapter sets out competency arrangements across the GDA and references [10] with respect to the inclusion of specific training for CDM and conventional H&S. Specific arrangements associated with conventional H&S are discussed in sub-chapter 4.8.5.

- Chapters 17 to 20 and 23 to 26 cover specific topics, including Human Factors [12], Structural Integrity [13], Mechanical Engineering [14], Civil Engineering [15], Reactor Chemistry [16], Fuel Transport and Storage [17], Construction and Commissioning Approach [18] and Decommissioning Approach [19]. This chapter discusses general management arrangements which relate to the production of these SSEC chapters. Details of the specific arrangements associated with these topics is discussed within the specific chapter.

- Chapters 14 to 16 and 21 to 22 primarily relate to the nuclear safety assessments, including Safety/Design Basis Accident Analysis [20], Beyond Design Basis Analysis and Emergency Preparedness (including Severe Accidents) [21], Probabilistic Safety Assessment [22] and External [23] and Internal [24] Hazards. This chapter discusses the management arrangements which relate to the production of these SSEC chapters including ensuring appropriate competent personnel and the iteration between design and safety analysis. Specific arrangements related to the safety assessments, including methodologies and procedures, are discussed in the relevant chapters and reference should be made to the GDA Safety Assessment Handbook [25] which collates related methodologies. This is further discussed in sub-chapter 4.8.5.

4.1.3.4 MSQA interfaces with Environmental and Waste related chapters

- PSR Chapter B11 Environmental Protection [26] describes how the fundamental objective relevant to the environmental case is achieved. This is done by summarising the following PER Chapters - Chapter 1 Radioactive Waste Management Arrangements [27], Chapter 2 Quantification of Effluent Discharges and Limits [28], Chapter 3 Radiological Impact Assessments [29], Chapter 4 Conventional Impact Assessments [30], Chapter 5 Monitoring and Sampling [31] and Chapter 6 Demonstration of Best Available Techniques [32].

- Closely related to the PER Chapters is B10 Radiological Protection [33], B13 Radioactive Waste Management [34] and Chapter B26 Decommissioning [19]. For all these chapters, the MSQA arrangements, as summarised in this chapter, are utilised to provide confidence in the quality of the production and approval of the related documentation. The individual chapters define specific strategies / methodologies / approaches utilised in the GDA (e.g. Chapter B26 [19] is based on the Decommissioning Strategy and an assessment of decommissioning waste inventories which is suitable for a concept design). These aspects are not repeated within this chapter.

- Specific environmental topics which strongly relate to MSQA and key processes, such as the Approach and Application to the Demonstration of BAT [35], are discussed further in sub-chapter 4.8.5.

4.2 OVERVIEW OF HOLTEC LIFECYCLE MSQA

The Requesting Party (RP) for the SMR-300 GDA is Holtec International, with the GDA project being managed by Holtec Britain, the UK subsidiary of Holtec International, under Holtec International's corporate quality management framework. As discussed in PSR Part A Chapter 1 [1] and 2 [3], the SMR-300 design has been developed in the United States (US), by a specific project team with a view to building the FOAK SMR-300 at Palisades in the US state of Michigan. Holtec plans to take full advantage of the Palisades FOAK SMR-300 reference plant licensing process and make only necessary adaptations to support licensing within the UK.

The UK SMR-300 design and assessment is founded upon the SMR-300 Palisades design, developed in the US under Holtec International's arrangements. This chapter presents an overview of the following MSQA arrangements:

- Holtec International's overarching MSQA arrangements.
- Holtec International's SMR-300 project MSQA arrangements for design development.
- Holtec Britain arrangements for managing the GDA process.

Holtec's MSQA framework is built upon extensive experience in nuclear project management, spanning reactor design, plant operations, decommissioning, and manufacturing. The framework aligns with international standards, such as ISO 9001:2015 [36] and American Society of Mechanical Engineers (ASME) codes, ensuring compliance with regulatory requirements, including 10 CFR 50, Appendix B [37], encompassing the full lifecycle from concept design through deployment to decommissioning.

Noting the early lifecycle stage of the generic SMR-300, this chapter presents a comprehensive understanding of MSQA related topics relevant to the delivery of GDA Step 2, i.e. up to approval of the SSEC for the generic SMR-300. In addition, this chapter looks forward to subsequent lifecycle phases and outlines the approach to key MSQA topics. An overview of the SMR-300 lifecycle stages, illustrating the developing SSEC and the focus of this chapter is provided in Figure 1.

Note the definition of MSQA used within this chapter is consistent with that used in the ONR technical guidance document for the GDA, ONR-GDA-GD-007 [38].

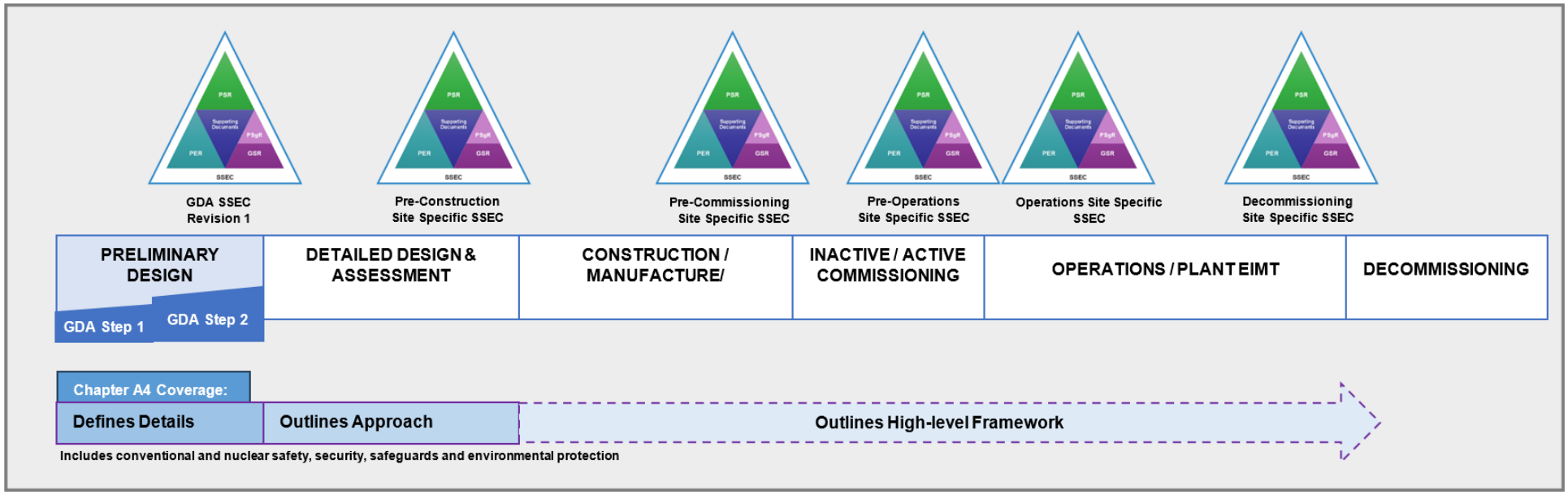

Figure 1: Overview of SMR-300 Through-Life Safety Case Strategy

4.3 LIFECYCLE MSQA CLAIMS, ARGUMENTS AND EVIDENCE

This chapter presents the Lifecycle MSQA aspects for the generic SMR-300 and therefore directly supports Claim 1.4.

Claim 1.4: Holtec has appropriate integrated project, quality, design and safety management arrangements to deliver a UK SMR-300 which is demonstrably safe and secure, protecting people and environment throughout its lifecycle.

Claim 1.4 has been further decomposed within this chapter to highlight key MSQA aspects related to the lifecycle of the generic SMR-300. The decomposition provides a structured and transparent approach to assessing the MSQA aspects across the generic SMR-300 lifecycle, ensuring clear accountability for different aspects of management and the consistent integration of MSQA considerations from initial design to future phases.

The Level 3 claims substantiated in this chapter are as follows:

Claim 1.4.1: Holtec has appropriate Quality Management arrangements to deliver a UK SMR-300.

Sub-chapter 4.5 discusses the Holtec quality management arrangements, describing the overarching Holtec Quality Management System (QMS) and MSQA framework.

Claim 1.4.2: Holtec has appropriate Project Management arrangements to deliver a UK SMR-300.

Sub-chapter 4.6 covers the Holtec project management arrangements pertinent to the development of the SMR-300 design and GDA projects, describing project control processes, organisational arrangements, document management, decision-making, governance, assurance and audit processes.

Claim 1.4.3: Holtec has appropriate Design Management arrangements to deliver a UK SMR-300.

Sub-chapter 4.7 sets out the Holtec design management arrangements, describing how the design development has been managed to ensure a safe and secure design which is compliant with safety and regulatory standards.

Claim 1.4.4: Holtec has appropriate Safety, Security and Environment Case management arrangements to deliver a UK SMR-300.

Sub-chapter 4.8 covers the Holtec SSEC management arrangements, describing how the management of the SSEC ensure appropriate quality.

Claim 1.4.5: Holtec has appropriate arrangements for future lifecycle phases to deliver a UK site-specific SMR-300.

Sub-chapter 4.9 covers the Holtec arrangements for future lifecycle phases, considering (as appropriate) how the MSQA arrangements will be developed beyond the GDA, focusing on ensuring a smooth transition from the GDA phase.

Table 1 shows the breakdown of Claim 1.4 and identifies in which chapter these claims are demonstrated to be met to a maturity appropriate for PSR Rev. 1.

Table 1: Level 3 Claims Covered by Chapter A4

Claim No.	Claim	Chapter Section
1.4.1	Holtec has appropriate Quality Management arrangements to deliver a UK SMR-300.	4.5 Holtec Quality Management Arrangements
1.4.2	Holtec has appropriate Project Management arrangements to deliver a UK SMR-300.	4.6 Holtec Project Management Arrangements
1.4.3	Holtec has appropriate Design Management arrangements to deliver a UK SMR-300.	4.7 Holtec Design Management Arrangements
1.4.4	Holtec has appropriate Safety, Security and Environment Case management arrangements to deliver a UK SMR-300.	4.8 Holtec SSEC Management Arrangements
1.4.5	Holtec has appropriate arrangements for future lifecycle phases to deliver a UK site-specific SMR-300.	4.9 Holtec Arrangements for future Lifecycle Phases

Appendix A provides a full Claims, Arguments and Evidence mapping for Chapter A4, which includes any lower-level claims, arguments and intended evidence needed to support the Claims in the table above.

4.4 LIFECYCLE MSQA CODES, STANDARDS AND METHODOLOGY

This sub-chapter outlines the codes, standards and methodologies used in the development of the MSQA arrangements for the generic SMR-300 design development and GDA projects. Sub-section 4.4.1 outlines the MSQA codes, standards and methodologies related to the SMR-300 design development in line with US regulatory guidance, while sub-section 4.4.2 focuses on the generic SMR-300 MSQA codes and standards that align with UK / GDA expectations.

PSR Part A Chapter 2 [3] provides an overview of significant codes and standards used in the design of the SMR-300. It includes the selected codes and standards that fulfil US Nuclear Regulatory Commission (NRC) requirements, as well as the strategy established for demonstrating compliance with UK Relevant Good Practice (RGP). Topic-specific codes and standards for each PSR chapter are listed in their respective sub-chapters.

4.4.1 SMR-300 Design Codes, Standards and Methodologies

The Holtec MSQA arrangements that have been used to develop the SMR-300 design have been developed in accordance with US NRC regulatory guidance and applicable US Code of Federal Regulations (CFR), American Society of Mechanical Engineers (ASME) standards, as well as international guidance from the International Organization for Standardization (ISO), as indicated in Table 2 below.

Table 2: SMR-300 MSQA Codes and Standards

Label	Title
U.S.NRC 10 CFR 50 Appendix B	Domestic Licensing of Production and Utilization Facilities Appendix B to Part 50 – Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants [37]
US NRC 29 CFR 1926	Safety and Health Regulations for Construction [39]
US NRC 29 CFR 1910	General Industry Occupational Health and Safety [40]
US NRC 29 CFR 1904	Recording and Reporting Occupational Injuries and Illnesses [41]
American National Standards Institute (ANSI) / American Industrial Hygiene Association (AIHA) Z10	Occupational Health and Safety Management Systems [42]
ISO 9001:2015	Quality Management Systems – Requirements [36]
ISO 14001:2015	Environmental Management Systems [43]
ISO 45001:2018	Occupational Health and Safety Management Systems [44]
ASME NQA-1	Quality Assurance Arrangements for Nuclear Facilities [45]
ASME Section III	Quality Assurance Programme [46]
ASME Section VIII	Quality Assurance Programme [47]
United States Nuclear Regulatory Commission Technical Report Designation (NUREG)-0800- Chapter 13	Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition – Chapter 13 Conduct of Operations [48]
U.S.NRC NUREG-0800- Chapter 17	Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition – Chapter 17 Quality Assurance [48]
Occupational Safety and Health Administration (OSHA)	Injury and Illness Prevention Program Guidelines [49]
International Atomic Energy Agency (IAEA) ISO Tecdoc-1335	Configuration Management in Nuclear Power Plants [50] (used as guidance for configuration management)

4.4.2 Development of the generic SMR-300 MSQA Arrangements

MSQA arrangements necessary to support the SMR-300 GDA and associated site licensing and permitting have taken account of UK legislation for nuclear facilities and international standards. This sub-chapter presents the key legislation, regulation and the guidance that has been followed to develop the MSQA arrangements for delivery of the generic SMR-300 GDA.

It should be noted that not all legislation, codes, standards and methodologies that are drawn upon in other SSEC areas are repeated, these are reported separately in each SSEC chapter. Notably, safety analysis methodologies for the development of the nuclear safety case to ensure compliance with UK expectations have been collated into the GDA Safety-Assessment Handbook [25] and are not repeated within this chapter (this interface is further discussed in sub-chapter 4.8.5.

To comply with ISO 9001:2015 [36] regarding the understanding of statutory and other requirements relevant to interested parties, the Holtec SMR-300 GDA Legal & Other Requirements document [51] has been developed. This Holtec Project Procedure (HPP) outlines the statutory, regulatory, and other applicable requirements for the Holtec SMR-300, along with the corresponding Holtec QA Procedures which address these requirements. Table 3 reports some of the legislative drivers listed in [51], which should be referred to for a more comprehensive list including regulations and guidance associated with conventional safety (e.g. Manual Handling Operations, Workplace, Electricity at Work). A list including UK Nuclear Site Health and Safety (NSHS) regulations and guidance, as well as RGP, is also reported in PSR Chapter B12 Nuclear Site Health and Safety and Conventional Fire Safety [10] with the detailed regulations and guidance sources not repeated here.

The Nuclear Installations Act 1965 (NIA) [52] sets out the licensing regime, which includes the attachment of conditions to nuclear site licences. The licence covers design, construction, commissioning, operation, and end of life / decommissioning for a nuclear power facility. Whilst the RP does not hold the formal duty holder responsibilities of a licensee during GDA, it is recognised that Licence Conditions 10 (Training), 12 (Duly Authorised and Suitably Qualified and Experienced Personnel (SQEP)), 14 (Safety Documentation), 17 (Management Systems), 20 (Modification to design of plant under construction) and 36 (Organisational Capability) are concerned with MSQA and are relevant to Steps 1 and 2 of a GDA.

The key Safety Assessment Principles (SAPs) relating to MSQA from the ONR SAPs for Nuclear Facilities [53] are summarised below. The associated guidance has been taken into account when developing the MSQA arrangements:

- MS 1 - Leadership and management for safety – Leadership.
- MS 2 - Leadership and management for safety - Capable organisation.
- MS 3 - Leadership and management for safety - Decision making.
- MS 4 - Leadership and management for safety – Learning.

Similarly, for the environment case reported in the PER, the Environment Agency's (EA) Radioactive Substances Regulation (RSR): Management and leadership for the environment: generic developed principles [54] and the associated guidance [55] have been considered when developing the MSQA arrangements.

When developing the UK SMR-300 security and safeguards requirements, ONRs Security Assessment Principles [56] and Nuclear Material Accountancy, Control and Safeguards Assessment Principles (ONMACS) [57] have been taken into account.

Further detailed requirements originate from the documentation shown below in Table 3.

Table 3: UK and International MSQA Guidance relevant to the generic SMR-300

Label	Title
HASWA 1974	Health and Safety at Work Act [58]
EA	The Energy Act 2013 [59]
NIA-65	Nuclear Installations Act 1965 [52]
-	The Nuclear Reactors (Environmental Impact Assessment for Decommissioning) Regulations 1999 [60]
HSE, IRR2017	Ionising Radiations Regulations 2017 [61]
DSEAR 2002	The Dangerous Substances and Explosive Atmospheres Regulations [62]
RRO 2005	The Regulatory Reform (Fire Safety) Order [63]
COMAH 2015	Control Of Major Accident Hazards Regulations 2015 [64]
CDM 2015	The Construction (Design and Management) Regulations 2015 [65]
-	The Management of Health and Safety at Work Regulations 1999 [66]
EPA90	Environmental Protection Act 1990 (EPA90) [67]
EPR 2016	Environmental Permitting (England and Wales) Regulations 2016 [68]
HSE, REPPIR19	Radiation (Emergency Preparedness and Public Information) Regulations 2019 [69]
NISR 2003	The Nuclear Industries Security Regulations (NISR) 2003 [70]
NSR 2019	The Nuclear Safeguards Regulations (EU Exit) 2019 [71]
HSG 65	Managing for Health and Safety Guidance [72]
L153	Managing health and safety in construction: Construction (Design and Management) Regulations. Guidance on Regulations [73]
LCs	Licence Conditions [74]
-	ONR Licensing Nuclear Installations [75]
-	ONR A guide to enabling regulation [76]
ONR SAPs	Safety Assessment Principles [53]
SyAPs	Security Assessment Principles [56]
ONMACS	ONR Nuclear Material Accountancy, Control and Safeguards Assessment Principles [57]
EA RSR	EA RSR: Management and leadership for the environment: generic developed principles [54]
-	Radioactive substances management: generic developed principles (Guidance) [55]
ONR-GDA-GD-006	ONR NPPs Generic Design Assessment Guidance to Requesting Parties [77]
ONR-GDA-GD-007	New Nuclear Power Plants: Generic Design Assessment Technical Guidance [38]
ONR, NS-TAST-GD-027	Training and Assuring Personnel Competence [78]
ONR, NS-TAST-GD-049	Licensee Core Safety and Intelligent Customer Capabilities [79]
ONR, NS-TAST-GD-051	The Purpose, Scope and Content of Safety Cases [80]
ONR, NS-TAST-GD-077	Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services [81]
ONR, NS-TAST-GD-096	Guidance on Mechanics of Assessment [82]
IAEA GSR Part 2	Leadership and Management for Safety (2016) [83]

4.4.3 Codes, Standards and Methodology Summary

There are differences in the way safety management arrangements are formulated for US and UK nuclear plant. A high-level, but wide-ranging, comparison between US and UK legislation is set out in the UK / US Regulatory Framework and Principles Report [84]. The comprehensive integration of US, UK, and international codes, standards and methodologies in Holtec's MSQA arrangements provides a robust foundation for delivering a UK SMR-300 which is demonstrably safe, secure, protecting people and the environment.

