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PSR Part A Chapter 5 Summary of ALARP

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5.1 INTRODUCTION

The Fundamental Purpose of the Generic Design Assessment (GDA) Safety, Security and Environment Case (SSEC)[1], as defined in Holtec Small Modular Reactor (SMR) GDA Preliminary Safety Report (PSR) Part A Chapter 1 Introduction [1], is:

SSEC Fundamental Purpose: '*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.'*

This PSR Part A Chapter 5 aims to summarise the PSR and conclude whether the PSR Fundamental Objective has been met. It then draws together the outcomes of the PSR, Preliminary Environmental Report (PER), Generic Security Report (GSR) and Preliminary Safeguards Report (PSgR) against their objectives to demonstrate that the Fundamental Purpose of the SSEC has been met.

The Fundamental Purpose is achieved through the Fundamental Objectives of the PSR, the PER, the GSR and the PSgR, which are:

PSR Fundamental Objective: *The PSR summarises the safety standards and criteria, safety management and organisation, claims, arguments and intended evidence to demonstrate that the generic SMR-300 design risks to people are likely to be tolerable and As Low As Reasonably Practicable (ALARP).*

PER Fundamental Objective: *The PER presents the environmental standards, criteria, and management arrangements to provide confidence that the design, construction, operation and decommissioning of the generic SMR-300 design protects people and the environment from harm and applies Best Available Techniques (BAT), incorporates Relevant Good Practice (RGP) and Operating Experience (OPEX).*

GSR Fundamental Objective: *Security risks are managed to protect workers and the public from a radiological event arising from the theft or sabotage of nuclear material or other radioactive material (or supporting systems) or through the compromise of Sensitive Nuclear Information (SNI).*

PSgR Fundamental Objective: *The UK generic SMR-300 Safeguards programme will support the delivery of the UK's obligations under the Voluntary Offer Agreement (VOA) and Additional Protocol (AP).*

The Fundamental Objectives then decompose to the individual overarching claims, with further Claims, Arguments and Evidence (CAE) in the respective chapters of each report that forms the SSEC. This is visualised in a simple hierarchy in Figure 1**.**

[1] The SSEC also considers safeguards. The generic SMR-300 safeguards case integrates with the SMR-300 SSEC via the SMR-300 Fundamental Purpose.

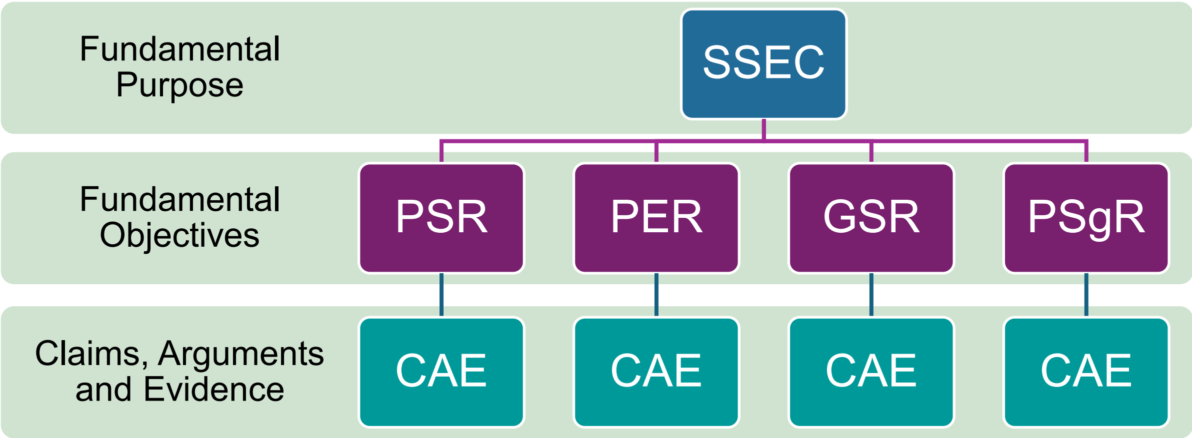

Figure 1: The Fundamental Purpose, Objective and CAE Hierarchy

5.1.1 Purpose and Scope

The purpose of this Chapter is to summarise the PSR and conclude whether the PSR Fundamental Objective has been met and that the risks associated with the SMR-300 are likely to be tolerable and ALARP. Further, it aims to draw together the outcomes of the PER, GSR and PSgR against their objectives to demonstrate that the Fundamental Purpose of the SSEC has been met.

An introduction to the ALARP principle and its legislative status within the UK is provided in sub-chapter 5.2 and sub-chapter 5.3 provides an overview of the ALARP Claims, Arguments and Evidence. Sub-chapter 5.4 provides a discussion of current standards, methods and guidance which are used to reduce risks within a United States (US) legislative regime, and their relevance to the demonstration that risks associated with the SMR-300 can be shown to be reduced to ALARP.

Central to the demonstration that the fundamental objectives have been met is the thread of CAE for the SSEC. The overall claims route map and its decomposition across the PSR, PER, GSR and PSgR is presented in Part A Chapter 3 [2].

All lower level claims across the various PSR chapters make a contribution to the overall demonstration of ALARP. Discussion of how Part A Chapter 5 consolidates and summarises these contributions across the PSR, is provided in 5.1.3 with the key contributions from each chapter in addition to an overarching summary of the PSR presented in sub-chapter 5.8.

In addition to its role of providing a summary of the PSR, Part A Chapter 5 also directly contributes to the demonstration of Claim 1 and Claim 2 by demonstration of specific claims. Part A Chapter 5 links to overarching SSEC Claim 1.

Claim 1: The generic Holtec SMR-300 design, and safety case are developed for a GB-context generic site using integrated project, quality and safety management arrangements that take cognisance of relevant good practice and adopt appropriate codes and standards in the context of the UK regulatory regime.

Claim 1 is an enabling claim that is demonstrated across Part A Chapter 2 [3], Part A Chapter [4] and Part A Chapter 5 of the PSR and provides an overarching justification of the design and safety principles, applicable codes and standards, safety management arrangements, historic development of the design and the approach to ALARP.

This chapter supports the claim that an ALARP methodology is derived and applied to the generic reference design as captured by Claim 1.5, and further discussed in sub-chapter 5.5.

Claim 1.5: An appropriate ALARP methodology is applied to the design process to ensure ongoing design decisions support the reduction of risks to ALARP.

Holtec is seeking to implement a pragmatic and holistic approach to ALARP which builds upon the design in the US. Design stability of a SMR-300 design which can be deployed in a global fleet is central to Holtec's deployment strategy. A stable design is one that is suitable for deployment in Great Britain (GB) or somewhere else in the world. Design stability is the concept that ensures that the impact of location specific requirements on the global fleet design are minimised and that the global fleet is optimised for safety and environmental aspects. The design stability process is intended to focus effort on addressing the greatest risk and supporting the safety and operational factors associated with a globally deployable reactor design. Lower-level risks and ALARP judgements made on a topic-by-topic, fault-by-fault and system-by-system basis are at risk of challenging the broader benefits of a pragmatic cost-effective approach, which supports the global deployment of the SMR-300. Further discussion on the design stability process is included within sub-chapter 5.5 of this Chapter.