Adoption of US NRC regulations and comparison with UK regulators' expectations, including applicable SAPs and Technical Assessment Guides (TAGs), demonstrate adherence to established safety, security, environmental and QA principles. The incorporation of internationally recognised management system standards reinforces best practices in quality, safety and environmental management. The UK regulatory framework, including licensing under NIA-65 [52] and environmental permitting requirements, ensure that safety management arrangements consider the full lifecycle of the SMR-300. Throughout the PSR claims are made that Holtec comply with appropriate design codes, standards and methodologies to deliver a generic SMR-300 that protects people and the environment.

This section provides evidence that Holtec's arrangements for delivery of the SMR-300, and therefore satisfaction of Claim 1.4, have been built on established codes and standards, and that mechanisms are in place to identify and understand differences between US and UK approaches.

4.5 HOLTEC QUALITY MANAGEMENT ARRANGEMENTS

Claim 1.4.1: Holtec has appropriate Quality Management arrangements to deliver a UK SMR-300.

This sub-chapter provides the arguments and evidence in support of Claim 1.4.1. This sub-chapter has been further decomposed into four arguments to address the claim.

- Holtec International have an appropriate mission, vision and values to deliver a safe and secure UK SMR-300 (A1)
- Holtec International have an appropriate MSQA framework to deliver a safe and secure UK SMR-300 (A2)
- The SMR-300 Design Project has an appropriate MSQA framework to deliver a safe and secure UK SMR-300 (A3)
- The generic SMR-300 GDA Project has an appropriate MSQA framework to deliver a safe and secure UK SMR-300 (A4)

This claim and supporting arguments are met by Holtec International's Quality Management System demonstrating the hierarchy of arrangements flowing from the companies' mission, vision and values, through the Holtec Quality Assurance Programmes (QAPs), to the generic SMR-300 design and GDA projects.

Sub-chapter 4.5.1 gives an overview of the Holtec SMR-300 general Business Vision. Sub-chapter 4.5.2 introduces the overarching Holtec MSQA framework and its cascade into the GDA Project specific MSQA documentation. Sub-chapter 4.5.3 outlines the MSQA arrangements specific to the SMR-300 design development project. Finally, sub-chapter 4.5.4 outlines the MSQA arrangements specific to the generic SMR-300 GDA project and supporting the development of the SSEC (looking forward to the production of the detailed design and assessment in support of the Pre-Construction Safety Report (PCSR)).

4.5.1 Holtec International SMR-300 Business Mission, Vision and Values

Claim 1.4.1 – A1: Holtec International have an appropriate mission, vision and values to deliver a safe and secure UK SMR-300.

Holtec have a mature QMS and practical experience in the application of its MSQA arrangements in a range of nuclear projects with Holtec's experience including site management, plant operations, reactor design, decommissioning and product manufacture. Further information can be found at https://holtecinternational.com/products-and-services/ [85].

Evidence for Claim 1.4.1 – A1 are:

- Holtec International's vision for the SMR-300 is to provide "Clean Energy for our Future". This is clearly set out on its website [85] with defined high-level goals:
  - Safe & Secure – Next generation reactor with walk-away passive safety features for unconditional safety.
  - Economical & Efficient – Innovative design delivers high performance on a small footprint, with an impressive service life.

- Dependable & Reliable – Technology is deployable in any region worldwide, without relying on local electric grids.
- Environment-Friendly – Plant produces a steady source of carbon-free power from fission, meeting climate goals.

- This vision and the associated goals provide the context for the MSQA arrangements for the SMR-300 discussed within this chapter. The mission, vision and values of the company are illustrated in Figure 2.

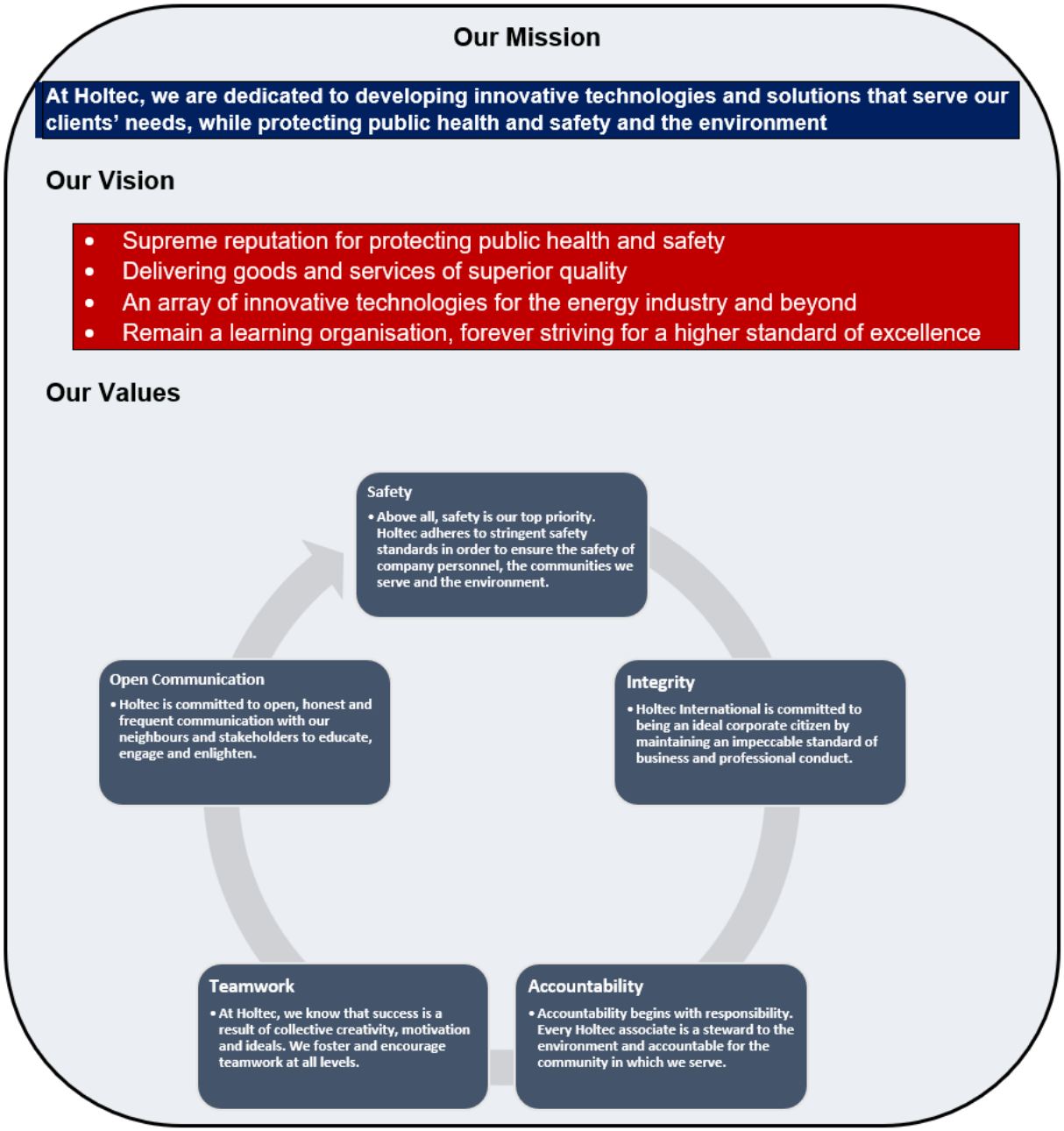

Figure 2: Holtec Company Mission, Vision and Values

4.5.2 Holtec International MSQA Framework

Claim 1.4.1 – A2: Holtec International have an appropriate MSQA Framework to deliver a safe and secure UK SMR-300.

The key evidence for demonstrating Claim 1.4.1 A2 is through Holtec's certificated QMS. The QMS meets the requirements of the BS EN ISO 9001:2015 standard [36] as well as the requirements defined in Part 50 of the US Code of Federal Regulations (10 CFR 50), Appendix B [37]. The requirements of the US NRC and the certificated QMS cover all aspects of QA relating to the SMR-300 lifecycle.

The Holtec QMS consists of Corporate Documents (CDs) setting out the overarching arrangements for effective quality management, assurance and governance for Holtec programmes. Holtec's CDs are top-level policy documents that establish the Holtec Quality Assurance Programme (QAP). The QAP is comprised of four distinct programmes:

- Nuclear Quality Assurance Programme (Holtec CD-03) [86] which sets out requirements to meet specific aspects of the CFR including 10 CFR 50, Appendix B [37] and ASME NQA-1 - Quality Assurance Requirements for Nuclear Facilities [45]. The program ensures that safety-significant Structures, Systems and Components (SSCs) and services meet compliance requirements through documented and controlled processes.
- ISO 9001 Quality Assurance Manual (Holtec CD-06) [87] with certification to BS EN ISO 9001:2015 Quality Management Systems [36]. The program ensures consistent product quality.
- ASME Section III Quality Assurance Programme Manual (Holtec CD-05) [88]. The program governs the design, procurement, and fabrication of nuclear facility components.
- ASME Section VIII Quality Assurance Manual (Holtec CD-08) [89]. The program provides detailed requirements for the design, fabrication, inspection, certification, and testing of pressure vessels.

CD-03 and CD-06 are most pertinent to the current design and assurance development phase of the SMR-300.

Holtec International are also certified to ISO 14001:2015 [43]. Registration of the Environmental Management System (EMS) incorporates Holtec's US sites. The Environmental, Health and Safety (EH&S) Management System Manual, CD-29 [90] provides the requirements for the EH&S system undertaken by the Holtec. The manual complies with ISO 14001:2015 and ISO 45001:2018 [44] for all applicable activities at each of the Company's divisions. These activities include the SMR-300 design development project which is based at the Camden site. Holtec Britain is also developing an EMS with the aim of gaining ISO-14001 accreditation.

The quality documentation is organised as follows:

- The top tier of the QAP is the Quality Assurance Manual (QAM) consisting of the CDs, a set of top-level policy documents establishing the corporate mechanisms for achieving and assuring quality. The Holtec QAM is not project specific.

- The second tier includes the Holtec Quality Procedures (HQPs). These set out how, for example, CD-06 will be implemented to meet specific clause requirements / activities under ISO 9001:2015. For example, HQP 3.0 [91] relates to Design Control. HQPs are not project specific.
- The third tier includes actionable instructions to individuals performing work and is comprised of a collection of Holtec Standard Procedures (HSPs) and HPPs. HSPs define general requirements aligned with CDs and HQPs, while HPPs are developed for specific projects.

The generic structure for the quality related documentation is illustrated in Figure 3 for the GDA Project (a similar cascade exists for the SMR-300 design project):

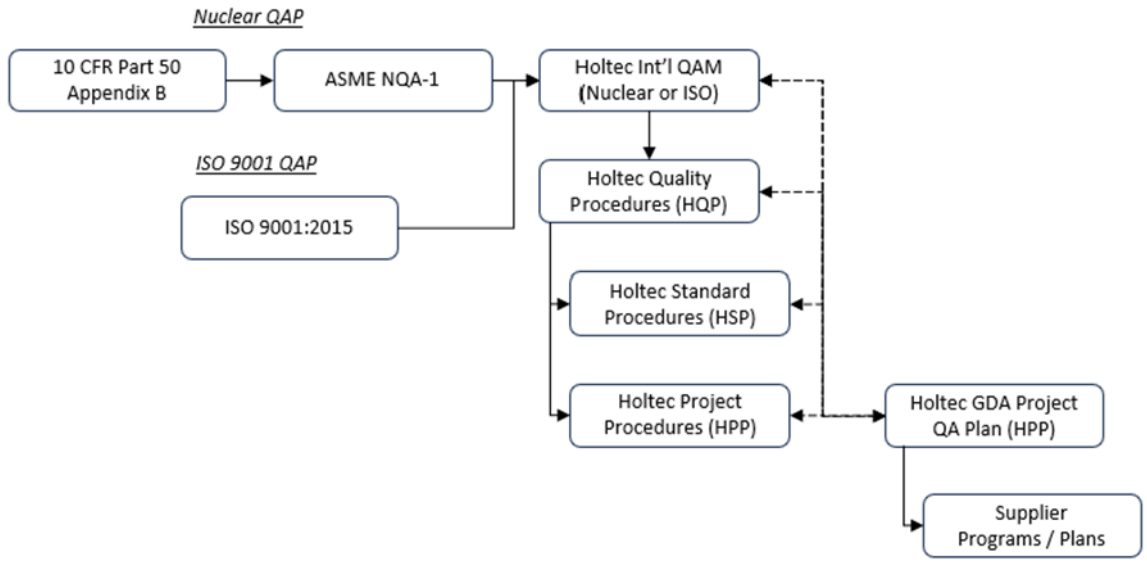

Figure 3: Illustration of Cascade of QA Arrangements to the SMR-300 GDA Project

Holtec's QAP provides a common framework for delivery of the generic SMR-300 design and GDA Steps 1 and 2 and will be the basis for the future development of the UK Site-Specific design.

Implementation of HSP-100206 (ISO 9001 - QA Program for Commercial Applications [92]) provides the mechanism for allowing HPP documents to be developed for specific projects. For example, the GDA Project Quality Plan (PQP) [93] is an HPP created under the HSP-100206 [92] as a quality plan for the generic SMR-300 GDA project, which in turn provides the framework for development of all process documents applicable to GDA. The GDA PQP builds on the existing Holtec QAP, focusing on areas that require modification or clarification to meet the GDA requirements. It provides an overview of the key HQPs and HSPs, and how these link to project specific HPPs pertinent to the delivery of the SMR-300 and later delivery phases.

As described in PSR Chapter A2 [3], the SMR-300 design development project evolved from the SMR-160 design development project and both link into the generic SMR-300 GDA project. Figure 4 illustrates the linkage between Holtec's QAP and the QA programmes associated with the SMR-300 design development and the GDA projects and the numbering used for the specific HPPs.

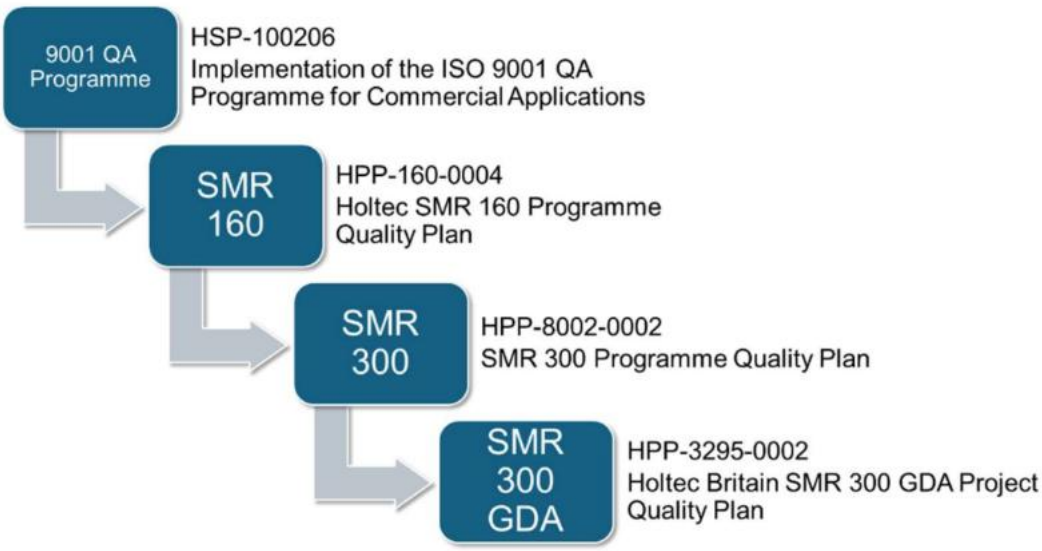

Figure 4: Relationship of SMR project specific QA Plans

The MSQA arrangements specific to the SMR-300 design development project are outlined in sub-chapter 4.5.3. The MSQA arrangements specific to the generic SMR-300 GDA project and supporting the development of the SSEC are outlined in sub-chapter 4.5.4.

An overview of the key HQPs and HSPs, and how these link to SMR-300 design and GDA project specific HPPs in the current and subsequent lifecycle phases is presented in the GDA PQP [93].

4.5.3 SMR-300 Design Project MSQA Framework

Claim 1.4.1 – A3: The SMR-300 Design Project has an appropriate MSQA framework to deliver a safe and secure UK SMR-300

Designed to meet the US NRC licensing requirements, the SMR-300 first deployment is planned at the US Palisades site. The design and assessment activities encompass the following major activities: preliminary and detailed design; preliminary analysis; development of a Preliminary Safety Analysis Report (PSAR); early engagement with nuclear regulators focused on the Palisades site; and physical testing to support for research, development and verification.

The principal sources of evidence supporting this argument are:

- SMR-300 Project Management Plan [94] guides the delivery of the SMR-300 Project. The PMP establishes the SMR-300 Project's scope, organisational framework, and performance plans. The activities set out in the PMP are to be performed in accordance with quality procedures outlined in the PQP, which implements applicable quality standards flowing from 10 CFR 50 Appendix B, ASME NQA-1 and ISO 9001:2015. The SMR PMP and PQP discuss and confirm compliance against specific criteria, e.g. document control.

- SMR-300 Project Quality Plan [95] - The PQP is supported by Holtec's Topical Report on the Quality Assurance Program for Holtec International's SMR Design and Construction (QAP TR) [96]. This provides a summary of the requirements defined within Holtec's QAP related to design, fabrication, construction, and testing activities for the SMR-300. Prepared in accordance with 10 CFR 50, Appendix B [37] and ASME NQA-1-2015 [45], as endorsed by Regulatory Guide (RG) 1.28 [97], it defines programmatic requirements that align with and expand upon requirements within [37] for applicable criteria including design and document control. The report supports a 10 CFR 50 Construction Permit Application and / or Limited Work Authorization in the US and serves as the primary document governing all important to safety (to include safety-related) activities at the Palisades project.

Subsequent phases of the SMR-300 project are defined for the construction and commissioning of the Palisades FOAK SMR-300 Nuclear Power Plant (NPP) in preparation for operations. Project specific HPPs for the SMR-300 design development / deployment of relevance to the GDA submission and development of the detailed design and assessments are captured in the GDA PQP.

4.5.4 Generic SMR-300 GDA Project MSQA Framework

Claim 1.4.1 – A4: The generic SMR-300 GDA Project has an appropriate MSQA framework to deliver a safe and secure UK SMR-300 (A4)

The SMR-300 design project provides the reference design for the generic SMR-300 GDA project, as explained in Section 4.7.7.1 The evidence items supporting this argument are principally the GDA PMP [98] and PQP [93]. These documents provide the management framework for the production and approval of the SSEC (based on the SMR-300 reference design) which is the primary Holtec deliverable from Step 2 of the GDA.

- GDA PMP [98] acknowledges nuclear safety is the primary objective and sets out the scope for the GDA project including Step 1 and 2 deliverables and the overall programme. It outlines key aspects such as organisational structure, project management, governance, funding, procurement, stakeholder management, document control process, project control, performance metrics, decision-making framework, and design assurance / control, all of which support of production of the SSEC documentation.

- GDA PQP [93] sets out how Holtec will meet the MSQA scope requirements to support the delivery of the generic SMR-300 GDA as well as other UK legal and other requirements in line with its accreditation to ISO 9001:2015 [36]. As explained in sub-chapter 4.5.2, in-line with corporate expectations, Holtec Britain works under the same QAP as Holtec International (both the Nuclear QAM [86] and ISO 9001 QAM [87] and their tiered implementing procedures). This is acknowledged by the GDA PQP [93] which signposts to relevant Holtec documentation and primarily focuses on areas that require modification, clarification or enhancement to support the delivery of the SMR-300 GDA Project. The areas of focus include Holtec Britain's organisation structure, nuclear safety culture, competence, communication, planning, quality assurance risks and opportunities, documentation control processes, SSEC management and

performance evaluation. The PQP also includes a view of all key processes relevant to the SMR-300 GDA delivery.

Where there is a need for GDA specific arrangements Holtec Britain produce, and implement, project specific procedures. For example, the HPP “Supplier Document Review, Approval and Integration” [99] clearly defines arrangements for the review and approval of GDA related supplier produced documentation to ensure their quality.

Where appropriate the PQP points to and is supported by documentation focusing on specific aspects. For example, the SMR-300 GDA Interested Parties Register and Issues Log [100] defines internal and external stakeholders outlines how their needs and expectations have been understood and monitored, in accordance with the requirements of ISO 9001:2015. The PQP also points to supporting processes / documentation which strongly relate to the GDA QAP and augment MSQA arrangements such as the SMR-300 Environmental Management Plan [101], Environmental Aspects Procedure [102] and the CDM Strategy [11].

The PQP also aims to provide confidence that Holtec has appropriate organisational knowledge, capability and arrangements to provide technical support, as the designer of the SMR-300, to the defined licensee / permit holder, during future design, construction, operation, maintenance and decommissioning phases (note that the post GDA Step 2 phases are further discussed in sub-chapter 4.9). This is partly achieved by providing an overview of Holtec’s wider QMS and the established arrangements (i.e. HQPs and HPPs) to ensure (for example) suitable manufacture and construction arrangements for nuclear classified SSCs.

4.5.5 CAE Summary

Holtec is an established project delivery organisation with a proven record on its many international projects including within the nuclear sector. Holtec’s QMS is mature and meets the requirements of ISO 9001:2015 and the US NRC, providing a framework for consistent high-quality delivery which encompasses nuclear safety expectations. The QMS is cascaded to the SMR-300 design and GDA projects as evidenced via the suite of Corporate Manuals, supporting HQPs and HSPs and the project specific PMP / PQPs and their supporting HPPs. The existing QMS provide a framework for the development of specific quality management arrangements to allow Holtec to support the delivery of the subsequent stages of the SMR-300 lifecycle. As such, Claim 1.4.1 is considered to be adequately met, commensurate with the project development stage.

4.6 HOLTEC PROJECT MANAGEMENT ARRANGEMENTS

This sub-chapter provides the arguments and evidence in support of the following claim:

Claim 1.4.2: Holtec has appropriate Project Management arrangements to deliver a UK SMR-300.

This sub-chapter provides the arguments and evidence in support of Claim 1.4.2. This sub-chapter has been further decomposed into four arguments to address the claim.

- Project control processes are in place to deliver a safe and secure UK SMR-300. (A1)
- Organisational arrangements are in place to deliver a safe and secure UK SMR-300. (A2)
- Document management processes are in place to deliver a safe and secure UK SMR-300. (A3)
- Decision-making, governance, assurance and audit processes are in place to deliver a safe and secure UK SMR-300. (A4)

The sub-chapter supports this claim and supporting arguments by providing an overview of the project control processes, organisational arrangements, document management, decision-making, governance, assurance and audit processes pertinent to the development of SMR-300 design and GDA projects. This focus is on the project phase through to the completion of GDA Step 2 noting that subsequent phases will see the engagement of the future licensee with Holtec supporting as the SMR-300 technology provider.

4.6.1 Project Control Processes

Claim 1.4.2 – A1: Project control processes are in place to deliver a safe and secure UK SMR-300.

Evidence to demonstrate this argument is met is provided through the PMPs for the SMR-300 [94] and GDA projects [98]. This is supported by project specific documentation which define project control processes covering the scope of work / activities, deliverables, planning and scheduling, cost management, risk / assumption / dependency management, schedule / resource management, data management on the respective projects. As described in sub-chapters 4.5.3 and 4.5.4 these arrangements work under the Holtec International QAP which fulfils the requirements of ISO 9001:2015 [36] which defines the need for project control processes.

The SMR-300 Project utilises an integrated project schedule to plan and execute work, as described the SMR-300 PMP [94]. The Project schedules are arranged with successive levels of detail, with successive layers articulating in greater detail the higher-level schedules.

4.6.2 Organisational Arrangements

Claim 1.4.2 – A2: Organisational arrangements are in place to deliver a safe and secure UK SMR-300.

The organisational arrangements pertinent to the SMR-300 design and GDA projects are summarised in the following sections:

- Section 4.6.2.1 – Organisational structure, roles and responsibilities.
- Section 4.6.2.2 – Competency and training.
- Section 4.6.2.3 – Nuclear safety culture.
- Section 4.6.2.4 – Stakeholder management and communication.
- Section 4.6.2.5 – Organisational learning and corrective actions.

4.6.2.1 Organisational Structure, Roles and Responsibilities

Evidence supporting the argument includes:

- HQP-1.0 Organization and Responsibilities [103] - The Holtec International quality management framework defines general requirements for organisational definition with more detailed requirements within supporting standard procedures including HSP-100101, Organization [104].

- The SMR-300 PMP [94] describes the organisational framework for the SMR-300 design project and associated key responsibilities. This is supported by the PQP [95] which confirms compliance with the QMS and defines further information on responsibilities including on Design Authority (DA) (further discussed in sub-chapter 4.7.1) and organisational aspects such as the cascade of QMS requirements to contractor organisations involved in nuclear safety related activities. Further information on functional and role responsibilities and organisational interfaces for the SMR-300 design / deployment at the Palisades site is provided in the QAP TR [96].

- SMR-300 Division of Responsibility Procedure [105] describes the SMR-300 project scope and division of responsibility (DOR) for entities performing design, engineering, procurement, fabrication, construction, installation and commissioning of the SMR-300 in the US.

- The Holtec Britain organisation structure, along with key roles and responsibilities for delivery of the generic SMR-300 GDA, is described in the GDA PMP [98] with additional quality focused information in the GDA PQP [93]. In certain areas the organisational structure is specifically defined for further clarity, e.g. SSEC production, review and approval [106] and security organisation. The organisation has developed to meet the resourcing requirements for delivery of the GDA Step 2.

In defining the roles and responsibilities, the DA function provided by the SMR-300 design team is recognised, as is the need to fulfil the ONRs Intelligent Customer (IC) expectations [79]. Hence, although Holtec Britain are not a licensee, competent personnel with UK domain knowledge are employed to manage SSEC development, to act as primary contacts with regulators and, for example, to review / approve work by technical support providers. Holtec Britain personnel are supported in the delivery by personnel from well-established, competent nuclear supply chain companies in addition to the wider Holtec International organisation, which as noted above provides the current DA function as part of the wider SMR-300 delivery programme.

The SMR-300 DA owns the SMR-300 design and has arrangements to control design work performed by external suppliers, delivering an IC capability for the SMR-300 design project. The principal SMR-300 evidence for this is provided through HPP-8002-0030, SMR-300 Supplier Document Acceptance, Review, and Integration [107]. Holtec International

management of the supply chain is managed through HQP-7.0, Control of Purchased Items and Services [108] and, in particular, Vendor Selection [109], the Approved Vendor List [110] and Vendor Surveillance [111] which require demonstration of compliance with Holtec's requirements. Holtec Britain are also able to demonstrate they are the Intelligent Client for UK work conducted to deliver the SSEC including having a clear line of sight from the SSEC to the underpinning justification evidence. Evidence of this control is explained in Section 4.6.3 on Document Management and Section 4.8.3 on SSEC Production Arrangements.

Future roles and responsibilities for deployment of the SMR-300 in the UK, including DA and Responsible Designers, are still to be determined. Further organisational development post-GDA is discussed in sub-chapter 4.9.

4.6.2.2 Competency and Training

Holtec have well-established requirements for determining training and qualification under the Nuclear QAM [86] and ISO 9001 QAM [87] which includes a number of standard procedures pertinent to the production of the design and SSEC, for example HSP-100203, Training Programs [112] and HSP-100303, Design and Analysis Personnel Qualifications [113]. These company arrangements provide the framework for assuring the competency and training of personnel involved in all aspects of the SMR-300 initiative.

The SMR-300 PMP and QAP TR [96] confirm compliance with the standard training and qualification requirements and note that qualifications for personnel involved in the SMR-300 design and assessment activities for specific activities is conducted in accordance with the Design Standard for the specific discipline, as explained in Section 4.7.2.1. Personnel assigned to perform design activities and to implement elements of the SMR QAP TR are qualified to perform their assigned tasks. The Company establishes and maintains formal induction, training, and qualification as necessary for personnel performing, verifying, or managing activities within the scope of the SMR QAP TR to achieve initial proficiency, maintain proficiency and adapt to technology changes, methods, or job responsibilities. The induction, training, and qualification programs are commensurate with scope, complexity, and importance to safety of the activities. Management oversight is paramount to ensuring personnel obtain the appropriate qualifications and are qualified to perform tasks assigned.

The training includes introduction to the QA system; On-the-Job Training (OJT), with assignment of a mentor; task specific qualifications; periodic training combining refresher training, project and targeted technical training; lessons learned and operational experience via pre-job brief and post-job reviews and company-wide distribution of lessons learnt. In addition, the SMR-300 Human Factors Engineering program [114] includes staffing and qualification analysis to determine the required number, and necessary qualifications of, personnel to complete tasks while meeting all regulations.

The generic SMR-300 GDA PMP [98] and PQP [93] note that Holtec Britain augments compliance with the established quality framework for training and qualification with a project specific competency and training procedure [115]. This requires a range of activities to ensure competent personnel including on-boarding of new staff; OJT; assessing the competency and experience of newly assigned personnel; identifying and managing training needs; safety case role qualification and ensuring compliance with regulatory requirements. Arrangements are in place to record the training / competency assessments and refresh where appropriate. Where

an individual is deployed in authoring, reviewing or approving the SSEC related reports, the SQEP evidence of individuals is captured in the quality records [116].

In support of the GDA project, additional training in UK context and regulatory framework has been produced on the GDA process, the ONR SAPs [53], ONR Security Assessment Principals (SyAPs) [56], and the EA's RSR: objective and principles [54]. Specific training on UK context has also been delivered to the US SMR-300 design teams, for example on ALARP and BAT and training on CDM 2015 requirements within the design development is being developed. This is to ensure that US SMR designers and leadership are aware of UK regulatory and licensing requirements and can appropriately support approval of the UK SMR-300 referenced design.

4.6.2.3 Nuclear Safety Culture

Holtec ensure a strong nuclear safety culture through on-boarding and refresher training via the implementation of its specific Safety Culture Monitoring Program, HSP-1013 [117]. Safety is a key feature of the Company Mission, Vision and Values (refer to Figure 2) and Holtec subscribes to the Institute of Nuclear Power Operations (INPO) Safety Culture Traits [118]. These traits are embodied in daily activities and reinforced by senior leaders and managers via focused nuclear safety monthly presentations, pre-meeting safety messages and regular enforcement of individuals responsibilities to ensure nuclear safety.

The development of the SMR-300 design itself is led by Holtec's design team members who have a focus on nuclear safety. Where specialist supply chain companies are used in the design development, Holtec has processes in place to ensure these companies demonstrate an effective nuclear safety culture through the DA's oversight of supply chain, as evidenced in Section 4.6.2.1.

Within the GDA project, nuclear safety culture is recognised as important within the PMP [98] and PQP [93] and is ensured by the following arrangements:

- Competency and training procedure [115] requires employees and embedded contractors to complete onboarding QA training, which includes nuclear safety culture;
- A Supplier Deliverables and Assurance Procedure is being developed to oversee effective nuclear safety culture within supply chain companies. This is executed through the Audit Programme [119] and considers compliance with nuclear safety expectations.

4.6.2.4 Stakeholder Management and Communication

The Holtec organisation recognises that project success is built on trusted relationships, strong communication and effective transfer of information between all key stakeholders. The generic SMR-300 GDA PMP [98] defines key stakeholders and their interactions, as illustrated on Figure 5. Holtec's project management processes ensure effective communication with these stakeholder groups.

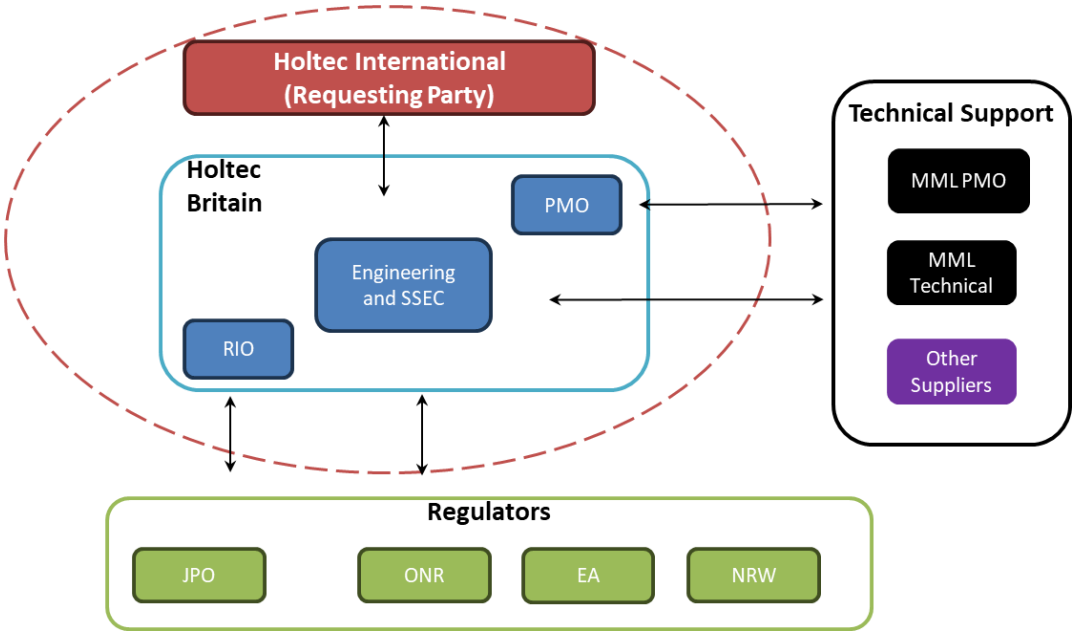

Figure 5: Illustration of key project stakeholders / interfaces

Holtec recognise that regulatory interactions are key to the success of the GDA (and beyond). Holtec Britain manage the interface with the regulators (ONR, EA and Natural Resources Wales (NRW)). To manage the interface, a Regulatory Interface Office (RIO) and Project Management Office (PMO) have been established meeting ONR expectations in [120]. Details of document transmittals and written exchanges, the frequency and type of meetings with the regulators and other stakeholders is captured in the SMR-300 GDA PMP [98] with additional information in the PQP [93].

Topic engagement meetings between the project and regulators are worthy of note as they are of particular importance to the success of the GDA. These technical meetings facilitated technical dialogue across safety, environmental and security and safeguard topics. Early in the GDA, Topic Engagement Plans (TEPs) were produced which, subsequently, informed the technical scope of the GDA. Each TEP is owned by a Topic Lead and overseen by a Responsible Manager. TEPs will be maintained to support future lifecycle phases and business planning activities post GDA Step 2. Outcomes arising from these regulatory topical engagement sessions are recorded and confirmed with the regulators and Holtec Britain through issuing to the Joint Programme Office (JPO), the regulators point of contact for GDA, as described in the PQP [93].

4.6.2.5 Organisational Learning and Corrective Actions

Holtec's quality framework includes a series of QA documents related to non-conformance and corrective actions which meet the requirements of the US NRC HQP-15.0 Control of Nonconforming Conditions [121] and HQP-16.0 Corrective Action [122] and associated HSPs. This drives continuous improvement activities, following the Plan-Do-Check-Act process. The SMR-300 programme has also implemented it's own Corrective Action Program (CAP). HPP-8002-0014 - SMR-300 Corrective Action Program: Issue Identification and Resolution [123]. This procedure establishes guidance for roles, responsibilities, and implementation of the

Holtec CAP for SMR activities. CAP issues (e.g., those affecting nuclear safety, quality, or compliance) are documented, managed and resolved by the CAP.

Via the quality framework, Holtec have established arrangements for operational learning and corrective actions building on their extensive experience in the design and safe operation of nuclear systems. Notably, the Holtec SMR-300 design builds on decades of experience in the safe operation of Pressurised Water Reactor (PWR) nuclear plants utilising information from IAEA and US NRC sources including from [124] and [125]. Information, learning and operational experience from the wider nuclear industry is distributed across the Holtec business in the form of General Briefs, Safety Work Stops etc. If changes are required to the Management System as a result of learning this will be similarly communicated and, if considered necessary, formal training is instigated.

Holtec have also established measures and governing procedures to promptly identify, control, document, classify, and correct conditions adverse to quality. Holtec procedures require all personnel to identify such conditions and procedures assure that significant conditions are documented in Holtec's corrective action program in order to allow for identification of cause and determination of actions to prevent recurrence. Significant conditions adverse to quality, significant adverse trends, the cause of the condition, the corrective actions taken are documented and reported to responsible management. The SMR-300 GDA PMP [98] and PQP [93] provide further details of Holtec's approach to organisational learning and corrective actions.

Notably, the Palisades build programme in the US will provide valuable Learning which will be fed into the detailed design and then implementation phases of the UK SMR-300. The process of sharing information / experience between the US project / design team and Holtec Britain is ongoing with information shared in a variety of forums including team alignment meetings, risk and decision meetings. Moreover, personnel from the Holtec Britain project are engaged with the SMR-300 design development project.

4.6.3 Document Management Processes

Claim 1.4.2 – A3: Document management processes are in place to deliver a safe and secure UK SMR-300.

Holtec's QMS is built on robust document management system, which is underpinned by the following evidence:

- HQP-5.0 Instructions, Procedures and Drawings [126];
- HQP-6.0, Document Control [127];
- HQP-17, Quality Assurance Records [128];
- HSP-101701, Quality Records [129];
- HPP-8002-0023, SMR-300 Document Control [130];
- HPP-8002-0030, SMR-300 Supplier Document Acceptance, Review, and Integration [107]
- HPP-3295-0047, GDA Internal Document Control Procedure [131]
- HPP-3295-0009, GDA Supplier Document Review, Approval and Integration Procedure. [99]

These procedures define general requirements for document production, management and record keeping. The SMR-300 Palisades PQP [95] confirms compliance with these requirements and defines project specific requirements on aspects such as supplier document review, approval and integration. This is supported by the QA Licensing Topical Report (HI-2230815), which presents evidence of the document management arrangements to meet NRC requirements.

HPP-8002-0023, SMR-300 Document Control [107] establishes document control, which is the act of assuring that documents are reviewed for adequacy, approved for release by authorised personnel, and distributed to and used at the location where the prescribed activity is performed. This procedure establishes the necessary measures to control the preparation, issuance, and revision of documents that specify quality requirements or prescribe how activities affecting quality, including organisational interfaces, are conducted to ensure that correct documents are being employed. This procedure provides instructions to prepare, review, approve, assign Quality Class, and control documents.