Part A Chapter 5 also links to Overarching SSEC Claim 2.

Claim 2: The design and safety assessment shows that the generic Holtec SMR-300 can be constructed, commissioned, operated, and decommissioned on a generic site in the UK with risks that are tolerable and ALARP.

Claim 2 is decomposed across the validation and verification lifecycle (V-Model), covering all safety analysis, engineering and cross-cutting topic discipline areas, and hence is evidenced across Part B Chapters of the PSR. Part A Chapter 5 looks across the Part B chapters to summarise the high-level arguments and evidence for the design stage to show that the risks to workers and the public are tolerable and ALARP. Part A Chapter 4 [4] 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. Part A Chapter 5 shows that Claim 2.4 can be met and that risks to the public and workers during the lifecycle of the generic SMR-300 will be reduced to ALARP.

Claim 2.4: The risk to workers and the public is tolerable and is as low as reasonably practicable, for the design, construction, commissioning, operation and decommissioning of the generic Holtec SMR-300.

The scope of this claim broadly aligns with the four tests of the ALARP demonstration, shown in Figure 2, which are integrated and demonstrated to a maturity appropriate for a PSR across this chapter.

Figure 2: The Four Tests of ALARP

The ALARP principle requires the following tests to demonstrate ALARP:

1. Ensuring that legislative/regulatory requirements are complied with – see sub-chapter 5.4.2.
2. Justification of the claim that the design follows RGP and that it has been used in the development of the design – see sub-chapter 5.4.3.
3. Assessment of the Tolerability Of Risk (ToR) through comparison with the nine numerical Targets in Office for Nuclear Regulation (ONR)'s Safety Assessment Principles (SAP) which translate the ToR framework [5], demonstrating that the risk is at least in the tolerable region i.e., meets Basic Safety Levels (BSL) – see sub-chapter 5.6.
4. Options should only be disregarded if the sacrifice is considered to be grossly disproportionate to the benefits of risk reduction that would be gained – see sub-chapter 5.7.

The PER Fundamental Objective is met by overarching Claims 3 and 4. The GSR and PSgR Fundamental Objectives are met by Security Claims (SyC) 1-7 and Safeguards Claims (SgC) 1-3. The links to these claims are summarised in sub-chapters 5.8 and 5.9 of this Chapter A5.

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

5.1.2 Assumptions

Assumptions which relate to this topic have been formally captured via the process defined in GDA Capturing and Managing Commitments, Assumptions and Requirements [6]. Further details of this process are provided in Part A Chapter 4 [4].

No assumptions have been identified within this document at the current revision.

5.1.3 Interfaces with other PSR Chapters

PSR Part A Chapter 5 is intended as a summary of the claims made throughout the SSEC and naturally links to all SSEC reports and their respective chapters. Figure 3 provides a high-level overview of how the SSEC interfaces with Part A Chapter 5. The overall summary against the Fundamental Purpose of the SSEC is provided in sub-chapter 5.10.

Each PSR Part B Chapter also has a dedicated ALARP summary, showing how each chapter contributes to the overall demonstration of ALARP for the generic SMR-300. For each PSR chapter, these are summarised in sub-chapter 5.8.

Whilst all PSR chapters with claims contribute to the overall ALARP demonstration, some chapters of the PSR provide a more significant contribution. Key interfaces include:

Part A Chapter 2 General Design and Site Characteristics [3] presents an overview of the design evolution, the fundamental design and safety principles, the adopted codes and standards and the reference design for the generic SMR-300. This is used for the demonstration that RGP has been followed, as well as providing the basis for the design decisions made prior to the start of the GDA process. Part A Chapter 2 [3] also introduces the numerical targets of which the demonstration of ToR is measured against.

Part B Chapter 10 Radiological Protection [7] presents the basis for demonstration that the risk is ALARP during normal operations in support of meeting the numerical targets 1-3 introduced in Part A Chapter 2 [3].

Part B Chapter 14 Safety and Design Basis Accident Analysis [8] presents the deterministic analysis for the SMR-300 following accident conditions and presents the basis for demonstration that the risk is ALARP in support of meeting the numerical target 4 introduced in Part A Chapter 2 [3].

Part B Chapter 15 Beyond Design Basis, Severe Accident Analysis, and Emergency Preparedness [9] provides an assessment of the SMR-300 following accident conditions that are low in frequency or high in consequence and presents the basis for demonstration that the risk is ALARP in support of meeting the numerical targets 5 and 6 introduced in Part A Chapter 2 [3].

Part B Chapter 16 Probabilistic Safety Analysis [10] presents the probabilistic analysis for the SMR-300 following accident conditions and presents the basis for demonstration that the risk is ALARP in comparison with the numerical targets introduced in Part A Chapter 2 [3].

Part A Chapter 4 Lifecycle Management of Safety and Quality Assurance [4], Part B Chapter 9 Description of Operational Aspects and Conduct of Operations [11], Part B Chapter 12

Nuclear Site Health and Safety and Fire Safety [12], Part B Chapter 25 Construction & Commissioning [13] and Part B Chapter 26 Decommissioning Approach [14] provide a description of the processes and procedures that will result in the management of risks during the respective lifecycle phases.