The SMR-300 GDA PQP [93] also confirms compliance with these corporate requirements and, along with the GDA PMP [98], provides more detail on document production, management and record keeping for the GDA Project. Key aspects are summarised below:

- A Document List (DL) is maintained which provides details of all documents that have been submitted to the regulators, including responses to Regulatory Queries (RQs), Regulatory Observations (ROs) and Regulatory Issues (RIs). A Master Document Submissions List (MDSL) [132], as a subset of the DL, is also available to precisely define what constitutes the latest versions of the GDA submission. In addition, an internal Submission List (SL) which contains all documents being produced through GDA, including those that are not to be submitted to the regulators is also maintained. The management arrangements around these documents are detailed in the GDA PMP. The arrangements are consistent with the expectations within ONR-GDA-GD-006 [77].
- All documents produced for the SMR-300 GDA Project are subject to Holtec documented information quality assurance processes. This is augmented by specific arrangements [99] to ensure documents meet the scope of the GDA, support the specific topic area and are written, reviewed and approved by SQEP individuals, providing a level of independent challenge from competent personnel who are experienced in the requirements of the UK regulatory system.
- HPP-3295-0047, GDA Document Control Procedure [131] and HPP-3295-0009, GDA Supplier Document Review, Approval and Integration procedure have been developed to manage GDA document production and quality.
- All approved documents are held on Holtec's established document management system (HIDOC), which provides the common data environment for the GDA project and wider company.
- For the GDA (and beyond), periodic sampling of incoming supplier documents will be conducted with results retained and key performance information included in the GDA Quality Performance Register, including information to demonstrate that authors, reviewers and approvers are SQEP. Where nonconformities are identified, these are recorded, and a corrective action issued against the supplier identifying required improvements and timescale for demonstrating compliance. Supplier SQEP and QA

arrangements for authoring, review and approval of their documents transmitted to Holtec will also be reviewed during supplier audits.

4.6.4 Decision-Making, Governance, Assurance and Audit Processes

Claim 1.4.2 – A4. Decision-making, governance, assurance and audit processes are in place to deliver a safe and secure UK SMR-300.

4.6.4.1 Governance and Decision Making

Holtec define requirements for governance and decision-making under HQP-1.0 [103]. Design decisions and the associated MSQA arrangements are discussed in sub-chapter 4.7. A Project Board, consisting of senior US and UK personnel, was specifically established for the generic SMR-300 GDA project to provide decision-making authority, as described in the GDA PMP [98]. The Project Board sets the framework for authority and accountability that determines how the project will make, communicate, and implement strategic decisions and solve problems that may arise during the project lifecycle. The Board also has governance responsibilities to monitor and oversee the resource plan, recommending adjustments to resources and their allocation. Due to the strong interface with the US SMR-300 design development activities, a US Project Manager is specifically embedded within the Holtec US SMR programme who has liaison responsibility between the US and UK programmes.

4.6.4.2 Assurance and Audit

Holtec have established arrangements for assurance and audit under the HQP-2.0, Quality Assurance Programme [133] and HQP-18.0, Audit [134], satisfying the requirements of ISO 9001 [36] and ASME NQA-1 [45].

The specific assurance and audit arrangements necessary to support delivery of the SMR-300 design activities are set out in the PQP [95] supported by the QAP TR [96]. This includes Holtec's assurance activities for SMR-300 design stages which provide the GDA SMR-300 Design Reference Point (DRP), as well as the arrangements ensuring SQEP individuals are involved in the design and review / analysis processes. Senior leadership and other engagement around the GDA have ensured that SMR-300 design team personnel have increased awareness of the UK specific assurance requirements around ALARP, BAT and the licensing arrangements providing increased confidence that these aspects will be embedded in the SMR-300 design development. Specifically, from a radiological perspective UK personnel have been involved in the review of the radiological design standard providing confidence that the approach is consistent with ALARA.

The SMR-300 PQP [95] sets out the specific assurance and audit arrangements associated with the GDA when reviewing the reference design packages and proposed design changes including definition of the reference design, production and approval of the SSEC and the consideration of UK licensing and permitting requirements, including ALARP and BAT. The associated assurance aspects are discussed further in sub-chapters 4.7 and 4.8.

HPP-3295-0038, Holtec SMR-300 GDA Audit Programme sets out the GDA project audit arrangements. This covers aspects such as the adequacy of safety culture monitoring, supply chain SQEP, QA records, design change management and CARs Register. Specific review arrangements were also defined to determine the readiness to progress into GDA Step 2 [135]. These readiness reviews were specific milestones placed on the project schedule to

demonstrate compliance with Holtec Britain MSQA arrangements, and to also satisfy regulatory expectations. As the SMR-300 project is not expected to progress into GDA Step 3 activities there are no specific readiness review arrangements for this transition. Post GDA activities are discussed in Section 4.9.

4.6.5 CAE Summary

This sub-chapter presents Holtec's project management arrangements in place to support successful delivery. It outlines the MSQA arrangements for various project management topics at the company level and their implementation within the SMR-300 design and GDA projects, providing the basis for assessing their adequacy.

In summary, all aspects considered were found to have appropriate arrangements in place for the delivery of the Step 2 GDA. As such, Claim 1.4.2 is considered to be adequately met, commensurate with the project development stage.

Further development of the project management arrangements for the subsequent stages is recognised as being required. In particular the project management arrangements for the transition to the post Step 2 GDA phase, i.e. the development of the Generic Pre-Construction SSEC, is required to be developed in conjunction with the SSEC approvals. This is further discussed in sub-chapter 4.9.

4.7 HOLTEC DESIGN MANAGEMENT ARRANGEMENTS

Claim 1.4.3: Holtec has appropriate Design Management arrangements to deliver a UK SMR-300.

This sub-chapter provides the arguments and evidence in support of Claim 1.4.3. Claim 1.4.3 is decomposed into arguments. The structure of this section is aligned closely with the SMR-300 Design Control Procedure [136] to cover the following arrangements which, as a whole, ensure that a safe and secure design is delivered:

- Design Authority (A1);
- Design Inputs and Requirements Management (A2);
- Design Control (A3);
- Design Interfaces (A4);
- Design Analysis, Verification and Validation (A5);
- Design Change (A6); and
- Reference Design (A7).

Design Control is a fundamental part of Holtec's management system under HQP-3.0 [91], which forms part of Holtec's QMS certification to ASME NQA-1 [45]. Delivery of design management arrangements for the SMR-300 is initiated from the SMR-300 PMP [94] . The PMP signposts to the relevant requirements and defines the scope of each technical discipline within the SMR-300 Palisades Project.

The following evidence is presented to demonstrate that suitable design controls are in place for delivery of the SMR-300 reference design:

- HQP-3.0, Design Control [91] and HSP-100301, Design Control [137] define Holtec's requirements for design control to ensure the overall acceptability of a specific design.

- HSP-100302, Design Specifications and Design Criteria Documents [138] establishes quality procedures for the preparation, review, approval, and retention of Holtec generated design specifications and design criterion documents, which is applicable to the SMR-300.

- HPP-160-3037, Design Evolution & Freeze for SMR 300 [139]. Early in GDA Step 1, the SMR design was modified to a 300 MWe design incorporating pumped circulation. This procedure was used to control transition of the design from the SMR-160 to SMR-300 to establish a new reference design at a conceptual level. This process is no longer in force though demonstrates evidence of early control in transitioning from SMR-160 to SMR-300.

- HPP-8002-1010, SMR-300 Design Control [136]. Consistent with the SMR-300 PQP [95], this procedure complies with HQP-3.0, HSP-100301, HSP-100302 and HSP-100303, Design and Analysis Personnel Qualifications [113]. This procedure defines the controlled, logical, systematic, comprehensive flow and hierarchy of design information to integrate and transform design inputs into design outputs for the SMR-300 project. The procedure describes the requirements and measures to assure that applicable regulatory requirements and the design basis, as defined in 10CFR50 Part

B Criterion III and as specified in the license application, for those structures, systems, and components are correctly translated into specifications, drawings, procedures, and instructions for the Palisades SMR project. The procedure defines technical disciplines against which design milestones, reviews and standards are set. Further description of the Design Control Procedure is provided in Section 4.7.3.

- HPP-8002-5008 Numbering, Coding, Tagging and Plant Breakdown Structure [140]. This procedure defines the SMR-300 plant and system breakdown structure and underpins the GDA Scope and GDA DRP [141].

- HPP-8002-0003, Design Decision and Risk Management Procedure [142]. Owing to the maturity of the SMR-300 design, proportionate configuration control is used to ensure control over design change. The requirements for configuration control are defined in [136]. This is further explained in Section 4.7.6.

- HPP-3295-0017, Design Management Procedure [143]. This procedure presents the process for managing changes to the SMR-300 design and is further defined in Section 4.7.6.

The arguments presented above are considered appropriate and proportionate for the current stage of SMR-300 design maturity. Prior to entering the further design phase development for UK deployment of the SMR-300, a comprehensive suite of UK design management arrangements will be implemented, that build on the arrangements identified in this PSR and align to ISO 15288, System Lifecycle Processes [144]. This will facilitate a technical governance approach that considers the roles of a UK Design Authority, Licensee and other stakeholders. This is addressed as a commitment within this section of the Chapter A4.

4.7.1 Design Authority

Claim 1.4.3 – A1. Design Authority arrangements are suitable to deliver a safe and secure UK SMR-300.

The SMR-300 DA is defined within SMR-300 PMP [94] and HPP-8002-5002, SMR-300 Division of Responsibility Procedure [105]. Holtec International, as the Requesting Party, serves as DA for the SMR-300 Palisades project and for the UK GDA. The DA is responsible for maintaining a consistent, coherent, and complete design basis record in-line with defined design requirements. The US-based SMR design team have detailed knowledge of the design and assessment of the SMR-300.

The DA is responsible for ensuring the consequences of any design decision are understood and for governing the acceptability of key deliverables. This is accomplished through several complementary processes to ensure that:

- The responsibilities of all stakeholders are clearly understood.
- Clearly defined design requirements are established.
- Project execution and design control measures are established to ensure design documentation created by Company personnel and other organisations are consistent, correct, and complete.

- Design changes are systematically evaluated in a manner appropriate for the potential level of significance, level of risk, and level of impact.
- Supplier documentation contributing to the design basis record is understood and evaluated for acceptance in a systematic manner based upon the safety significance of the scope, the qualifications of the supplier, and associated risk.
- Access to the necessary engineering and scientific skills and knowledge commensurate with the scope of design activities is ensured.

Key procedures supporting the delivery of DA capability include:

- HPP-8002-0023, SMR-300 Document Control [130]. Described in Section 4.6.3
- HPP-8002-0030, SMR-300 Supplier Document Acceptance, Review, and Integration [107]. Described in Section 4.6.3.
- HPP-8002-0006, SMR Procedure for Pre-Job Briefs and Post-Job Reviews [179] promotes error prevention and detection behaviours with quality self-review and dialogue. It is used to identify design interfaces, ensures competent personnel are assigned to the task and promotes understanding of what to accomplish and what to avoid. It also provides an opportunity to raise awareness of important activities (work and mitigation) and to mentally rehearse the performance of assigned activities.

Holtec Britain do not intend to be the licensee or operator for the SMR-300 in the UK. It is expected that Holtec will be a Responsible Designer for the SMR-300, which is stated as an assumption (A_MSQA_035) in Holtec's CAR Register [5]. The UK licensing organisation and therefore Design Authority for the UK SMR-300 is not yet defined. Following the GDA, the knowledge within Holtec (and its subcontractors) will be required to transfer to the future licensee, as required to meet UK licensing requirements.

4.7.2 Design Inputs and Requirements Management

Claim 1.4.3 – A2. Design Inputs and Requirements Management are suitable to deliver a safe and secure design

4.7.2.1 Design Inputs

Clearly defined design inputs are essential to form the foundation of the design process and to ensure that the final design is accurate, complete, and verifiable. Design inputs must be identified, derived from valid sources such as design requirements, regulatory requirements, codes, standards, and the design basis, documented, reviewed, and approved to avoid ambiguity and ensure consistency throughout the design process. The design inputs are specified to the level of detail necessary to permit the design activities to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes. Figure 6 shows the SMR-300 design document hierarchy, as defined in Design Control Procedure.

Properly specifying design inputs:

- Ensures compliance with applicable regulations and standards
- Reduces risk of design errors or costly rework
- Supports traceability from requirements to final product
- Facilitates verification and validation of design outputs

- Promotes clear communication among all stakeholders

The Design Control Procedure [136] describes and provides instructions to ensure the above requirements are met for design inputs for the Palisades SMR project. Specifically, the procedure instructs the control of design inputs, via measures such as Design Standards, PJBs, personnel qualifications (i.e., Preparer, Reviewer, and Technical Discipline qualifications), the Design Integration Review (DIR) process, and design verification. This procedure also establishes and describes the hierarchy of design requirements.

Design requirements should begin with top-level regulatory and licensing requirements, followed by applicable codes and standards, project-specific design criteria, and technical specifications.

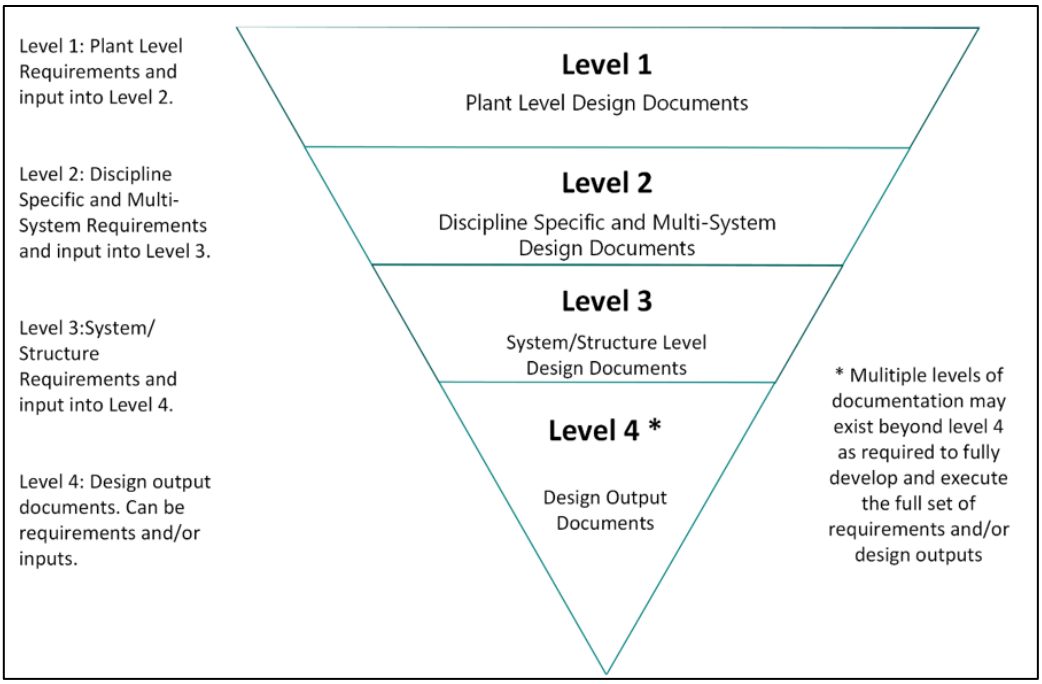

Figure 6: **SMR-300 Design Document Hierarchy**

4.7.2.2 SMR-300 Requirements Management

This section should be read in conjunction with Section 4.7.3.5 on Configuration Management and Section 4.7.6.7, Future UK Design Management.

The SMR-300 Top Level Plant Design Requirements document, HI-2240251 [145] , records the top-level requirements, which forms part of the GDA Reference Design. The Electric Power Research Institute's (EPRI) Utility Requirements Document (URD) is the primary source of requirements and design intent used within this document. Holtec's interpretation of the top-level requirements from the URD is described herein and the URD further supports the development of the SMR-300 design philosophy. EPRI URD guidance encompasses both industry experience and current regulations to present a clear, complete statement of requirements for the next generation of nuclear plants. Electric Power Research Institute, Report No 3002003129 Advanced Nuclear Technology: Advanced Light Water Reactor Utility Requirements Document Revision 13, 2014.

As defined in the GDA DRP [141], system requirements are identified for each system through System Requirement Notebooks and Operating Condition Notebooks. These were originally produced in accordance with HPP-160-3033, System Requirements Notebook Development [146] and HPP-160-3034, System Operating Conditions Notebook Development [147]. System Operating Condition Notebooks provide requirements, typically based on sizing calculations and technical reports. System Requirement Notebooks typically provide a more detailed breakdown of requirements from the EPRI URDs but may also capture requirements from the following sources:

- Safety requirements.
- Information derived from previous similar design and development activities.
- Statutory and regulatory requirements.
- Standards and codes of practice.
- Potential failure modes or to address potential consequences of failure.
- Lessons learned and operational experience.

In addition, cross-cutting SMR-300 requirements are also defined within project-wide Design Standards. Such documents provide project-specific guidance and requirements for specific design aspects, signposting to design specifications. See SMR-300 Design Standard for Civil-Structural Workflow [148] as an example. The index of applicable project design standards is provided in PSR Part A Chapter 2 [3] and referenced from the DRP [141]. These standards continue to be developed through implementation of the Design Control Procedure. SMR-300 requirements are currently managed through a requirements datafile. Holtec consider that the aforementioned arrangements provide suitable and sufficient evidence that requirements have been identified appropriate for this stage of SMR-300 design maturity and the PSR.

Through the SMR-300 Design Control Procedure [136], Holtec is transitioning to a new requirements framework. Requirements management will be aligned to the structure in the Design Document Hierarchy, as shown in Figure 6 and further explained below:

- **Level 1** – SMR-300 Top Level Plant Design Requirements Document [145]
- **Level 2** – Specifications are created for the purpose of detailing requirements that must be met. Including, but not limited to a customer contract specification, licensing document, purchasing specification or design specifications in accordance with HSP-100302 [138]. SMR Specifications are used to define general characteristics and design philosophy requirements for the SMR-300.
- **Level 3** – System Design Requirement (SDR) documents will be created to a document used to house all design requirements for a specific SMR-300 system and will flow down from Level 1 and 2 documents. Implementation of SDRs is considered part of the commitment to fully implement the Design Control Procedure (C_MSQA_107).
- **Level 4** – Design Document(s): A design document that translates the plant-level, discipline-specific, and system-level design input documents into detailed design output documents. Examples include drawings, calculations, and SDDs.

The management of requirements will be proceduralised through a System Design Requirements Development and Management Procedure as part of the Requirements Management Tool and full implementation of the Design Control Procedure [136] – see Commitment C_MSQA_107. This will require SDR documents to be created and maintained

for each system in the SMR-300 design, which will be based on existing documentation as discussed above. This will further improve the integration of requirements and is linked to project milestones, see Section 4.7.3.1. As such, evidence cannot yet be presented to show full implementation of Claim 1.4.3 and therefore a GDA commitment has been raised.

Holtec is also developing a SMR-300 requirements management framework that shall document, communicate and control requirements (or constraints) that stem from the design, safety case or any other aspect throughout the lifecycle of the project. Requirements management and the associated verification and validation efforts will ensure that the plant can be operated safely for its design life, that environmental impacts are controlled and that it can be decommissioned safely.

A SMR-300 requirements management tool and database will be implemented to ensure all requirements are uniquely identified, categorised and organised into a hierarchy with relationships and configuration information/baselines identified. Owners of requirements will be identified to enable integration with future design quality plans and that verification & validation needs are systematically identified and clear to all stakeholders. Interface management information will be presented in the requirements management tool to ensure alignment of key connection points.