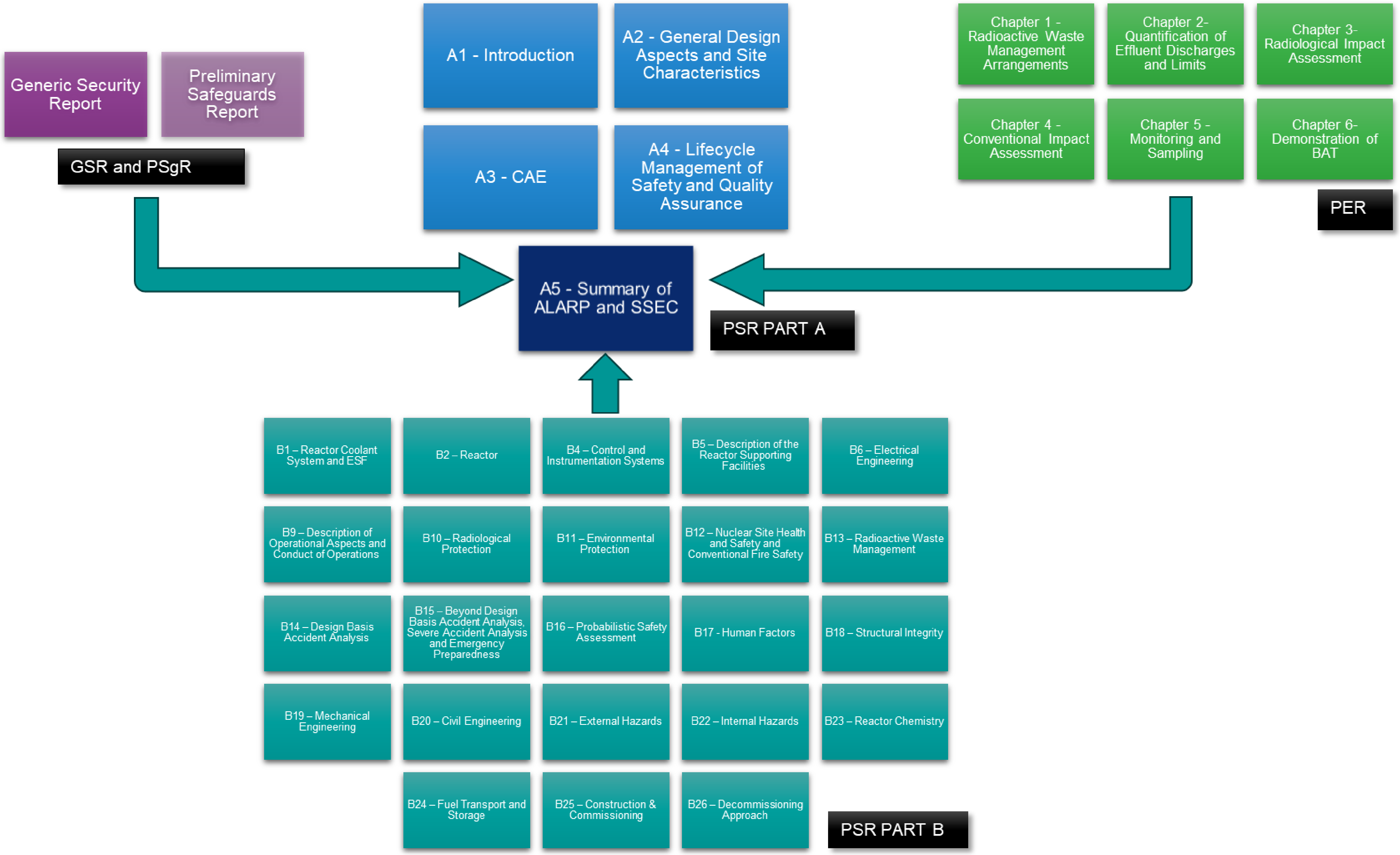

Figure 3: Synopsis of the SSEC in Chapter A5

5.2 OVERVIEW OF THE ALARP PRINCIPLE

As part of GDA, the Requesting Party (RP), Holtec International, has a fundamental requirement to set out the process to reduce risks to ALARP. A risk has been reduced ALARP when further risk reduction is not justified as further reduction would be grossly disproportionate in regard to money, time and effort.

The term ALARP arises from UK health and safety legislation (the Health and Safety At Work Act 1974 – HASWA [15]), which requires that (HASAWA sect. 2):

"*It shall be the duty of every employer to ensure, so far as is reasonably practicable, the health, safety and welfare at work of all his employees.*"

and (HASAWA sect. 3):

"It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health or safety."

The phrase So Far As Is Reasonably Practicable (SFAIRP) in this and similar clauses, is interpreted as leading to a legal requirement that any risk must be reduced to a level that is ALARP and applies to all stages of the facility lifecycle (see 'Ownership and Management of ALARP' [16]). The ALARP terminology is used in the UK nuclear industry and is synonymous with SFAIRP.

The regulatory framework sets out high level goals in terms of safety principles and risk targets that are captured in the SAPs [5]. The ToR policy in Health and Safety Executive (HSE) documents 'The Tolerability of Risk from Nuclear Power Stations' [17], 'Reducing Risks, Protecting People' are key framework documents setting out how risk decisions are made in the UK and are fully reflected in the SAPs [5] and ONR Technical Assessment Guide (TAG) 005 [18]. "Tolerability" refers to the general willingness of society as a whole to live with a risk so as to secure certain benefits.

By looking at risks from radiation exposure directly, ALARP takes account of the contributions to absorbed dose from lifetime (stochastic) factors (i.e., the build-up of everyday exposure) and instantaneous (non-stochastic/deterministic) factors (i.e., accidental exposures, which may be greater and can lead to deterministic effects). So, ALARP considers the risks from both normal operations (everyday exposures) and accident conditions (sudden exposures). It also applies to everyone who is exposed to this risk – the operator, site worker or the public. The SAPs specify a Basic Safety Objective (BSO), below which risks are considered broadly acceptable and above which ALARP is required to be demonstrated. Unacceptable risks are above the corresponding BSL specified in the SAPs.

Broadly acceptable risks are those that are commensurate with or smaller than the ordinary day-to-day risks that most people accept as part of their daily life (e.g., in crossing the road or undertaking routine rail and air travel)[2]. Unacceptable risks are those that would be considered too high even for those who tolerate higher personal or professional risks (such as workers in the highest risk professions such as offshore fishing or mining) and save for some exceptional minority groups, would not be tolerated for the majority for any significant period.

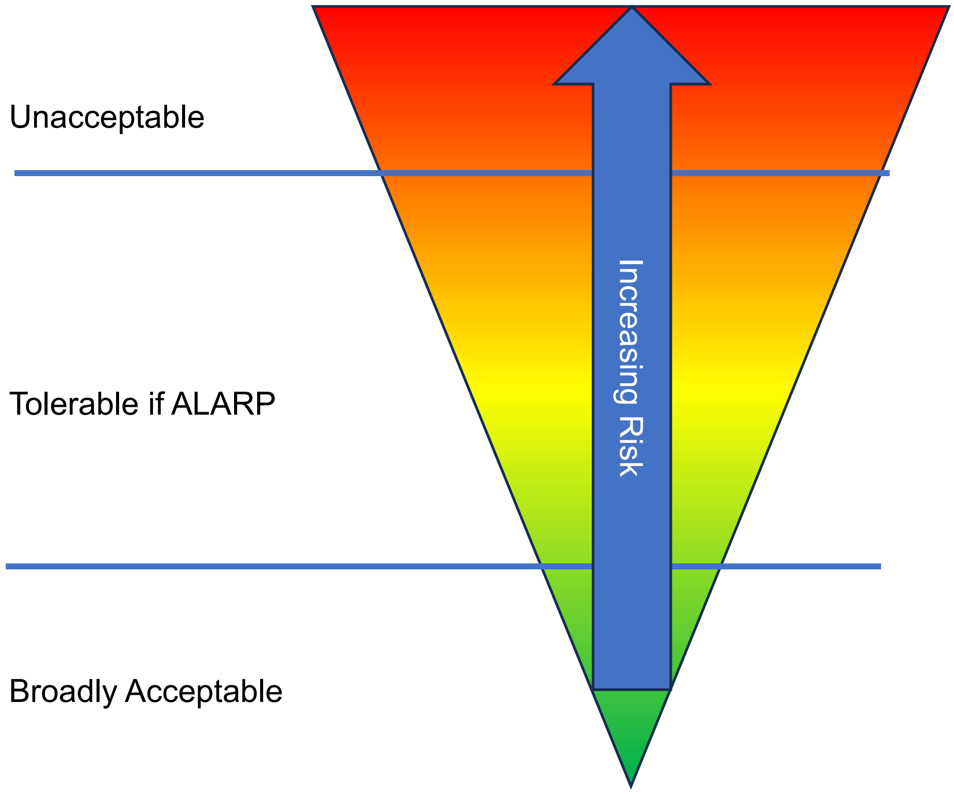

Figure 4: The Tolerability of Risk Concept

It is important to note that the legal duty for duty holders to reduce risks to ALARP is independent from the ToR concept. Duty holders are required by law to reduce risks to ALARP regardless of whether the level of risk is judged to be tolerable or not by the regulators. It is possible for a risk to be 'unacceptable' (i.e., in terms of its magnitude to wider society and thus subject to the highest level of regulatory attention) even if the duty holder has met its legal obligation to ensure that the risk, despite its magnitude, is still reduced to a level that is ALARP. Likewise, it is possible for a risk to be 'broadly acceptable', and therefore not attract any

[2] An important distinction, not covered here, is the notion of voluntary and involuntary risks. The Tolerability of Risk from Nuclear Power Stations [5] para. 24, implies that the public demand higher standards of risk control for involuntary risks, such as nuclear power plant operations.

significant regulatory attention, while the duty holder has not, or is yet to, demonstrate the risk is reduced to ALARP.

The concept of RGP plays a crucial role in linking the non-prescriptive approach to recognised codes and standards needed for design, in determining whether control measures are sufficient to reduce risks ALARP, particularly for well-known and well-understood risks, and is the starting point in the ALARP demonstration. RGP is the standards for controlling risk that have been judged and recognised by the ONR as satisfying the law, when applied to a particular relevant case in an appropriate manner.

5.3 ALARP CLAIMS, ARGUMENTS AND EVIDENCE OVERVIEW

The primary purpose of a CAE approach is to capture the golden thread of a safety case narrative demonstrating how plant and operational evidence is brought together to justify that a high-level or fundamental claim is true. In the context of the generic SMR-300, that is how the Fundamental Purpose of the SSEC (presented in Part A Chapter 1 [1]) is achieved.

The Fundamental Purpose follows a golden thread throughout the SSEC to CAE via the fundamental objectives of the PSR, PER, GSR and PSgR. This linkage is holistically presented in Part A Chapter 3 of this PSR [2].

The PSR Fundamental Objective links to overarching SSEC Claim 1.

Claim 1: The generic Holtec SMR-300 design, and safety case are developed for a GB-context generic site using integrated project, quality and safety management arrangements that take cognisance of relevant good practice and adopt appropriate codes and standards in the context of the UK regulatory regime.

Overarching Claim 1 covers safety management arrangements and is an enabling claim covering the processes and arrangements used to develop and manage the design and is decomposed into several Level 2 claims which are supported across Part A Chapter 2 [3], Part A Chapter 4 [4] and Part A Chapter 5.

This chapter supports the claim that an appropriate ALARP methodology has been derived and applied to the generic reference design, Claim 1.5.

Claim 1.5: An appropriate ALARP methodology is applied to the design change process, to ensure ongoing design decisions support the reduction of risks to ALARP.

The design stability process is intended to focus effort on addressing the greatest risk and supporting the safety and operational factors associated with a globally deployable reactor design, and is discussed further in sub-chapter 5.5 of this Chapter.

The PSR Fundamental Objective also links to overarching SSEC Claim 2.

Claim 2: The design and safety assessment shows that the generic Holtec SMR-300 can be constructed, commissioned, operated, and decommissioned on a generic site in the UK with risks that are tolerable and As Low As Reasonably Practicable (ALARP).

Overarching Claim 2 is predominantly decomposed across the V-lifecycle with Claims 2.1-2.3 evidenced by Part B Chapters, as shown in Figure 5. However, Claim 2.4 is cross-cutting to show that at all phases (i.e. safety analysis, design, construction, installation and commissioning, operation and decommissioning), that consideration of ALARP is undertaken.

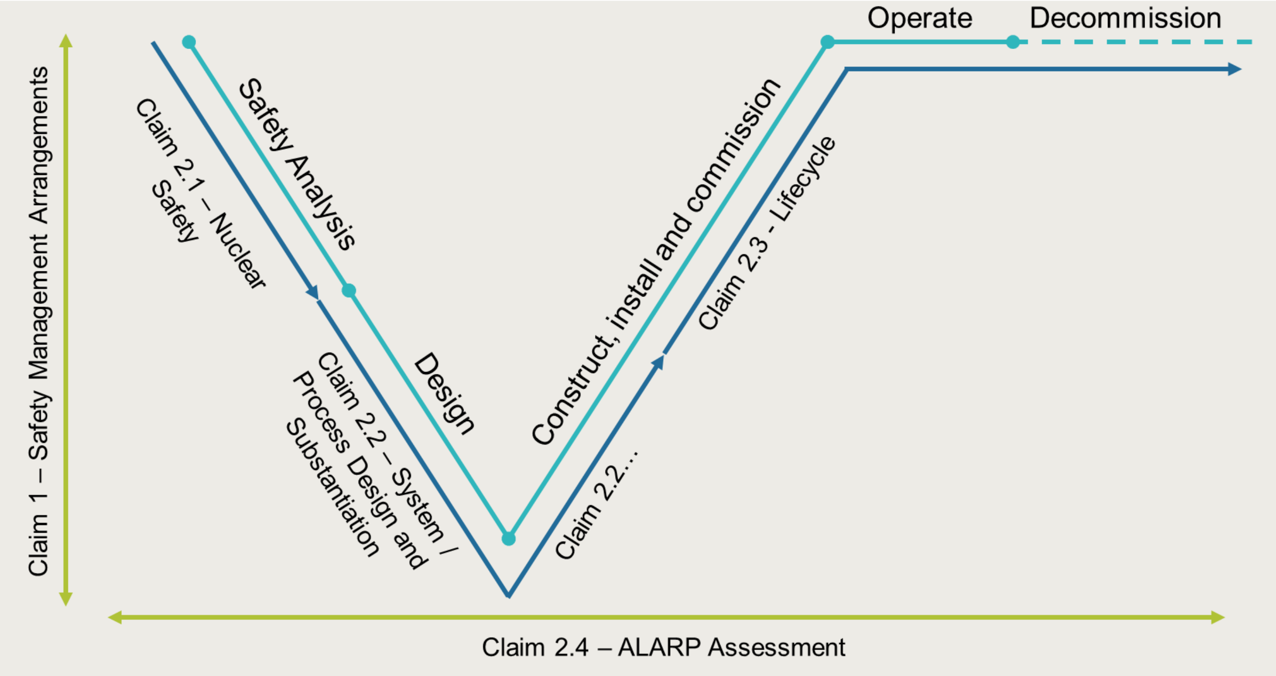

Figure 5: CAE "V-model"

This chapter describes the ALARP status to date and presents high level arguments and evidence that demonstrate that the risks from the full lifecycle of the SMR-300 can be reduced ALARP at a level proportionate to the design maturity in GDA. This chapter supports the claim that the risks to workers and the public is tolerable and ALARP for all lifecycle stages of the SMR-300.