As part of future UK SMR-300 deployment and to support the needs of future licensees, a UK SMR-300 Requirements Management Plan will be developed. Requirements management is intimately linked to the delivery of SMR-300 Design Milestones, as shown in Figure 7, which for the UK design will be delivered through System Engineering Management Plan (SEMP), see C_MSQA_112 and Configuration Management Plan, see C_MSQA_111.

C_MSQA_110 - A Commitment is raised to complete the integration of a Requirements Management Tool and associated database with the SMR-300 design management arrangements. Target for Resolution - Issue of Pre-Construction SSEC.

4.7.3 SMR-300 Design Control Process

Claim 1.4.3 – A3: A suitable and sufficient Design Control Process exists to control delivery of a safe and secure UK SMR-300 design.

The Project uses HPP-8002-1010, SMR-300 Design Control [136] to describe the design process and implement the QA requirements of NQA-1, Requirement 3, Design Control, including provisions to control design inputs, the design process, analysis, design verification, change, records, and interfaces, including organisational interfaces both internally within Holtec and externally with Suppliers.

These provisions assure that design inputs (such as functional performance, design bases, regulatory requirements, environmental conditions, codes and standards, customer specifications) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions) so that the design output contains or references appropriate acceptance criteria that can be traced to the design input in sufficient detail to permit verification, as required. Each of these activities are performed using a graded approach commensurate with the relevant nuclear safety significance.

The Design Process is comprised and controlled through the development of the following essential deliverables and measures, including:

- Project Plans
- Plant Technical Requirements Document
- Discipline-specific Design Standards
- System Design Requirements
- Engineering Drawings
- Analysis Documentation
- System Design Descriptions

The SMR-300 Design Control process includes multiple stages of design reviews and interfaces, including during individual design document development where interdisciplinary reviews are performed and during the design integration review process where packages of design documents are reviewed by an interdisciplinary committee of experts and stakeholders. Establishing and controlling these interfaces is crucial to promoting coordination and communication, using the latest design information, preventing design conflicts, and ensuring compatibility.

The design process procedure addresses responsibilities, required reviews, approval stages, and interfaces between disciplines. This structure ensures that all aspects of the design are planned, traceable, and subject to appropriate oversight. The importance of documenting and following a design procedure includes:

- Ensuring consistency in how design activities are carried out across projects and teams
- Providing traceability and accountability, allowing for audits and quality reviews
- Facilitating communication and coordination among team members and stakeholders
- Supporting compliance with regulatory and customer requirements
- Allowing for verification and validation of the design against its inputs

The SMR-300 Design Control procedure is still to be fully implemented, and hence evidence is unable to be presented to fully underpin this claim within GDA[2]. Therefore, Holtec have raised a commitment to ensure full implementation of this procedure is implemented.

C_MSQA_107: The Design Control Procedure (HPP-8002-1010) and the use of Design Integration Reviews (DIRs) is central to Holtec's control of design development. The implementation of the Design Control Procedure requires further evidencing. A Commitment is raised to evidence the implementation of the Design Control Procedure and DIRs. Target for Resolution - Issue of Pre-Construction SSEC.

4.7.3.1 Design Milestones

The SMR-300 Design Control Procedure defines a set of milestones for the SMR-300 development which link design maturity to project decision points. Milestones are specific to

[2] [REDACTED]

each system or structure, such that each component can be assigned to a system or structure. The SMR-300 design is considered to at different stages of maturity though in the main, on the pathway to Milestone 20 (Preliminary Design). For certain Long Lead Items, design activity is at Milestone 30. This recognises that confirmatory Design Integration Review (DIR) assessment is needed to ensure all milestone activities are complete for proposed gates. The following milestones are prescribed in the procedure, as represented in Figure 7:

- **Milestone 10 Conceptual Design**: Initial requirements and Design Bases documentation.
- **Milestone 20 Preliminary Design/Ready for Procurement**: Requirements finalised; equipment specifications issued to Suppliers; and Design Bases sufficiently progressed to support initial licensing basis.
- **Milestone 30 Detailed Design/Procurement Complete**: Final Supplier design data accepted and Design Bases documentation updated.
- **Milestone 40 Detailed Design/Ready for Construction**: Design Bases finalised and sufficient for construction.

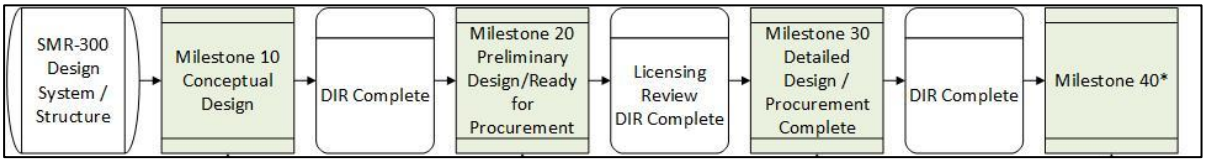

Figure 7: SMR-300 Design Milestones

4.7.3.2 Design Standards

The Design Standards are used by each technical discipline, as described in SMR-300 Design Control Procedure. The Design Standard shall provide a descriptive representation of the discipline's scope of work, scheduling information, major deliverables, including Milestones, and the workflow entailing sequences, key interfaces, computer programs used for drawing, modelling and/or analysis, applicable standards and procedures (non-exhaustive), and assigned responsibilities. The design standards applicable to the SMR-300 design for the purposes of GDA fundamental assessment are identified in the GDA DRP [141] and further identified in PSR Part B Chapters.

4.7.3.3 System Design Descriptions (SDD)

System Design Descriptions are developed in accordance with HPP-160-3001 System Design Description Procedure [149]. The SDD document shall define the system in sufficient detail to permit verification that the design satisfies the design inputs from the System Design Requirement (SDR) document.

4.7.3.4 Design Integration Review (DIR)

DIRs are used to demonstrate completion of respective design process Milestones as judged by the Design Integration Review Committee. The process ensures that reviews are held to decide if agreed criteria for the respective Milestone completion have been met. Note that the procedural requirements for DIRs, at the point of PSR authoring are in development. Commitment C_MSQA_107 is raised to capture the need to evidence full implementation of the Design Control Procedure [136].

4.7.3.5 Configuration Management

SMR-300 configuration control is managed through the SMR-300 Design Control Procedure. As stated within the procedure, NQA-1 requires that configuration management processes shall be implemented at the earliest practical time prior to facility operation. The Design Authority establishes when and to which extent configuration management will be required. Proportionate configuration management has been established by the Design Authority for the GDA Reference Design. More comprehensive configuration management is expected to be established in accordance with the SMR-300 Design Control Procedure [136].

A UK Configuration Management Plan (CMP) will be created to be a living document which outlines the approach for managing configuration items, ensuring safety, compliance, and consistent quality control throughout the project. Key aspect of configuration management system are:

- Requirements Management Tool. As described in Section 4.7.2.2, a requirements management tool will implemented, which shall be based on an Engineering Lifecycle Management (ELM) approach, where configuration will be controlled. When fully implemented this will enable mobility between requirements, design documents and the safety case. Understanding the impact of design or performance changes on the entire SSEC is critical to demonstrate control of nuclear safety. Through satisfaction of commitments C_MSQA_110 (Requirements Management Tool) and C_MSQA_111, it is expected that LC19 requirements to maintain design integrity will be met.

- Document version control forms an important part of design and safety case configuration control. The HIDOC system plays a key role in tracking documentation and recording changes and dependencies between interrelated documents. Document management controls are explained in Section 4.6.3. Robust measures for recording of design and SSEC information will be needed to ensure future handover of documents to a future UK Licensee meet the expectations of ONR's Licence Condition 6 – Record Management.

An Engineering Schedule plays a crucial role in supporting Configuration Management by providing structure, visibility, and control over the timing and sequence of engineering activities that impact configuration baselines. This is key to enabling safety analysis to be linked to engineering activities and substantiation. The requirement for an Engineering Schedule and an example template for the schedule is further discussed in PSR Part B Chapter 19 [14]. Holtec have accordingly raised a commitment to deliver an Engineering Schedule as part of future UK deployment.

C_MSQA_111 – A Commitment is made to produce a Configuration Management Plan (CMP) and an Engineering Schedule to support design management of the UK deployment of the SMR-300. Target for Resolution - Issue of Pre-Construction SSEC.

4.7.3.6 Design Records

Design documentation and records shall include not only the final design documents, such as drawings, specifications, and revisions to those documents, but also documentation that identifies the important steps in the design process, including sources of design inputs that support the final design. The Design Control procedure specifies that all design documents

are treated as records in accordance with HSP-101701, Quality Records [129]. This is addressed in Section 4.6.3.

4.7.3.7 Management of SMR-300 Layout

Design control of layout follows the guidelines as laid out in the SMR-300 Design Control Procedure, HPP-8002-1010 [136]. The Civil Engineering team by being responsible for the production of design specification documents of buildings followed by the General Arrangement (GA) drawings, are owners of the layout of the SMR-300.

When the civil team creates the initial building layouts, they use the best available information regarding equipment sizing, number of tanks etc. and use this to locate and size rooms. The civil models are then imported into Smart Plant 3D to help inform layout and visualisation of the plant. Updating and revising these general arrangement drawings for the general layout of the plant must conform to the configuration processes laid out in SMR-300 Design Control Procedure.

The Design Development Team have ownership of the detailed layout process. It is important to state that the 3D model is not Quality Assured (QA). Rather the GA drawings used to provide inputs into it are QA, and the drawings produced from the model will be subject to quality and configuration control. An example of this would be Piping Isometrics, which will be produced from the 3D layout. These drawings are QA and are subject to the NQA-1 [45] design process and configuration controls as set out in [136]. The 3D model is version controlled and isometric outputs from the model are also subject to QA. See Section 4.7.3.5 for Holtec's approach to configuration control.

The Layout design will progress throughout detailed design and will be further supported by detailed analyses, for example, stress analysis work will be conducted for pipework, which will then incorporate new layout changes due to flexibility calculations, pipe supports etc. After this process, the Constructability, Operability, Maintainability and Safety (COMS) is considered as part of the Design Integration Reviews to confirm cross disciplinary optioneering of the layout. This is to ensure that layout aspects which are derived from the top-level plant requirements and the design philosophy are successfully integrated into the physical plant design.

The following documents (non-exhaustive) also influence the detailed SMR-300 layout:

- HF guidance as set out in SMR-160 Design Standard for HF: Maintenance, Inspection and Testing [150]. These HF design standards then inform the requirements to produce the relevant general arrangement drawings by the civil engineering team. Specific operational and human factors input, is solicited in the pre-job brief for a drawing and then is captured in the redlines and comments of a document/drawing in line with the HI NQA-1 design process.
- Equipment and Piping Layout Guidelines for Ensuring Radiation Exposures ALARA .
- SMR-300 Design Standard for Radiation Protection.
- SMR-300 Design Standard for Grouping and Separation the primary purpose of which is for implementing appropriate grouping and separation methodologies to ensure that plant SSCs can perform their safety functions during and following a design basis event.
- SMR-300 Specification – Environmental Conditions.

4.7.3.8 SMR-300 Ageing and Degradation

The identification and understanding of Ageing and Degradation mechanisms is necessary to inform safe design development and forms part of Holtec's approach to design. Consideration of Ageing and Degradation mechanisms and the suitability of materials is explicitly required as part of the SMR-300 design process [136]. Material selections are based on literature sources, operating experience and, if necessary, independent testing in a manner consistent with the safety importance of the relevant SSC. Ageing and Degradation is closely linked to EIMT requirements (PSR Part B, Chapter 9) and Plant Chemistry (PSR Part B Chapter 23) and further information is available on these in their relevant PSR Chapters. In relation to the potential impact on maintenance, the operating arrangements of the SMR-300 to date assume that there are no permitted maintenance states where Engineered Safety Features (ESFs) within containment are made unavailable. This will be confirmed as part of normal development activities. Further discussion of single failure tolerance of the SMR-300 (including maintenance states) is provided in Design Challenge – Single Failure Criterion in Passive Safety Systems [151].

Design configuration controls ensure that the Top-level Operability and Maintainability, Performance, and Design Life requirements referenced from EPRI URD Tier 2 Chapter 1 Section 3.2.4, Section 3.3, Section 7.7.2 and NEI 97-06 & 03-08 are incorporated into the design for EIMT and Ageing and Degradation.

Requirements for the SMR-300 design are derived from NRC guidance, compliance with relevant design codes (primarily ASME Subsection XI), and the incorporation of elements from the EPRI Utility Requirements Document (URD). These collectively inform the design and the associated EIMT activities, thereby determining which degradation and ageing mechanisms are to be addressed. The extensive Operational Experience (OPEX) and Recognised Good Practice (RGP) associated with Pressurised Light Water Reactors have shaped the development of ASME design codes, NRC regulations, and EPRI guidance. As these standards underpin the SMR-300 design requirements, there is confidence that the design processes and associated management arrangements adequately account for key degradation and ageing mechanisms.

In parallel with the increasing maturity of the UK-specific deterministic safety analysis, fault studies, and hazard assessments, further work will be undertaken on ageing and degradation management. This work will support novel aspects of the SMR-300 design that are important to safety, such as the use of an annular reservoir, which may not be fully covered by existing guidance/OPEX on degradation mechanisms. Furthermore, UK policy requirements for higher-reliability components (refer to Chapter B18) demand more robust evidence of the systematic approach taken to manage degradation and ageing in the SMR-300. This includes using appropriate techniques for both Pre-Service and In-Service Inspection in accordance with UK Recognised Good Practice (RGP). A GDA Commitment has been raised to give confidence that these activities will be delivered in support of future UK deployments of the SMR-300.

C_MSQA_109 - The design of the SMR-300 and the management arrangements in place are informed by degradation and ageing mechanisms. A Commitment is raised to present this mechanistic understanding in the form of an ageing and degradation strategy and verify SMR-300 arrangements and activities for degradation management

in the UK Context. Target for Resolution: Issue of UK Long Lead Item and SSC procurement specification.

4.7.4 Design Interfaces

Claim 1.4.3 – A4: Design Interfaces are suitable and sufficient to deliver a safe and secure UK SMR-300.

Design interfaces are the points of interaction between different disciplines, teams, or organisations involved in a project. Establishing and controlling these interfaces is crucial to promoting coordination and communication, using the latest design information, preventing design conflicts, and ensuring compatibility. Design interfaces are documented and accomplished using an assortment of measures, as described below.

- Interface control. Organisations to establish and use procedures for identifying, managing, and documenting design interfaces.
- Responsibilities and communication. Defines responsibilities for interface control and ensures that communication across teams and contractors is formalized and documented.
- Review and approval. Interface information is reviewed and approved just like any other critical design input or output.

The Design Control Procedure [136] describes and provides instructions to ensure the above requirements are met for design interfaces for the SMR-300 design. Specifically, Design Control Procedure ensures control of design interfaces, via measures such as Design Standards, PJBs, the DIR process, and design verification. The project design process includes multiple stages of design interfaces, including during individual design document development where interdisciplinary reviews are performed and during the DIR process where packages of design documents are reviewed by an interdisciplinary committee.

4.7.5 Design Analysis, Verification and Validation

Claim 1.4.3 – A5. Design analysis, verification and validation arrangements are in place to deliver a safe and secure UK SMR-300.

4.7.5.1 Design Analysis

Holtec's requirements to perform design, analysis, verification and validation is evidenced from HSP-100301 Design Control Procedure [137] and the SMR-300 Design Control Procedure, HPP-8002-1010 [136]. SMR-300 design analysis and validation is specified for each technical discipline within Design Standards and associated workflows. An example is provided through the SMR-300 Design Standard for Civil-Structural Workflow [148].

Design analyses must be clearly documented, technically sound, and traceable to approved design inputs. This demonstrates the technical adequacy of the design and ensures that design decisions are justifiable and verifiable and are compliant with applicable codes, standards, and regulatory requirements. Design analyses include:

- Identification of inputs and assumptions
- A clear description of methods used

- Calculations and results
- Conclusions that demonstrate the design meets requirements
- Review and verification by qualified personnel

The design control procedure describes and provides instructions to ensure the above requirements are met for design analyses for the SMR-300 design. Specifically, this procedure instructs the control of design analyses, via measures such as Design Standards, PJBs, personnel qualifications (i.e., Preparer, Technical Disciplines, and Computer Program qualifications), the DIR process, and design verification.

Design analysis is performed to confirm the expected performance of designs and to ensure that the specified design requirements (including the safety security, safeguards or environmental protection requirements) are adequately substantiated. Design analysis activities are performed by personnel qualified in the applicable area of knowledge. Specific types of design analysis are prescribed in the Holtec Design Standards and analysis specification. Design Standard workflows also define the iteration between design and safety analysis.

4.7.5.2 Design Verification

Verification requires the review of documents, design, and code to verify that all the project requirements are met. Another way to define verification is as the process of checking that the result of a development phase meets the requirements set at the start of that phase. Verification can happen at different stages throughout the product development lifecycle. The result from one phase of verification may form part of the input for another phase.

All project design records are independently reviewed in accordance with the applicable procedure for that design record type. The independent reviewer is qualified in the knowledge area for each design record and uses checklists or other tools to aid in verification. In addition, design records may be additionally required to undergo further supplemental verification by one or more of the following methods:

- Additional independent review(s).
- Alternate calculations.
- Testing.

Technical experts from interfacing engineering disciplines are included in the verification process as appropriate to the content of a particular design record (e.g. design specification or SDD) and according to the competency and training necessary. Table 5 captures the relevant management system processes that are specifically related to design verification. Examples of verification processes:

- HSP-101101 Computer Programs [152] establishes standard procedures for the development, control, verification, validation and documentation of computer programs used for Safety Significant activities.

- Drawing Standardisation Procedure [153] establishes the requirements to be adhered to by design and engineering personnel in the preparation, review, approval, and revision of engineering drawings. This procedure is being updated for SMR-300 under project code 8002.

- SMR Procedure for Pre-Job Briefs and Post-Job Reviews [163] promotes error prevention and detection behaviours with quality self-review and dialogue. It is used to identify design interfaces, ensures competent personnel are assigned to the task and promotes understanding of what to accomplish and what to avoid. It also provides an opportunity to raise awareness of important activities (work and mitigation) and to mentally rehearse the performance of assigned activities.

4.7.5.3 Design Validation through Integral and Separate Effects Testing (ISET) facility

To obtain test data needed for code validation of the SMR-300 plant, the Integral and Separate Effects Testing (ISET) facility is used to build a scale representative model of the SMR-300 performing, measuring, and recording the tests. This is a key part of SMR-300 validation as evidenced in the following report: Objectives for SMR-300 Integral Effects Test (IET) Program [154].

The integral effects test (IET) configuration is being designed to perform scaled nominal operations and design basis events (DBEs) pertinent to the SMR-300. It shall simulate scaled down versions of the Primary side, Secondary side, and Engineered Safety Features (ESF), along with supporting systems. These will allow for near prototypic operations of the Primary side using an electrically heated core. For simplicity the Secondary side will not include a turbine system. Instead, Feedwater (FW) shall be drawn from the demineralized water source, run through preheaters and the SG, and then the steam shall be either dumped to atmosphere or used in the heat exchanger (HX) to preheat the FW.

The Steam Generator (SG) separate effect test (SET) configuration of the facility shall be designed to simulate the full-height, but reduced tube number, SG. Testing in the SG SET will focus on observing the heat transfer conditions of the SG during simulated steady and transient operating conditions.