Claim 2.4: The risk to workers and the public is tolerable and is as low as reasonably practicable, for the design, construction, commissioning, operation and decommissioning of the generic Holtec SMR-300.

Claim 2.4 has been further decomposed within Part A Chapter 5 into three sub-claims. This decomposition is aligned with the following key aspects which align with the 'tests' of ALARP introduced in sub-chapter 5.1.1:

Claim 2.4.1 - The design of the SMR-300 and planned activities are developed to meet legislative requirements and adopt relevant good practice.

Claim 2.4.2 - The safety assessment demonstrates that radiation risk to workers and the public is tolerable and As Low As Reasonably Practicable (ALARP).

Claim 2.4.3 - Consideration is given to implement options to reduce risk, with a focus on issues that make a more significant contribution to risk, such that no further reasonably practicable options are identified.

Together these aspects support a demonstration that there are no further reasonably practicable options to reduce risk and the risk associated with the proposed activities is ALARP.

Table 1 shows the breakdown of claims and identifies in which section of this chapter of the PSR they are demonstrated to be met to a maturity appropriate for this issue of the PSR (v1).

Table 1: Claims Covered by Chapter A5

Claim No.	Claim	Chapter Section
1.5	An appropriate ALARP methodology is applied to the design change process, to ensure ongoing design decisions support the reduction of risks to ALARP.	5.5 Design development and consideration of ALARP
2.4.1	The design of the SMR-300 and planned activities are developed to meet legislative requirements and adopt relevant good practice.	5.4 Adoption of Relevant Good Practice
2.4.2	The safety assessment demonstrates that radiation risk to workers and the public is tolerable and As Low As Reasonably Practicable (ALARP).	5.6 Tolerability of Risk
2.4.3	Consideration is given to implement options to reduce risk, with a focus on issues that make a more significant contribution to risk, such that no further reasonably practicable options are identified.	5.7 Options Considered to Further Reduce Risk

Appendix A provides a full CAE mapping for Part A Chapter 5 which includes any lower level claims, arguments and evidence needed to support the claims in the table above, This includes identification of evidence available at PSR v1 and aspects for future development of evidence to support these claims beyond PSR v1.

5.4 ADOPTION OF RELEVANT GOOD PRACTICE

Claim 2.4.1: The design of the SMR-300 and planned activities are developed to meet legislative requirements and adopt relevant good practice.

Argument: The SMR-300 has been designed against the US legislative framework with a view to global deployment. The design process has taken account of appropriate OPEX and recognition of RGP in order to support reduction of nuclear safety risks to ALARP.

Evidence:

- **Assessment of Codes and Standards** – Part A Chapter 2 [3] explains the selection of Codes and Standards to meet the requirements of the US NRC and CFRs, specifically title 10 CFR Part 50. Each of the PSR Part B chapters also includes a dedicated codes and standards section. Any potential challenges or any risks identified for compliance with UK codes and standards are identified within the Part B Chapters. These are reflected within the ALARP Summary Table in Appendix B.
- **Top Level Plant Requirements Document** [19] - The Holtec SMR Top-Level Plant Design Document [19] serves as the design philosophy and high-level requirements of all Holtec SMR designs. Content for this document was primarily adopted from Holtec's interpretation of tier 1 and tier 2 chapter 1 of the Electric Power Research Institute (EPRI) Utility Requirements Document (URD) [20]. The requirements are derived from a mixture of US Nuclear Regulatory Commission (NRC) EPRI / EPRI therefore demonstrating a strong leg case of learning from 80+ years of Pressurised Water Reactor (PWR) OPEX.
- **UK-US Regulatory Framework and Principles Report** [21] - This report outlines the RP's understanding of both regulatory regimes and identifies key differences in the regulatory frameworks operated in the US and the UK, thus demonstrating that the RP understand the differences between the US and UK approaches and any further work which may need to be done.
- **Safety Principles Alignment Review** [22] - This report presents an alignment review of the ONR SAPs and SyAPs against the NRC Generic Design Criteria (GDC) for Nuclear Power Plants (NPP) and SMR-300 Top Level Plant Design Requirements (which includes both Holtec SMR-300 Objectives and EPRI requirements) and other relevant NRC regulations and guidance. This comparison provides further confidence that the current principles against which the SMR-300 design is being developed will be met and where evidence for this will be presented. Identification of specific areas of alignment in equivalency are also provided, with links to relevant Design Challenges which have been raised to address these areas. These are discussed further in Part A Chapter 2 [3].

This sub-chapter outlines the codes, standards, methodology and RGP that are relevant to the demonstration of ALARP for the SMR-300.

5.4.1 Codes, Standards and Methodologies to Reduce Risks from the SMR-300

The SMR-300 basis of design has been produced in line with US regulations and takes due cognisance of good practice such as International Atomic Energy Agency (IAEA) guidance. The SMR-160 also successfully completed Phase 1 of the Canadian Nuclear Safety Commission (CNSC) "Pre-Licensing Review of a Vendor's Reactor Design". This vendor design review provided early feedback on the SMR-160 design, addressing CNSC regulatory requirements. The development of nuclear design has responded to extensive international co-operation, especially through organisations like the IAEA, in which both the US and the UK regulators have been major contributors. On this basis, good engineering practice in the US should imply good engineering in the UK:

- Holtec International has used sound and historically successful engineering principles to develop the SMR-300 design in the US, using Codes and Standards that are, in many instances, recognised as RGP in the UK.
- The US is a signatory to various United Nations (UN) nuclear treaties and conventions, therefore the US NRC regulatory framework is consistent with IAEA Safety Fundamentals, Requirements and Guides, and the recommendations of the International Commission on Radiological Protection (ICRP)[3], as is the UK regulatory framework.

Nuclear power plant designs in the US and UK are likely to settle on similar engineering solutions for a given technical problem even though both countries have very different regulatory frameworks.

5.4.1.1 US Prescriptive Approach

Within the US, the NRC specifies the design Codes and Standards that must be used, although exceptions are permitted subject to justification. Endorsed codes, together with the versions of the codes (which may not be the latest versions) are promulgated through NUREG-0800 [23]. This requires the NRC to have substantial engagement with code committees and the development of individual codes. An advantage to the US industry is that these codes are automatically well matched to the NRC regulatory approach, and in many cases, written specifically to respond to NRC regulatory concerns.

The NRC start off with high-level design principles or GDC, which are supported by regulatory advice specifying a large number of compliance codes and standards and prescriptive acceptance criteria (e.g., NUREG-0800) which also specify a larger number of compliance Codes and Standards. These codes are highlighted in Part A Chapter 2 [3].

In the US, the use of the safety analysis (deterministic and probabilistic) in the classification of claimed safety systems is required to meet GDC 1 within the 10 Code of Federal Regulations (CFR) Part 50 regulations [24], namely that related to quality standards and records such that Structures, Systems and Components (SSCs) important to safety shall be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions to be performed. This is considered to be consistent with the requirements placed on designers within the UK regulatory regime.

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[3] Note that the NRC regulatory framework is based upon the 1977 Recommendations of the ICRP – ICRP 26 [39], whereas the UK, and the majority of the world implement the 2007 Recommendations of the ICRP – ICRP 103 [38].

By following the US regulatory approach to the classification of systems, the design has adopted the approach set out in Regulatory Guide 1.26 [25] which provides the basis for implementing GDC1 on the basis of four distinct quality (for safety) groups (A to D) for any component containing water, steam, or radioactive material in light-water cooled nuclear power plants. It should be noted that these classification requirements apply to containment systems; the criteria for safety-related electrical and Instrumentation and Control (I&C) systems and equipment for the US are set out in the Institute of Electrical and Electronic Engineers (IEEE) 603 Standard [26] whereby electrical and I&C system equipment and components are classified as Class 1E or Non-Class 1E in accordance with definitions also stated in the IEEE 603 Standard [26]. It is acknowledged that these classifications will also need to take account of UK context within the developing safety report for Step 2 and beyond.

The NRC has benchmarked Reg. Guide 1.26 [25] against the IAEA guidance on categorisation and classification of safety systems within IAEA Specific Safety Guide (SSG)-30 [27] and has concluded that Reg. Guide 1.26 [25] generally incorporates similar guidelines and is generally consistent with the basic safety principles provided in SSG-30 [27]. This also informs the UK context in terms of the approach to safety function categorisation and safety system classification set out in the equivalent ONR TAG in ONR-TAG NS-TAST-GD-094 [28].

5.4.1.2 US Goal Setting and Risk-Informed Approaches

The US regulatory system is prescriptive but contains elements that are goal setting and risk-informed, such as the As Low As Reasonably Achievable (ALARA) principle applied in the US in relation to radiation exposures. In addition, Holtec has considered risk-informed approaches in event classification from the Nuclear Energy Institute (NEI) and produced a well-developed Probabilistic Safety Analysis (PSA)-informed design to complement decisions.

The following subsections describe Holtec's approach to these goal setting and risk-informed codes and standards used in the US.

5.4.1.2.1 ALARA Principle

ALARA is defined in the US Code of Federal Regulations Title 10 Part 20 [29] as:

ALARA means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilisation of nuclear energy and licensed materials in the public interest.

ALARA is an example of a design goal (in this case a dose target) to improve the design over and above the requirements specified in 10 CFR 50 [24] (see sub-chapter 5.4.1.1). Put simply, a designer that meets 10 CFR 50 [24] and the associated US codes and standards for a PWR is obliged to consider, not just the legal limits for radiation exposure, but '*making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical*'.

In the UK the ALARP concept is applied which is different to ALARA and is explored further in sub-chapter 5.4.2.2.

5.4.1.2.2 NEI Risk-Informed Event Classification

In addition to the event classifications within Appendix A to 10 CFR 50 'General Design Criteria' [24, 30] and Chapter 15 of the Standard Review Plan in NUREG-0800 [31] (or plant states in SSR 2/1 'Specific Safety Requirements, Safety of Nuclear Power Plants: Design' [32]), Holtec have also considered the application of risk-informed approaches. NEI 18-04 'Risk-Informed Performance-Based Technology Inclusive Guidance for Non-Light Water Reactor Licensing Basis Development' [33] in support of US NRC Regulatory Guide 1.233 'Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications For Licences, Certifications, and Approvals for Non-Light-Water Reactors' [34] are two recent guidance documents used in the US. Even though these documents are guidance for non-light water reactors, they give a systematic approach that is not technology-dependent and relates the event classification to frequency-consequence criteria in a similar way to that applied by the ONR (although the criteria are different).

Holtec has considered this risk-based approach to the classification of Licensing Basis Events (LBEs) in its Deterministic Safety Analysis (DSA). PSR Part B Chapter 14 Safety and Design Basis Accident Analysis [8] contains the methodology for identification and assessment of fault conditions relevant to the Holtec generic SMR-300 design, which is based on the DSA approach used in the US. Part B Chapter 14 [8] is further described in sub-chapter 5.6.3 for the compliance with risk targets and sub-chapter 5.8 for the overall demonstration of ALARP.

5.4.1.2.3 PSA-Informed Design

One area that is considered standard practice in the US is to use Probabilistic Risk Assessment (PRA) (or PSA) - informed design. Applicants under the 10 CFR 52 licensing framework [35] are required by NRC regulations to develop a PRA (10 CFR 50.71(h)) and to provide a description of the PRA results in licence applications (e.g., 10 CFR 52.79). The primary motivation to use inputs from a PRA in the selection of LBEs is that the PRA is the only tool available that has the systematic capability to identify the events that are specific and unique to a new reactor design.

The depth of PSA/PRA development for the SMR-300 is explored in Part B Chapter 16 Probabilistic Safety Analysis [10] which contains the methodology and preliminary findings of the PSA for the generic SMR-300 design. This is described in sub-chapter 5.6.5 for the compliance with risk targets and sub-chapter 5.8 for the overall demonstration of ALARP.

5.4.2 UK and International Guidance used in Development of the Generic SMR-300

The single biggest difference in US and UK regulatory approach identified is that the UK Government has established the risk ALARP principle in statute which drives much of the UK regulatory process as it applies to safety cases, including the non-prescriptive approach. Nevertheless, US codes are used extensively around the world, including in the UK, where many are recognised as RGP.

US and UK legislation differ in worker radiation dose limits (50 mSv y^{-1} vs 20 mSv y^{-1}), which informs the design and worker arrangements. The SMR-300 meets the US defined ALARA principle and reduces worker dose as priority. The IAEA international Basic Safety Standards [36] and the European Basic Safety Standards Directive [37] both implement the latest ICRP recommendations [38] regarding setting of dose constraints as part of dose optimisation. Dose constraints are not enshrined within the US (NRC) legislative framework in relation to operational exposures as this was not included within ICRP-26 [39], however, as per good practice in the US, Holtec have set a design target/constraint. [REDACTED] Further discussion on this is provided within the Radiation Protection Design Standard [40] and justification for the constraints selected is presented in the generic SMR-300 Dose Management Strategy [41]. The SMR-300 documentation complies with the US NRC requirements to meet prescribed dose limits and also to reduce occupational doses ALARA. Holtec aim to demonstrate that RGP has been followed, risks are reduced to acceptable levels and potential exposures of on-site workers and members of the public are ALARP (or capable or being reduced to ALARP, subject to further design development).