4.7.6 Design Change

Claim 1.4.3 – A6. Design change control arrangements are in place to deliver a safe and secure SMR-300 design.

Design change arrangements are applied proportionately at this stage of SMR-300 design maturity. SMR-300 design changes are managed by the Design Authority through HPP-8002-0003, Design Decision and Risk Management Procedure. The Design Decision and Risk Management Meeting, which includes representatives from the UK, sits monthly to review emergent design risks and proposed changes. This follows a graded approach, proportionate to the maturity of the design and in alignment with US NRC expectations. Holtec International intends to implement further design change procedures as part of full implementation of the Design Control Procedure.

HPP-3295-0017, GDA Design Management Procedure was produced to meet the needs of GDA; demonstrating proportionate application of ALARP and BAT to meet UK legislative and regulatory expectations; a mechanism to inject UK challenge into the SMR-300 design; and to better interface with SMR-300 design management. [REDACTED]

The design management process is shown in Figure 8 and explained in the sub-sections below.

4.7.6.1 Design Stability

[REDACTED]

The SMR-300 design has been developed against US NRC requirements. Throughout the GDA, Holtec have assessed the GDA Reference Design against UK legislative requirements and regulatory expectations. The aim being to identify design risks that may reduce confidence in the design being ultimately licensed in the UK. Where a design risk is identified, a design risk is raised on the risk register and mitigation strategy developed. This process is illustrated in Figure 8. The Design Management Procedure [143] allows consideration of the wider benefits of ensuring a stable design / consistency between the US and UK designs in addition to the more specific considerations.

Where appropriate, the process enables Holtec Britain to challenge UK regulatory expectations where US NRC practice can be shown to deliver an ALARP/BAT solution. Endorsed design challenges are passed to the Design Authority for consideration through the Design Decision and Risk Management Committee. Where UK originating Design Challenges lead to modification of the SMR-300, the design change is required to go through the US design decision process.

4.7.6.2 UK Design Challenges

When a Design Stability argument cannot be made, the design risk progresses to the Design Challenge stage. Dependant on categorisation, this drives the development of a Design Challenge paper, which presents options and a recommendation for presentation to the DAC Committee, see Section 4.7.6.5. Where endorsed Design Challenges papers propose change to the SMR-300 design, the recommendation is sent to the SMR-300 Design Authority for consideration. A list of Design Challenges is presented in PSR Part A Chapter 2 [3].

4.7.6.3 Design Decisions

The SMR-300 Design Decision and Risk Management procedure [142] applies a graded approach to design changes and a risk informed decision making process, proportionate to significance and the level of maturity for a concept design. Design decisions, may be supported by decision paper which provides optioneering and consideration of the impact on safety. Design decisions are recorded in a database, with formal monthly meetings held to update design risks and make decisions on proposed changes. The UK Design Challenge is considered by the Design Authority to either modify or retain design.

4.7.6.4 Prospective Design Changes

GDA Reference Design is required to align with the SSEC, to facilitate a regulatory assessment, in accordance with Guidance to Requesting Parties [77]. In a fast-moving project in the early stages of design maturity this creates a number of challenges particularly around misalignment between design and SSEC. The Design Management Procedure introduces the concept of UK Prospective Design Changes (PDC), where any approved SMR-300 design change against the GDA Reference Design is reviewed and assessed through a UK lens to understand the impact on GDA.

The GDA Project also recognised a need to ensure that design changes originating from the SMR-300 design receive a proportionate ALARP and BAT assessment, which includes optioneering. The PDCs are used to make initial ALARP and BAT judgements on the change, identify commitments and identify any impacts on the SSEC. The procedure also ensures key decisions are auditable and are robustly evaluated against appropriate safety, security, safeguards, and environmental criteria so that a risk-informed conclusion can be made to demonstrate that the chosen design option is the most practicable. SMR-300 GDA ALARP Guidance Document [155] and RSR-BAT Guidance [156] describe the use of the Design Management Process, as illustrated in Figure 8, when determining the appropriateness of a PDC.

4.7.6.5 Design Adaptation Committee

The UK Design Adaptation Committee (DAC) is used as a competent technical governance committee to review, advise and endorse: design challenges, PDCs and GDA scope and Reference Design changes. The DAC is made up of a quorate membership including safety, security and environmental representative and representation from the SMR-300 Design Authority. The PDCs and Design Challenges are recorded on the DAC register, which is managed by Holtec Britain and kept under frequent review.

[REDACTED]

Figure 8: Design Management Process

4.7.6.6 ALARP and BAT in Design

As noted above and within the PMP, the Holtec organisation understands the requirement to demonstrate that the generic SMR-300 design satisfies the ALARP and BAT principles. Chapter A5 ‘Summary of ALARP and the SSEC’ [4] , sets out the approach to demonstration of ALARP and how this is integrated into the Design Management Process. Chapter A5 also provides the overall demonstration of ALARP for the SSEC and describes the integration between ALARP and BAT, including how conflicts between safety, security, safeguards, and environmental protection criteria are managed. PER Appendix - Approach and Application to the Demonstration of BAT [16] sets out Holtec’s approach for taking into account BAT methodologies and principles in the generic SMR-300 design. The Holtec procedure Management of SSEC [68] covers the whole process for production and management of the SSECs during the GDA.

4.7.6.7 Future UK Design Management

Design documents and evidence underpinning this PSR will be required to be handed over to a future licensee. Arrangements to support document management and design records are explained in Sections 4.6.3, Section 4.7.3.6 and Section 4.9.

[REDACTED]

For UK deployment of the SMR-300, and subject to future appointment of a Licensee, design reviews are expected to be integrated with Project Gateway Reviews to confirm UK design readiness is met for each major lifecycle milestone.

C_MSQA_108: Design Manuals and System Engineering Management Plans (SEMP) are considered best practice for the management of design development. These documents have not yet been produced for the UK GDA. A Commitment is made to produce a UK Design Manual and a UK System Engineering Management Plan to support management of future UK SMR-300 design development. The UK Design Manual and UK SEMP will define, amongst other things, technical governance arrangements and division of responsibility between the Licensee and Responsible Designers. Target for Resolution - Issue of Pre-Construction SSEC.

4.7.7 Reference Design Definition

Claim 1.4.3 – A7. Reference design arrangements are in place to deliver a safe and secure UK SMR-300

The Holtec SMR-300 design is being developed to meet the US NRC licensing requirements with first deployment planned at the US Palisades site. This argument is principally evidenced from the SMR-300 Design Control Procedure.

4.7.7.1 GDA Design Reference Point

A key requirement of a GDA is the definition of a reference design which forms the basis of the Step 2 GDA submission and SSEC. This requirement has been met by the production of an SMR-300 GDA Reference Design, as detailed in GDA Design Reference Point Report 1.1, HI-2240648 Rev 2 [141]. This is a specific set of design documents at defined version numbers, which is used as the basis for the SSEC. This reference design definition ensures there is a consistent and coherent approach to the maturity of evidence against which the safety of the plant is justified. The point at which this list is issued is referred to as the DRP. The history and description of the SMR-300 and GDA DRP can be found in PSR Part A Chapter 2.

4.7.7.2 Design Reference Point Management

Changes to the GDA Design Reference Point are managed by Holtec SMR-300 GDA Scope and Design Reference Point Change Procedure, HPP-3295-0048 [157]. This ensures control of the GDA DRP, through a simple process that includes optioneering and gaining agreement from the Regulators.

[REDACTED]

4.7.8 CAE Summary

This sub-chapter presents Holtec's Design Management arrangements to support the delivery of a safe and secure UK SMR-300. These arrangements are drawn from Holtec's existing quality and design governance systems, adapted to meet the expectations of the UK GDA process. Holtec's arrangements are considered to be sufficient against US NRC requirements to deliver a SMR-300 design, at this stage of project maturity.

The chapter identifies where there is further work required to fully substantiate Claim 1.4.3 and raises commitments where further evidence is required to demonstrate satisfactory implementation of arrangements. Noting the early lifecycle stage of the generic SMR-300, the evidence presented demonstrates that Holtec has stablished a design management approach that is appropriate for this stage of design maturity. Commitments raised will be progressed and are expected to be addressed ahead of the Pre-Construction SSEC delivery.

4.8 HOLTEC SSEC MANAGEMENT ARRANGEMENTS

This sub-chapter provides the arguments and evidence in support of the following claim:

Claim 1.4.4: Holtec has appropriate Safety, Security and Environment Case management arrangements to deliver a UK SMR-300.

The sub-chapter achieves these aims by describing the SSEC development strategy, its structure and production management arrangements including management of GDA commitments along with the management arrangements for specialist aspects of the SSEC. The following arguments are presented:

- The SSEC development strategy is suitable to deliver a safe and secure UK SMR-300 (A1).
- SSEC production and management arrangements are suitable to deliver a safe and secure UK SMR-300 (A2).
- The management arrangements for GDA Commitments are suitable to deliver a safe and secure UK SMR-300 (A3).
- The management arrangements for specialist aspects of the SSEC are suitable to deliver a safe and secure UK SMR-300 (A4).

4.8.1 SSEC Development Strategy

Claim 1.4.4 – A1: The SSEC development strategy is suitable to deliver a safe and secure UK SMR-300

As noted in sub-chapter 4.1, the Fundamental Purpose of the SSEC is to demonstrate that the generic SMR-300 can be constructed, commissioned, operated, and decommissioned on a generic UK site fulfilling the future licensee's legal duties to be safe, secure and protect people and the environment.

A staged development strategy has been adopted for the SSEC development to achieve this purpose. This recognises that the understanding of the SMR-300 design and operations and associated safety, environment and security requirements develop through the life cycle along with the stakeholder expectations.

The details of the SSEC staged development strategy are presented in the SMR-300 Through-Life SSEC Strategy [6] and summarised below:

- The staged SSEC development involves the update of the reference design and supporting assessments at key points in the SMR-300 lifecycle, as illustrated on Figure 1. Each stage of the SSEC development builds on information from the previous stage and looks forward appropriately to subsequent stages.
- The SSEC considers the requirements of nuclear / conventional safety and environment and security and the related stakeholders and ensures an appropriate balance across these requirements as part of the design and associated decision-making processes.
- Staged SSEC documents are aimed at permissioning progress through the key lifecycle phases, taking due cognisance of stakeholder input. This is shown in Table 4.

The staged SSECs expected to be produced for the SMR-300 on its journey to being operated and ultimately decommissioned, are summarised along with the activities primarily permissioned by the SSEC:

- The design and safety assessments underpinning these staged SSECs progressively develops with the level of detail maturing to support the developing lifecycle phases and justify the nuclear safety risks associated with each activity. Each of these stages is discussed in more detail in the Through-Life SSEC Strategy document [6].
- This staged approach is broadly consistent with the staged safety case submissions proposed within the ONRs TAG-051 [158].

Table 4: Staged SSEC Development

Staged SSEC	Permissions commencement of …
GDA SSEC Revision 1 (this document)	Preliminary / detailed design and assessment
Pre-Construction Site-Specific SSEC	Construction / manufacture
Pre-Commissioning Site-Specific SSEC	Inactive / active commissioning
Pre-Operations Site-Specific SSEC	Operations
Operations Site-Specific SSEC	Continued operations
Decommissioning Site-Specific SSEC	Decommissioning

Post-production of the GDA SSEC, the focus will be on the production of a Generic Pre-Construction SSEC. This is a necessary interim stage prior to the selection of a specific site for the first UK SMR-300 deployment and the selection of a licensee organisation who will take responsibility for, and lead the delivery of the SSEC, with Holtec providing support as the Responsible Designer. This Generic Pre-Construction SSEC is not listed above as it is not intended to permission any activities but to act as the focus for progression of the UK SMR-300 design and assessment ensuring momentum is maintained on delivery.

The SMR-300 GDA SSEC (this document) presents claims, arguments and evidence which is commensurate with a concept level full plant design and supporting assessment. The GDA SSEC is based on a clear reference design for the SMR-300 at DRP1.1 [141] which is based on the Palisades design, as discussed in Section 4.7.7.

The approved GDA SSEC (at Revision 1) will be issued to the UK regulators for review / to inform their consideration of the fundamental adequacy of the generic SMR-300 reference design and associated SSEC in order to identify any potential ‘showstoppers’ that may preclude deployment of the design. The two-step GDA will culminate in a statement from the regulators of the fundamental adequacy of the generic SMR-300 SSEC.

4.8.2 SSEC Structure

The GDA SSEC is structured hierarchically as illustrated in Figure 9. The Tier 1 documents set out the overall Claims. These are supported by the Tier 2, 3 and 4 reference documents as illustrated in Figure 9 which indicates the nature of the documents in the four tiers.

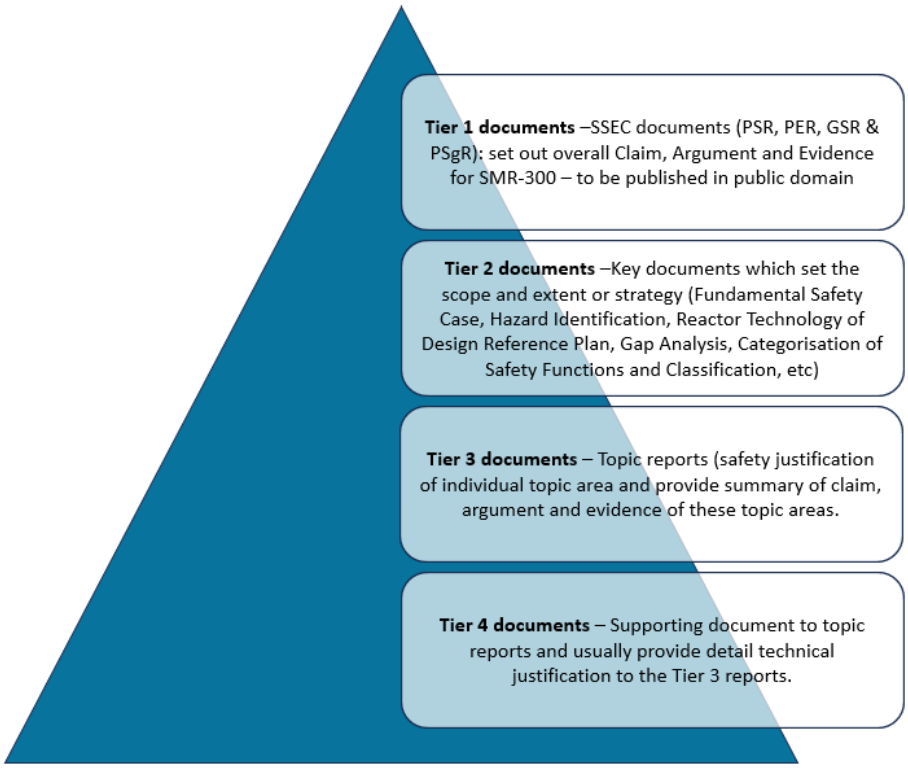

Figure 9: Holtec GDA SSEC Document Hierarchy

The four Tier 1 documents constituting the SSEC are described is PSR Part A Chapter 1.

The safety, environmental, security and safeguard documents have overlapping attributes and requirements. These are brought together in the PSR whose main “A” chapters over-arch all other elements of the SSEC. The inter-connected nature of the PSR, PER, GSR, PSgR and the underpinning documents is illustrated in Figure 10.

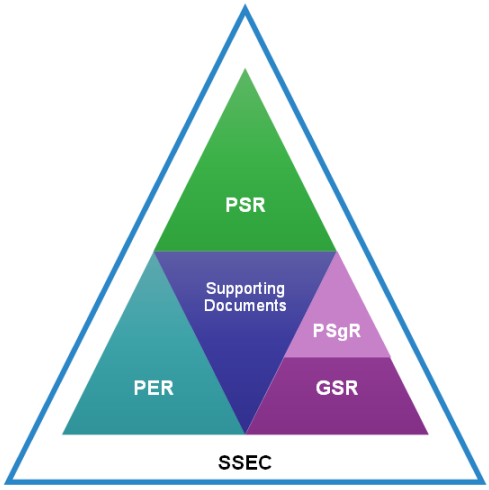

Figure 10: Illustration of Inter-connected nature of SSEC

More detailed information on the tiered structure of the SSEC, including the fundamental objects for the PSR, PER, GSR and PSgR and the supporting chapter listing and contents is presented in Part A Chapter 1 [1].

Post-GDA it is envisaged that the SSEC will maintain a similar structure to that used for the GDA SSEC but will necessarily be expanded to present the detailed CAE necessary to underpin a Pre-Construction SSEC. However, the structure will be determined by the future licensee and permit holder during the post-GDA period.

4.8.3 SSEC Production and Management Arrangements

Claim 1.4.4 – A2: SSEC production and management arrangements are suitable to deliver a safe and secure UK SMR-300

This sub-chapter summarises the production and management arrangements for the SSEC documentation. The preparation, review and approval of the reports constituting the SSEC are recognised as critical activities for the SMR-300 GDA project to ensure high quality submissions. The Through-Life SSEC Strategy document [6] defines principles which underpin the development of the SSEC.

To support the production and management of the SSEC, specific arrangements have been implemented within HPP-3295-0012, SMR-300 GDA Management of Safety, Security and Environmental Cases [106]. These arrangements apply to the top-tier SSEC documentation (i.e. PSR, PER, GSR and PSgR). They define management processes including - development of scope, strategy and specification of the SSEC; authoring of the SSEC; review of the SSEC; approval of the SSEC and the identification and management of unresolved issues arising from the SSEC (refer to sub-chapter 0). The arrangements ensure multiple layers of checking, review and proportionate independent challenge. This is considered necessary as, although Holtec is not a nuclear site licensee where safety reports would be categorised based on their significance, the top tier reports are considered to be equivalent to a plant safety case, which would normally be associated with the highest category. As such, similar robust arrangements have been applied to the top-tier documents with respect to checking and independent challenge to ensure the quality of the SSEC documents as illustrated in Figure 11.

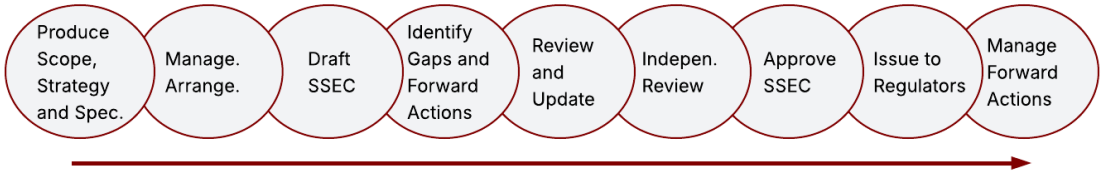

Figure 11: Illustration of the Process for Management of the SSECs

Management of the SSEC also involves the broader arrangements defined in the GDA PMP [98] and PQP [93] and supporting procedures such as those related to document security, classification and commercial sensitivity [159]. Notably the following also contribute to ensuring the quality and consistency of the SSEC documentation:

- The GDA project specific competency and training procedure, HPP-3295-0005 [115] ensures appropriate SQEP resources support SSEC delivery including authoring, verification, subject independent review. Further information on competency and training relevant to the SSEC and the records kept is presented in sub-chapter 4.6.
- The Safety, Security and Environment Overarching Quality Plan and Records, HPP-3295-0018 [116] provides detailed quality assurance arrangements to deliver the SSEC including - definition of responsibilities (such as appointment of a SSEC Manager to lead and assure the appropriate quality level / lead reviewers and independent reviewers); definition of quality plans for the assurance arrangements; provision of templates for chapter plan review / comment sheets and the required quality records (include quality and SQEP records for each chapter).
- The GDA DRP defines the baseline on which all SSEC documents are based. The GDA DRP and its history is described in PSR Part A Chapter 2. HPP-3295-0048, UK GDA Design Reference Point and Scope Change Process, [143] defines the process for managing changes to the DRP. These documents ensure consistency and control across the SSEC documentation during production, review and approval.
- GDA Managing Commitments, Assumptions and Requirements [4] defines the process for managing commitments arising from the GDA. This is further discussed in 0.