The SMR-300 documentation to meet the US NRC requirements meets prescribed limits, rather than requiring risks to be reduced SFAIRP.

Further information on the differences in the regulatory frameworks operated in the US and the UK are outlined within the UK-US Regulatory Framework and Principles Report [21] which acts as a guide for the technical development of work and alignment of the SMR-300 design to the UK legislative and regulatory regime during the GDA process. Holtec have produced a detailed comparison [21] between US and UK radiological protection legislation including the Ionising Radiation Regulations (IRR)17 [42], and associated Approved Code Of Practice (ACOP) and guidance [43] against equivalent US legislation, consolidated guidance and regulatory guides. This supports the ALARP demonstration and discussion captured in Part B Chapter 10 Radiological Protection [7].

5.4.2.1 Guidance on ALARP

The fundamental principles of ALARP in radiological protection in the UK are documented in IRR17 Regulation 9 [42], ACOP L121 [43], SAPsthis RGP wil, TAGs and Technical Inspection Guides (TIG). The ACOP holds special legal status and by demonstrating that these RGP have been followed, it can be demonstrated that the design and operation must also be ALARP. This is captured in Part B Chapter 10 [7].

The ONR SAPs [5], NS-TAST-GD-005 [18], and the Ownership and Management of the ALARP Good Practice Guide [16] provide a useful insight for the RP to understand how a safety case is evaluated and specifically, how a proposed design is considered to have demonstrated the risk is ALARP. The ALARP methodology has been developed against the background of requirements from these sources. This RGP will be implemented in the progression of the generic Holtec SMR-300 design beyond GDA in order to demonstrate that risks are reduced ALARP.

5.4.2.2 ALARP, ALARA and BAT

In the UK there is a difference between ALARA and ALARP. The differences between ALARP and ALARA are understood by Holtec, and further description of this has been provided in the UK-US Regulatory Framework and Principles Report [21].

Within the UK context, ALARA is applied to management of radioactive substances and wastes. In the UK context, the mechanisms for optimisation (ALARP, ALARA, BAT) require those that create the risk to demonstrate that they have done everything reasonably practicable to reduce risks, balancing the level of risk posed by their activities against the measures needed to control that risk - whether in money, time or resources.

For the Holtec SMR-300 design, ALARA is achieved by establishing design dose targets based on OPEX and the adoption of RGP. Thus, there are synergies of detail between ALARA and ALARP even if not of overall concept with minor differences between them.

5.4.3 Relevant Good Practice

Good practice is the generic term for those standards for controlling risk which have been judged and recognised by both HSE and ONR as satisfying the law when applied to a particular relevant case in an appropriate manner, as explained in ‘Assessing Compliance with the Law and the Use of Good Practice’ [44]. Hence, the use of RGP is central to the demonstration of ALARP for health and safety, nuclear and environmental law.

The application of health and safety law (i.e. the HASWA [45]) ultimately results in a requirement to reduce the risks to ALARP – as explained in sub-chapter 5.4. For nuclear safety risks, the ONR identify RGP as the body of ‘practice’ that is ‘good’ and ‘relevant’ (ONR-TAST-GD-005 [18] ‘Regulating duties to reduce risks to ALARP’).

Any deviations from the ‘RGP’ (as implied) will be scrutinised and require justification. The justification must demonstrate that the ‘alternative’ guidance and good practice is relevant, up to date, fully applicable to the facility and circumstances in question and meets the intent of regulatory guidance. The important point is the contribution of the RGP to demonstrating that risks are reduced to ALARP.

5.4.3.1 Recognising Good Practice in the SMR-300 Design

The SMR-300 basis of design has been produced in line with US codes and standards and takes due cognisance of good practice used in the US and elsewhere (e.g., EPRI, NEI, IAEA). For the GDA process, Holtec consider ‘good practice’ to encompass practices that have been recognised for use in nuclear reactor plant designs by authoritative bodies and are considered relevant to their application within the generic SMR-300 design.

Historic evolution of the Holtec SMR design to its present 300MWe configuration, history of the design evolution and the current design status of the SMR-300 have been summarised in Part A Chapter 2 [3].

ONR does not approve or specify nuclear codes and standards but does provide advice on the RGP in its regulatory guidance. It is for the RP to choose the standards and justify that they are RGP during the two-step GDA.

Holtec aims to demonstrate, through the information presented in the SSEC, that good practice has been followed, risks are reduced ALARP, or are capable of being reduced to ALARP, demonstrating safe practice in alignment with UK regulatory and legislation requirements. To do this, the design has been assessed by suitably competent individuals across the topic areas as indicated in Figure 3. Each topic area within the SSEC has focussed on the methodologies, approaches, codes, standards, and philosophies used for the SMR-300 design and whether they are consistent with what would be considered as good practice in the UK context (i.e., as specified in the ACOP or regulatory guidance). In many instances there is good alignment between adopted codes, standards and methodologies for the generic SMR-300 design and UK context expectations of good practice. However, in several instances further work is still required to fully demonstrate Claim 2.4.1. This exercise is summarised in sub-chapter 5.8 to identify the key contributions from each Chapter to this 'leg' of the ALARP argument. Any differences are also highlighted where they appear within the SSEC, with work proposed to address any inconsistencies taken forward as GDA Commitments or Design Challenges to be progressed via the Design Management Process [46].

5.4.3.1.1 Fundamental Safety Principles and Top-Level Plant Requirements

The Holtec SMR Top-Level Plant Design Document [19] serves as the design philosophy and high-level requirements of all Holtec SMR designs. Content for this document was primarily adopted from Holtec's interpretation of tier 1 and tier 2 chapter 1 of the EPRI URD [20]. EPRI URD guidance encompasses both industry experience and current US regulations to present a clear, complete statement of requirements for the next generation of nuclear plants. The design philosophy included in the Top-Level Plant Design Document [19] serves as the guiding principles for the intended design of the Holtec SMR plant. These guiding principes govern the approach to plant design and serve as inspiration to design requirements. The top-level design requirements are specific actionable statements that shall be met to ensure the philosophy is achieved.

Further discussion of the Holtec safety principles and their alignment with UK expectations is provided in Part A Chapter 2 [3].

5.4.3.1.2 The Use of OPEX

The Holtec US SMR design development has been strongly influenced by reviews of OPEX. Senior Reactor Operators (SRO) and experienced operating nuclear power plant engineers are involved with an integrated systems engineering design process. This OPEX-informed process is in alignment with the structured and prescriptive US NRC licensing approach, the core design principles, and the design decision process (see sub-chapter 5.5).