The SSEC is recognised as the totality of documented information and arguments developed that substantiate the safety, security and environmental aspects of the plant and associated operations. As illustrated in Figure 9, the documentation comprising the SSEC can be visualised across a number of levels (referred to as ‘Tiers’).

Tier 2 and 3 documents are directly referenced from SSEC Chapters. The production of Tier 1 documentation includes a check that any supporting Tier 2 and 3 references are available on the HIDOC management system and are approved for use. Tier 4 documents are lower-level references which support the Tier 2 and 3 documentation and typically contain detailed design and safety analysis. The production and approval of all these documents is assured under HQP-6.0 [127], supported by specific procedures. The documents can be considered to be consist of:

- Documents produced by Holtec Britain and supported by the UK supply chain where quality is assured by application of the dedicated GDA Supplier Document Review, Approval and Integration procedure, HPP-3295-0009 [99] and Internal Document Control Procedure, HPP-3295-0047 [131]. These process and control are further explained in Section 4.6.3. These are supported by the application of procedure to ensure competent personal [115] and the provision of quality plans / records [116].
- Key SMR-300 design documentation (e.g. System Design Descriptions (SDDs)) which are authored by Holtec International, follow the Holtec process, as described in Section 4.6.3.

The associated quality process and records associated with these two processes are described further within them. All approved documentation is held on HIDOC as the common data environment.

Figure 12 below illustrates how the overarching MSQA arrangements developed for the GDA project (primarily as part of Step 1) provide the framework for the production / quality assurance of the SSEC documents. Sub-chapter 4.5 describes how the MSQA arrangements fit within the Holtec quality management framework.

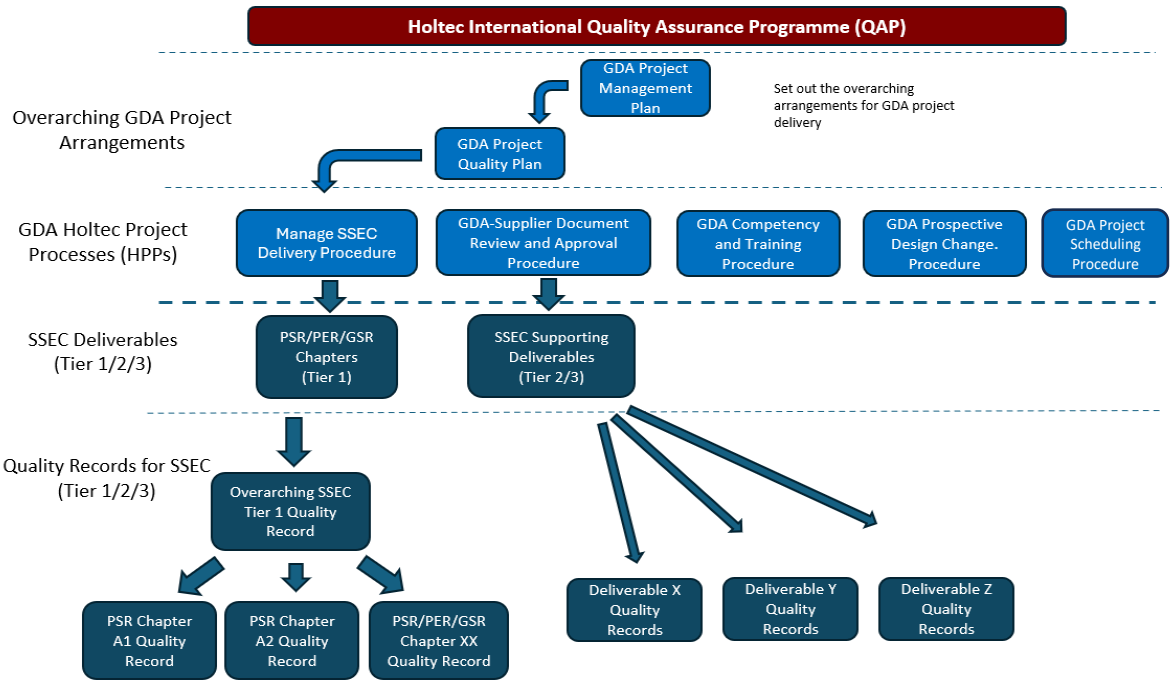

Figure 12: MSQA arrangements supporting delivery of SSEC and supporting deliverables

4.8.4 Management of GDA Commitments

Claim 1.4.4 – A3: The management arrangements for GDA Commitments are suitable to deliver a safe and secure UK SMR-300

A GDA Commitment is defined (in summary) as "*a stated intent or undertaking made by the Requesting Party that affects the SMR-300 design intended for deployment to a UK site*." Commitments may require additional safety / environmental analysis, a change to the design or operational procedures.

During the production and approval of the SSEC, GDA commitments may arise, including as a result of a:

- Need for additional evidence identified in a Step 2 deliverable (if judged significant to safety and a gap against the maturity expected for a SSEC).
- Need for additional evidence identified during authoring of the SSEC chapter (if judged significant to safety and a gap against the maturity expected for a SSEC).
- Need to raise a future Design Challenge.
- Need to undertake further work as a result of a Design Challenge.
- Need to incorporate a UK Prospective Design Change in a future UK DRP.
- Need to undertake further work as a result of a UK prospective design change (e.g. optioneering study).

GDA commitments are not raised where the need for future work is considered to be “normal business”, i.e. where there will be resolution as part of the normal staged design / SSEC development. This definition is utilised to ensure that significant issues may be prioritised to ensure proportionality in advance of UK deployment. The arrangements for managing GDA commitments are defined within HPP-3295-0013, GDA Manage Commitments, Assumptions and Requirements [4]. This procedure defines the process / expectations for identification, categorisation, documentation, review, approval, communication and resolution along with roles and responsibilities. The process is illustrated in Figure 13.

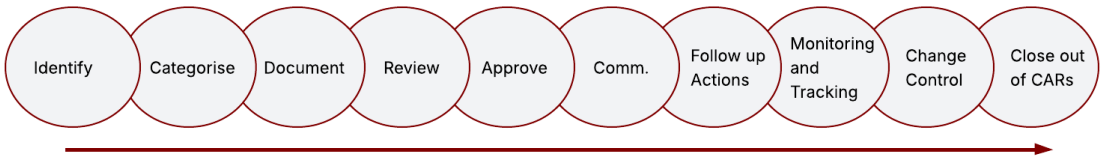

Figure 13: Outline of the Process for the Management of the GDA Commitments

The GDA CAR Register is the document used to record the progress of the CARs through this process. Post-GDA, the CAR Register will be utilised as an essential input to the scope and specification of the developing future SSECs, as set out in the Manage SSEC Process [106]. The CAR Register [5] will ensure that commitments remain clear, visible and their resolution managed with progress / close-out recorded. Further details of commitments raised in PSR v1 are provided in PSR Chapter A5. This will form part of any hand-over package to the future operator / licensee organisation.

4.8.5 Management Arrangements for specialist aspects of the SSEC

Claim 1.4.4 – A4: The management arrangements for specialist aspects of the SSEC are suitable to deliver a safe and secure UK SMR-300

Sub-chapters 4.8.1 to 4.8.3 discuss the SSEC staged development strategy, its general structure and the framework established by Holtec for the production, review, approval of the SSEC documentation including management of commitments. These arrangements apply generically across all safety, environmental and security processes / documentation.

This sub-chapter provides a brief overview of management arrangements for specialist aspects. The aim is to provide confidence in the comprehensive nature of the SSEC in these specialist areas but not to repeat information presented elsewhere in the SSEC, in particular the outcomes of the specific safety, environmental and security assessments.

4.8.5.1 Management of Conventional Safety

Ensuring the safety of workers and the public during the lifecycle of the SMR-300 project is recognised as essential by Holtec. This will be achieved by an SMR-300 delivery organisation with excellent safety leadership and culture and through compliance with all relevant UK health and safety legislation. Most notably;

- Health and Safety at Work etc. Act 1974 [58];
- Management of Health and Safety at Work Regulations 1999 [66], and;
- Construction (Design and Management) Regulations 2015 [65].

Other relevant legislation, regulation and RGP are defined in more detail within Chapter B12 Nuclear Site Health and Safety and Conventional Fire Safety [10].

Of particular importance during the current SMR-300 design development phase is the application of the CDM 2015 [65]. The UK SMR-300 is a notifiable project under CDM 2015 and will need to comply with those regulations. Holtec is the Responsible Designer and, as such, will comply with the Designers' Duties set out in CDM 2015. Those Duties require Holtec to ensure that the project is safe, So Far As Is Reasonably Practicable (SFAIRP) across the NPP lifecycle.

As required by CDM 2015, Holtec will also ensure:

- Competent personnel are available to deliver the design.
- They cooperate and coordinate effectively and efficiently with other parties on the project.
- They provide accurate information about the residual design risks and on how they can be further mitigated and ensure this is effectively communicated to those who need to know.

The GDA Reference Design [141] (refer to sub-chapter 4.7.7) is based on the design developed to meet applicable US codes and standards, including the OSHA regulatory system [49]; it has not explicitly been developed to comply with CDM 2015 or other UK specific legislation. As such, it is recognised that the design may need to be developed to address UK requirements in some areas.

A CDM Strategy [11] has been produced which defines the approach to ensure that the design complies with CDM 2015 and other relevant UK regulations. Implementation of the CDM Strategy is set out in the Nuclear Site Health and Safety Management System (SMS) Report [160]. The SMS report focuses on the implementation of the CDM Strategy but also sets out general arrangements for effective safety management in regard to aspects such as;

- safety leadership;
- safety culture;
- behavioural safety;
- cooperation and coordination, and;
- RGP.

In summary, a review of the SMR-300 Standard Design Process against UK health and safety regulatory requirements has been initiated following presentation of a Design Challenge to the DAC, following the process set out in HPP-3297-0017 [143].

As part of the development of the health and safety management system, consideration is being given to ensuring compliance with ISO 45001 [44].

For this stage of the project, where the focus is on the GDA activities, the risks to employees, the general public, etc. relate to those risks existing in the standard office environment. The arrangements for controlling those risks are set out in the Holtec Britain Office Health and Safety Manual. The scope of this manual is set out in the SMS report [160].

In relation to subsequent project lifecycle phases, assumptions have had to be made, but it has been assumed that Holtec will remain in the role of Responsible Designer and provide design support throughout the project lifecycle. As Responsible Designer, Holtec will continue to discharge the Duties of Designer (as defined in Regulation 9 of CDM 2015 [65]) throughout those phases with the aim of ensuring that designers duties have been discharged and the design is safe and remains safe SFAIRP.

It is recognised that the context in which those Designers' Duties are discharged, will change as the project moves through its various phases. Holtec's response to those changes is discussed in the SMS report [160]. And for each phase, the report outlines how Holtec will continue to successfully discharge their duties as a designer.

Training and briefing on CDM 2015 is an integral part of Holtec's approach and will encompass;

- A broad understanding of CDM 2015;
- Specific training on Designers' Duties;
- Skills training focussing on delivering effective design risk reviews;
- The arrangements for dealing with the key areas of difference between the US and UK health and safety regulatory regimes.

Chapter B12 [10] sets out more details on the approach to upskilling and competency management.

4.8.5.2 Management of Nuclear Safety

No nuclear hazards may arise during the SMR-300 design, construction, commissioning phases until nuclear material is brought onto site. However, Holtec recognise that nuclear safety needs to be considered throughout the design development process and ensuring the integrity of the design and safety assessments is essential to ensure nuclear safety during the later (active commissioning, operational and decommissioning) phases. This emphasises the importance of robust MSQA arrangements, particularly in the early phases, and also having appropriate nuclear safety and design assessments to ensure that safety measures (engineered and operational) are robustly identified, designed, substantiated and implemented to deliver the defined safety functions within iterative design and safety assessment processes.

The SMR-300 reference design in support of the GDA [141] has been developed and assessed against US expectations. Holtec recognised that demonstration against UK regulator expectations would be an essential part of the GDA. Hence an integral part of the GDA has been the identification of US design and assessment processes which differ from UK expectations and the conduct of additional design and safety assessments to address the delta.

To ensure clarity on these additional safety assessments, a Safety Assessment Handbook [25] has been produced. The SAH is considered to contribute to the MSQA arrangements as it provides a 'how to guide' on the safety assessments and associated processes / methodologies utilised within the safety assessments related chapters, ensuring consistency and demonstrating compliance with UK expectations.

Figure 14 illustrates the overall relationship between the nuclear safety assessments, the design development and substantiation, the outputs of the assessments and the PSR chapters:

- **Design and Safety Principles, Safety Management and Methodologies:** Chapters A2, A4, the SAH and the Through-life SSEC define the overarching arrangements for the development of the design and nuclear safety case.
- **Safety Assessments:** Chapters B14 - B17, B21, B22 detail the safety assessments conducted in support of the GDA using the arrangements described in the SAH [25] and the results.
- **Design Development and Substantiation:** Chapters B1, B2, B4 - B6 and B13 report the design and its substantiation against the safety requirements (commensurate with the concept design development) along with the construction and commissioning considerations.
- **Operational Arrangements:** Chapters B9, B10 and B15 capture the outputs from the design and safety assessments with the aim of ensuring that these will be robustly implemented to ensure nuclear safety during operation of the SMR-300. These will ultimately include the limits and conditions, engineered safety measures (SSCs with defined safety requirements), operational safety measures, EIMT and emergency arrangements.
- **Chapter A5:** presents a summary of the SSEC and the ALARP justification.

For the GDA the maturity of the CAE within the individual chapters and supporting the overall conclusion is commensurate with a concept design - this will mature as the detailed design and assessments develop to deliver a robust Pre-Construction Site Specific SSEC.

Importantly, the diagram illustrates the design and safety iteration with key points in the diagram showing feedback loops between safety analysis, design and operational arrangements. An engineering schedule will be developed as part of future UK design development to enable the link between safety analysis and the engineering substantiation of the case. This is further discussed in PSR Part B Chapter 19.

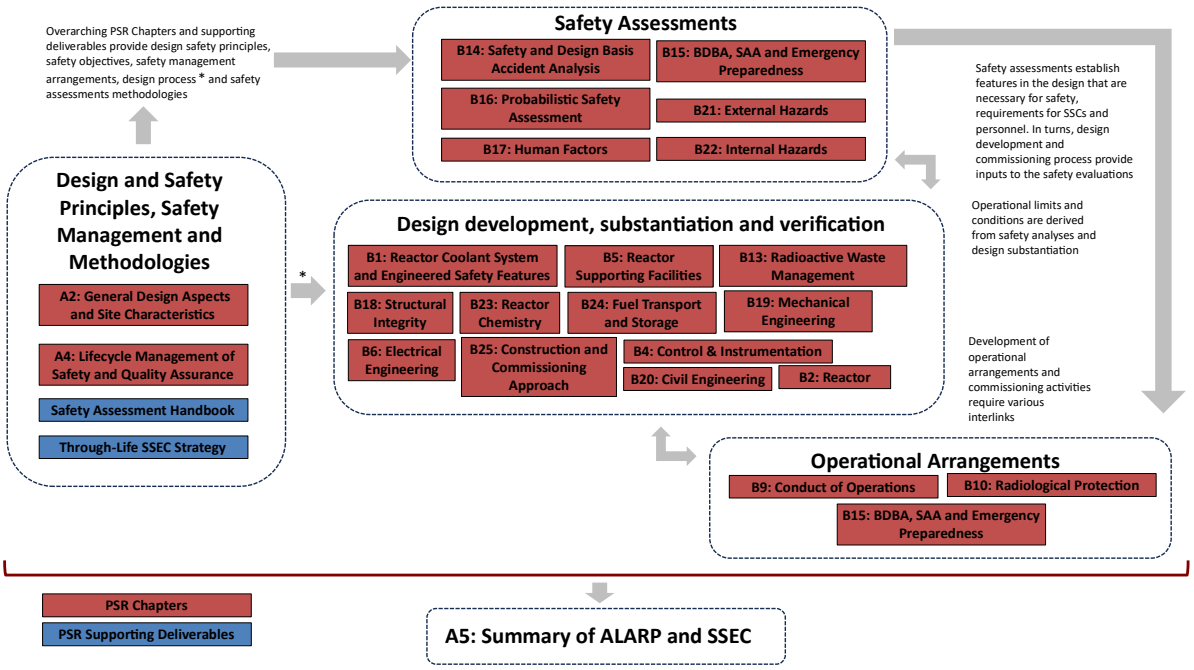

Figure 14: Illustration of Nuclear Safety Assessments, Design, Outputs and Chapters

4.8.5.3 Environmental Management

Sub-chapter 4.1.3 generally outlines the structure of the PER and the interfaces with this MSQA chapter. Specific environmental topics which relate to MSQA are discussed below.

4.8.5.3.1 Development of Environmental Management System / Compliance with ISO 14001:2015

As noted in sub-chapter 4.5.2, Holtec International are certified to ISO 14001:2015 [43] and this registration includes the SMR-300 design development project. CD-29 [90] implements the requirements of this standard, complying with both ISO 14001:2015 [43] and ISO 45001:2018 [44] defining the need to identify, communicate environmental aspects and address the associated risks. This provides confidence that environmental aspects associated with the SMR-300 design development project are being considered.

Holtec Britain are developing an Environmental Management Systems to support the SMR-300 UK initiative with the aim of gaining ISO 14001 certification for the UK SMR-300 GDA and subsequent UK implementation phases. This is underpinned by the Holtec Britain Environment Policy [161]. The following have been produced to ensure robust management of environmental risks, progressing toward this accreditation:

4.8.5.3.2 RSR-BAT Demonstration

Sub-chapter 4.7 discusses the role of the Design Stability Toolkit [162], which includes the need to consider BAT and ALARP, when assessing potential design changes to the GDA reference design in accordance with the Design Management process [143]. The need to demonstrate BAT derives from the Radioactive Substances Regulation under Schedule 23 of Environmental Permitting (England and Wales) Regulations (EPR) 2016 (as amended). The

prospective operator of the SMR-300 (to be decided by the UK Government) will need to apply for an RSR environmental permit and upon issue of the RSR permit undertake operations which demonstrably utilise BAT. To support BAT considerations during the design phase, Holtec Britain have produced:

- Approach and Application to the Demonstration of BAT [35] provides guidance on the principles and requirements that apply to BAT under RSR in addition to the wider environmental optimisation philosophy relevant to the generic SMR-300.

- SMR-300 GDA RSR-BAT Guidance [156]. This document details the approach to demonstrating how the SMR-300 design complies with RSR environmental permit conditions relating to the application of BAT. The guidance is applicable to the engineering design and methods of operation for all lifecycle stages of the SMR-300 which have an effect on the production, management, and monitoring of radioactive discharges and waste, and to the preparation of wastes for the disposal. Guidance on roles / responsibilities, systematic processes and a proportionate approach is included about options assessment and production of BAT statements / studies / assessments. Management of BAT demonstrations is provided along with information on communication and dissemination.

In order to collate the BAT demonstrations PER Chapter 6 has been introduced.

4.8.5.3.3 Environmental Protection Functions and Measures

The EPR 2016 [68] places a requirement on nuclear operators to prevent harmful discharges to the environment by ensuring environmental protection measures are in place. These measures must be demonstrated to be BAT. Where SSCs are identified to deliver these functions, they must be correctly operated and maintained in accordance with the conditions on the Environmental Permit.

The Holtec SMR-300 GDA Environmental Protection Functions and Measures Identification Methodology [163] has been produced to capture guiding principles and a methodology that demonstrates Holtec Britain's arrangements for identifying and adequately managing SSCs that perform an EPF.

4.8.5.4 Security Management Arrangements

The Nuclear Industries Security Regulations (NISR 2003) [70] sets out legal requirements to protect Sensitive Nuclear Information (SNI) as well as protecting nuclear material from sabotage and theft. Through the GDA, Holtec have ensured compliance with these requirements via robust security management arrangements. The holistic approach adopted involves three key enablers as illustrated in Figure 15 - a robust security management system; appropriate security infrastructure with a blend of protective physical, cyber and personnel security measures within which to deliver the required protection with supporting security governance, leadership, culture, and behaviour.

Figure 15: Security Compliance Enablers

The GDA security management arrangements have been developed under CD-44, the Holtec Britain Security Manual [164]. The manual is supported by a range of procedures designed to ensure the security of SNI as illustrated in Figure 16.

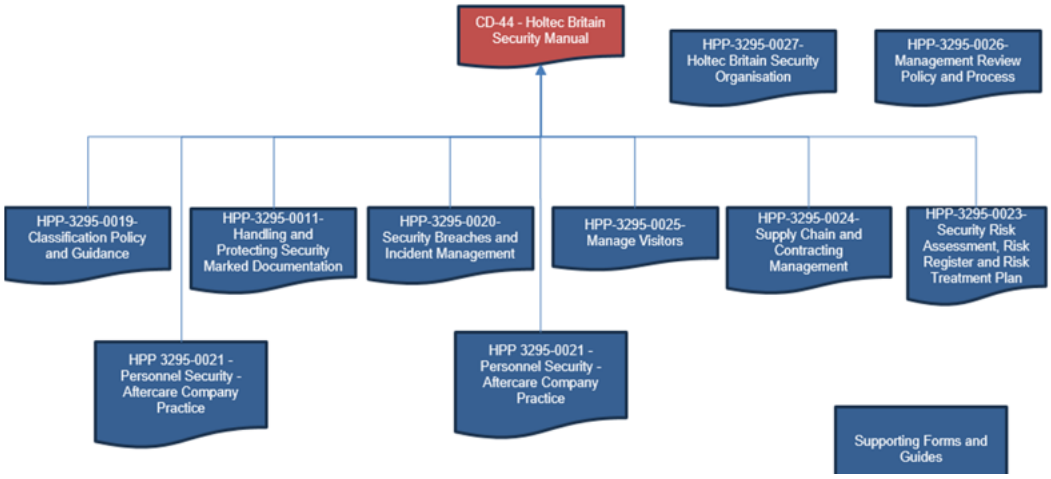

Figure 16: Illustration of Security Management Arrangements

The future SMR-300 licensee will have a legal requirement under NISR 2003 to implement an approved security plan to protect nuclear material at the site from sabotage and theft, and to protect against the compromise or loss of SNI within the site. The delivery of these requirements is facilitated by the application of ONR SyAPs [56] during the nuclear security GDA activities and application of the 'Secure by Design (SbD)' principle by Holtec during the design development. These aspects are further discussed in the GSR [8].

4.8.5.5 Safeguards Management Arrangements

The Nuclear Safeguards Regulations (NSR 2019) [71] places legal requirements on holders of civil nuclear material in the UK to account for, and control, Qualifying Nuclear Material (QNM) and provide safeguards information in support of the UK domestic civil nuclear safeguards regime.

The PSgR [165] demonstrates Holtec's understanding of the NSR 2019 requirements and how the developing SMR-300 design will be compliant. The PSgR presents the SMR-300 Safeguards Programme which was developed to ensure compliance with NSR 2019 and the UK's international obligations under the UK / IAEA Voluntary Offer Agreement (VOA) and Additional Protocol (AP) along with export controls in relation to nuclear weapons programmes. The SMR-300 Safeguards Programme is also compliant with the ONMACS assessment principles.

The arrangements necessary to implement the site-specific safeguard and non-proliferation requirements will be developed post-GDA. The future nuclear licence holder supported, where appropriate, QNM by Holtec as the technology provider, will have a legal requirement to maintain a system for accounting and control of QNM and to report prescribed safeguards information to ONR. The delivery of these requirements is facilitated by the application of the 'Safeguards by Design' (SgBD) principle by Holtec during the GDA and associated design development. The first issue of the SgBD Basic Technical Characteristics (BTC) has been submitted to ONR as part of the GDA Step 2 submissions.

4.8.6 CAE Summary

Holtec have mature arrangements to manage safety, security and environmental protection requirements on its many international projects. These arrangements have been extended to the GDA project to deliver the SSEC for the generic SMR-300 addressing UK-specific requirements. This sub-chapter sets out the management arrangements developed to ensure the quality of the conventional / nuclear safety and security / safeguard documentation in support of the generic SMR-300 GDA. As such Claim 1.4.4 is considered to be met commensurate with the development stage of the UK SMR-300 delivery initiative.

4.9 HOLTEC ARRANGEMENTS FOR FUTURE LIFECYCLE PHASES

This sub-chapter provides the arguments and evidence in support of the following claim:

Claim 1.4.5: Holtec has appropriate arrangements for future lifecycle phases to deliver a UK site-specific SMR-300.

The following arguments are presented to answer Claim 1.4.5:

- The management arrangements for development of the detailed design and SSEC are suitable to deliver a safe and secure UK SMR-300 (A1).

4.9.1 Arrangements for development of detailed design and SSEC

Holtec International, as the Requesting Party, will only complete a 2-Step GDA and do not intend to progress to a Step 3. Holtec Britain will transition into a focus on further developing the SMR-300 for deployment in the UK, noting that Holtec International maintain focus on development of the SMR-300 reference design for deployment at Palisades in the US. The SSEC will transition into the production of the site Pre-Construction SSEC as described in the Through-life SSEC [6]. An OPEX exercise will be conducted at the end of Step 2 to determine improvements based on the experience gained from the Step 2 GDA activities. Holtec Britain is not intending to be the UK Licensee or Operator (A_MSQA_035) and therefore any future SSEC development will require engagement with future plant owners and operators.

Following successful completion of the GDA Step 2, Holtec Britain, with the support of Holtec International and other strategic partners, will continue developing the UK SMR-300 design and associated SSEC justifications. This development work will be prioritised on the progression of the GDA Resolution Plans and Commitments and those aspects which are generic, in order to most effectively utilise resource and minimise potential for nugatory work. Holtec's collective arrangements are considered suitable and sufficient to manage deliverables for the purposes of configuration control and record keeping, to enable future licensees to meet regulatory expectations and requirements of a Site Licence holder. Note that overall RD responsibilities are expected to be managed by Holtec Britain with direct support from Holtec International for GDA scope activities.

Topic Engagement Plans (TEPs) are not planned to be re-issued to support GDA Step 2 but Holtec may choose to utilise them as a planning tool to support follow on Generic Pre-Construction activities. The future role / use of the TEPs will be reviewed to determine their value as part of the regulatory engagement strategy.

[REDACTED]

The developments will be captured in a Generic Pre-Construction SSEC which will be a transition document which is not intended to permission physical works.

[REDACTED]

4.9.2 The Capable Organisation Post-GDA

Holtec International recognise the organisational challenges to deliver a SMR-300 at a specific site within the UK through the detailed design, construction, manufacture, installation and

commissioning phases. Holtec Britain will grow organisational capability and capacity in order to support further UK SMR-300 design development and UK site-specific SMR-300 design activities.

The Holtec Britain organisation will be further developed to support a robust Responsible Designer capability for the detailed design and assessment phases and beyond, noting that the competency requirements will necessarily evolve to support the demands of the subsequent project / operational phases.

Holtec is well placed to meet these challenges, noting:

- Holtec have an established network of global partners that have been working with Holtec to develop the US reference design.
- HDEC is a global strategic partner to Holtec's SMR programme, formalised by signing a partnership agreement in November 2021, of which HDEC will perform the detailed design of the BoP and prepare the full plant construction specification for the SMR-300 globally.
- Holtec also has a global partnership arrangement with MELCO for their safety system digital I&C platform, which is a proven design with significant operational experience from Japanese NPPs. There are other international supply chains in support of the UK development.
- Holtec Britain intends to lead and provide the major nuclear components (SMR vessels, internals, Steam Generators, ECCS equipment, heat exchangers, tanks), through its manufacturing facilities in UK and international supply chain.
- Within the UK, Holtec have bolstered their established international partnerships by developing the UK key supply chains through additional strategic relationships with UK based organisations.
- Holtec have also identified a number of specific areas requiring specialist knowledge and experience and Holtec has therefore established relationships with companies and higher education establishments who bring the knowledge and experience required in the identified capability areas.

The organisation for post GDA design within UK will need to be developed to ensure sufficient capability in place to continue SMR-300 deployment. The organisation will be based on the structure established in GDA, though grown to increase capability and capacity.

The existing Holtec organisation has capability in all areas and will develop further in order to support role of Responsible Designer. Currently, Holtec Britain has created a UK team in Bristol to provide the main regulatory interface and produce all new content and deliverables required for the GDA. The capability and capacity of the Holtec Britain team has been based on the scope and disciplines defined for GDA. Future resource will need to consider scope beyond the Nuclear Island, expanding to the Balance of Plant (BOP) and totality of the licensed site. Future resourcing beyond GDA will be designed based on definition of activities, core capability needs and the SMR-300 delivery model, which is still to be fully defined.

From an environmental perspective Holtec Britain will be responsible for assessing the environmental protection performance of the SMR-300's lifecycle phases and will need to demonstrate to UK regulators and the prospective operator that the reactor will be compliant to operate under UK law.

4.9.3 CAE Summary

This sub-chapter presents Holtec's arrangements for future lifecycle phases to support the safe and secure delivery of a UK site-specific SMR-300. It provides the arguments and supporting evidence for Claim 1.4.5, focused on the adequacy of future management arrangements for the development of the detailed design and Site-Specific Environmental Case (SSEC) (A1).

Noting the early lifecycle stage of the generic SMR-300, Holtec has established proportionate plans and partnerships to enable a smooth transition into future detailed design and site-specific phases. These include continued regulatory engagement, further development of organisational capability in Holtec Britain, and leveraging established global supply chain partnerships. The approach taken does not foreclose future options and provides flexibility for integration with a future UK licensee.

In summary, Holtec's post-GDA arrangements are judged to be appropriate for the current stage of development. Claim 1.4.5 is therefore considered to be met at a level commensurate with the project maturity. Future development of organisational capacity, design scope, and engagement with the prospective licensee will be essential for successful delivery beyond GDA.

4.10 CHAPTER SUMMARY AND CONTRIBUTION TO ALARP

This sub-chapter provides an overall summary and conclusion of the A4 chapter and how this chapter contributes to the overall demonstration of ALARP for the generic SMR-300. Chapter A5 [7] sets out the overall approach for demonstration of ALARP and how contributions from individual chapters are consolidated.

This sub-chapter therefore consists of the following elements:

- Technical Summary;
- ALARP Summary and Demonstration of Relevant RGP;
- GDA Commitments and Forward Actions.
- Conclusion.

A review against these elements is presented below under the corresponding headings.

4.10.1 Technical Summary

PSR Chapter A4 demonstrates the following Level 3 claim to a maturity appropriate for a PSR:

Claim 1.4: Holtec has appropriate integrated project, quality, design and safety management arrangements to deliver a UK SMR-300 which is demonstrably safe and secure, protecting people and

Holtec has appropriate Quality Management arrangements to deliver a UK SMR-300. Holtec is an established project delivery organisation with a proven record on its many international projects including within the nuclear sector. Holtec's Quality Management System is mature and meets the requirements of ISO 9001:2015 and the US NRC, providing a framework for consistent high-quality delivery which encompasses nuclear safety expectations. The quality arrangements are cascaded to the SMR-300 design and GDA projects as evidenced via the suite of Corporate Manuals, supporting processes and the project specific PMP / PQPs and their supporting procedures. The existing QMS provide a framework for the development of specific quality management arrangements to allow Holtec to support the delivery of the subsequent stages of the SMR-300 lifecycle.

Project Management arrangements are considered to be demonstrably in place for the delivery of the Step 2 GDA. Further development of the project management arrangements for the subsequent stages is recognised as being required. In particular the project management arrangements for the transition to the post Step 2 GDA phase, i.e. the development of the Generic Pre-Construction SSEC, is required to be developed in conjunction with the SSEC approvals.

Holtec have defined Holtec's Design Management arrangements to support the delivery of a safe and secure UK SMR-300. These arrangements are drawn from Holtec's existing quality and design governance systems, adapted to meet the expectations of the UK GDA process. Holtec's arrangements are considered to be sufficient against US NRC requirements to deliver a SMR-300 design, at this stage of project maturity.

The chapter identifies where there is further work required to fully substantiate Claim 1.4.3 and raises commitments where further evidence is required to demonstrate satisfactory

implementation of arrangements. Noting the early lifecycle stage of the generic SMR-300, the evidence presented demonstrates that Holtec has stablished a design management approach that is appropriate for this stage of design maturity. Commitments raised will be progressed and are expected to be addressed ahead of the Pre-Construction SSEC delivery.

Holtec's Safety, Security and Environment Case management arrangements, as presented, are considered adequate to deliver a UK SMR-300. Holtec have mature arrangements to manage safety, security and environmental protection requirements on its many international projects. These arrangements have been extended to the GDA project to deliver the SSEC for the generic SMR-300 addressing UK-specific requirements. Chapter A4 sets out the management arrangements developed to ensure the quality of the conventional / nuclear safety and security / safeguard documentation in support of the generic SMR-300 GDA. As such Claim 1.4.4 is considered to be met commensurate with the development stage of the UK SMR-300 delivery initiative.

Noting the early lifecycle stage of the generic SMR-300, Holtec has established proportionate plans and partnerships to enable a smooth transition into future detailed design and site-specific phases. These include continued regulatory engagement, further development of organisational capability in Holtec Britain, and leveraging established global supply chain partnerships. The approach taken does not foreclose future options and provides flexibility for integration with a future UK licensee. In summary, Holtec's post-GDA arrangements are judged to be appropriate for the current stage of development. Future development of organisational capacity, design scope, and engagement with the prospective licensee will be essential for successful delivery beyond GDA.

4.10.2 ALARP Summary

4.10.2.1 Options Considered to Reduce Risk

While this Chapter does not directly present or evaluate specific engineering design options, it plays a crucial role in establishing the framework and processes that enable the systematic consideration of options to reduce risks in accordance with regulatory expectations for ALARP (As Low As Reasonably Practicable) and BAT (Best Available Techniques). The arrangements described in Section 4.7 and specifically Section 4.7.6, Design Change, describe and present evidence that enables optioneering in both US and UK context.

The design management arrangements ensure that design changes, requiring a Holtec International Design Decision, consider options and assess impacts of the change on nuclear safety, environment and conventional safety, among other disciplines. Where SMR-300 design changes originate from the Design Authority, a proportionate ALARP and BAT assessment is performed by Holtec Britain, which includes optioneering. The PDCs are used to make initial ALARP and BAT judgements on the change, identify commitments and identify any impacts on the SSEC.

4.10.2.2 Demonstration of RGP

RGP associated with Pressurised Light Water Reactors design has shaped the development of US NRC regulations, EPRI guidance and the associated quality management processes for delivery of the SMR-300. The Holtec QAP is founded on recognised industry standards including IAEA, INPO, WANO and ISO certification.

Specifically in design management, there is confidence that the design processes and associated controls are appropriate for this stage of design and for a Step 2 fundamental GDA assessment. There are however differences in regulatory expectations between the US and the UK that will need to be addressed. Future UK delivery of the SMR-300 will encapsulate RGP through meeting ISO, IAEA and UK Regulatory expectations.

4.10.3 GDA Commitments

GDA Commitments which relate to this Chapter have been formally captured in the Commitments, Assumptions and Requirements process. Further details of this process are provided in Part A Chapter 4. The GDA Commitments raised in Chapter A4 are:

C_MSQA_107: The Design Control Procedure (HPP-8002-1010) and the use of Design Integration Reviews (DIRs) is central to Holtec's control of design development. The implementation of the Design Control Procedure requires further evidencing. A Commitment is raised to evidence the implementation of the Design Control Procedure and DIRs. Target for Resolution - Issue of Pre-Construction SSEC.

C_MSQA_108: Design Manuals and System Engineering Management Plans (SEMP) are considered best practice for the management of design development. These documents have not yet been produced for the UK GDA. A Commitment is made to produce a UK Design Manual and a UK System Engineering Management Plan to support management of future UK SMR-300 design development. The UK Design Manual and UK SEMP will define, amongst other things, technical governance arrangements and division of responsibility between the Licensee and Responsible Designers. Target for Resolution - Issue of Pre-Construction SSEC.

C_MSQA_109: The design of the SMR-300 and the management arrangements in place are informed by degradation and ageing mechanisms. A Commitment is raised to present this mechanistic understanding in the form of an ageing and degradation strategy and verify SMR-300 arrangements and activities for degradation management in the UK Context. Target for resolution: Issue of Long Lead Item and SSC procurement specification.

C_MSQA_110: A Commitment is raised to complete the integration of a Requirements Management Tool and associated database with the SMR-300 design management arrangements. Target for Resolution - Issue of Pre-Construction SSEC.

C_MSQA_111: A Commitment is made to produce a Configuration Management Plan (CMP) and an Engineering Schedule to support design management of the UK deployment of the SMR-300. Target for Resolution - Issue of Pre-Construction SSEC.

4.10.4 Conclusion

This chapter summarises the overarching quality arrangements and design development processes in place to deliver Holtec International's SMR-300. It identifies the claims, arguments and currently available evidence that form the basis of the safety case for the Lifecycle Management of Safety and Quality Assurance throughout the lifecycle of SMR-300 to a maturity aligned to a Preliminary Safety Report. As the design and safety case are developed, evidence will be provided to substantiate these claims and arguments.

Holtec's MSQA framework is built upon extensive experience in nuclear project management, spanning reactor design, plant operations, decommissioning, and manufacturing. The framework aligns with international standards, such as ISO 9001:2015, and American Society of Mechanical Engineers (ASME) codes, ensuring compliance with regulatory requirements, including 10 CFR 50, Appendix B, encompassing the full lifecycle from concept design through deployment to decommissioning.

Noting the early lifecycle stage of the generic SMR-300, this chapter presents a comprehensive understanding of MSQA related topics relevant to the delivery of GDA Step 2, i.e. up to approval of the SSEC for the generic SMR-300. In addition, this chapter looks forward to subsequent lifecycle phases and outlines the approach to key MSQA topics.

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4.12 LIST OF APPENDICES

Appendix A PSR Part A Chapter 4 CAE Route Map

Table 5: PSR Part A Chapter 4 CAE Route Map

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