It is acknowledged that the SMR-300 design, to achieve a passive safety philosophy, contains certain more novel aspects, for which OPEX is not as readily available from existing reactors. Such aspects have been addressed in relevant PSR safety analysis and engineering Chapters.

5.4.3.1.3 ALARP Demonstration for the GDA Reference Design

It is considered good practice that a Design Reference Point (DRP) [47] is used as the basis for each safety report production, particularly in the early lifecycle phases to ensure there is a consistent and coherent approach to the maturity of evidence against which the safety of the plant is justified. It is also normal practice for the reference configuration to continue to develop between each safety report, as changes will inevitably occur during the evolution of the design. Part A Chapter 4 [4] provides a description of the management of safety during the lifecycle phases of development of the generic SMR-300. The GDA reference design for the generic SMR-300 is given in Part A Chapter 2 [3]. This incorporates all the design development, design evolution (that being the specific change from SMR-160 to SMR-300) and any other design changes that have been applied up until the point of issue.

Development of the SMR-300 DRP did not explicitly account for UK-specific BAT or ALARP requirements (which is reasonable for a design initially developed for the US regulatory regime). However, the assessment against UK expectations and the assessment of risk, via the undertaking of GDA Step 2, has identified a number of Design Challenges for the GDA reference design, resolution of which supports ALARP and BAT demonstration.

5.4.4 CAE Summary

Holtec consider 'good practice' to encompass practices that have been recognised for use in nuclear reactor plant designs by authoritative bodies and are considered relevant to their application within the generic SMR-300 design. This sub-chapter shows how good practice is recognised in the SMR-300 design and how OPEX has been considered extensively in the design development process. Holtec International has used sound and historically successful engineering principles to develop the SMR-300 design in the US, using codes and standards that are, in many instances, recognised as RGP in the UK.

In many instances there is good alignment between adopted codes, standards and methodologies for the generic SMR-300 design and UK context expectations of good practice. However, in several instances further work is still required to fully demonstrate Claim 2.4.1. The evaluation against RGP has been summarised for each PSR chapter/topic area in sub-chapter 5.8. Where risks exist in meeting UK expectations, Design Challenges have been raised within Step 2. For Design Challenges and other issues that cannot be closed within Step 2, GDA commitments have been raised to ensure closeout beyond GDA, these have been formally captured in the Commitments, Assumptions and Requirements (CAR) process [6]. Further details on this process are provided in Part A Chapter 4 [4].

Whilst Claim 2.4.1. cannot be fully demonstrated at this stage, the evidence presented to date and processes in place to manage identified Design Challenges and GDA Commitments, provide confidence that Holtec is proceeding with a design which will be able to demonstrate the planned activities are developed, to meet legislative requirements and adopt RGP.

5.5 DESIGN DEVELOPMENT AND CONSIDERATION OF ALARP

Claim 1.5: An appropriate ALARP methodology is applied to the design change process, to ensure ongoing design decisions support the reduction of risks to ALARP.

Argument: An ALARP methodology has been defined for the SMR-300. This methodology includes a Design Management Process [46] to ensure the appropriate application of the ALARP principle when considering options for risk reduction during design activities.

Evidence:

- **Design Management Process** [46] - This process sets out a gated process which is used to identify design challenges and endorse prospective design changes, to be implemented in a future reference design for UK deployment. The Design Management Process [46] also helps identify where proportionate optioneering is required to support design challenges and prospective design changes.
- **ALARP Guidance Document** [48] **-** This document includes the regulatory principles of ALARP and provides an optioneering methodology for undertaking ALARP assessment. It is applicable to the design phase of the lifecycle of the GDA and for the design development post-GDA.
- **Design Stability Toolkit** [49] - This document gives guidance on the approach to the consideration of design stability when demonstrating risks are reduced to ALARP and the use of BAT. This document provides guidance on the application of factors which impact on design stability including time, cost, effort and fleet deployment and the need to demonstrate in the UK that risks and impacts have been optimised.

This sub-chapter outlines Holtec's GDA Design Management Process in the context of the developing generic SMR-300 design to ensure UK requirements are embedded. This covers the following topics:

- The design evolution and design decision process followed by Holtec International for the SMR-300 that gives the SMR-300 Reference Design for the GDA.
- The Design Management Process for the generic SMR-300 that captures the prospective design changes made during the GDA and in the future.

Part A Chapter 2 [3] presents an overview of the design evolution, the fundamental design and safety principles and the GDA reference design for the generic SMR-300. Part A Chapter 4 [4] presents an overview of the overall Design Management Process [46].

5.5.1 Historic Holtec International Design Evolution and Design Decision Processes

In the early design stage of the SMR-160, a number of position papers were developed, which remain relevant to the SMR-300 design. These defined the initial basis of design (e.g., materials of construction) and the rationale for those choices (e.g., proven in use in similar applications, code compliance etc). These also featured some early, high level, optioneering. Where innovative design solutions have been incorporated into the design, these have been developed with the aim of reducing complexity, improving passive safety, increasing reliability or provision of improved defence in depth.

Table 2: Position Papers Relevant to the SMR-300 Design

[REDACTED]

The major design development in the history of the SMR-300 is the evolution from SMR-160 to SMR-300.

The design evolution and freeze process [50] addressed:

- The major evolution from the SMR-160 to the SMR-300 and the management of that change.
- Requirements, such as performance requirements.
- Concept design and plant configuration, such as configuration of systems.
- Design parameters, such as process conditions.
- Capital and operational costs.

This process allowed the new conceptual layouts of the RCS, ESFs, Containment Structure (CS), Annular Reservoir (AR), Containment Enclosure Structure (CES) and Reactor Auxiliary Building (RAB), and all other SSCs affected by the design evolution to be provided. Once the new conceptual layout for the SMR-300 design was completed, the design freeze process was commenced and subsequent design change managed via the US Design Decision and Risk Management process, discussed further in Chapter 5.5.3.2.

5.5.2 Design Management Process

The process by which design development of the DRP is managed by Holtec is referred to as the Design Management Process [46].

The Design Management Process [46] sets out a gated process which is used to identify design challenges and endorse prospective design changes, to be implemented in a future reference design for UK deployment. A high level overview of the key stages of the Design Management Process is set out in Figure 6 below and this consists of four main parts:

1. Design Stability.
2. Design Challenge.
3. US Design Decision and Risk Management.

4. UK Prospective Design Change.

Risks to the design are first identified and tested against relevant ALARP considerations (Gate 1), with significant risks escalated more formally as a design challenge (Gate 2). These design challenges are considered formally within the US design decision process (Gate 3) and can ultimately lead to a prospective change to any future DR for deployment in the UK (Gate 4).

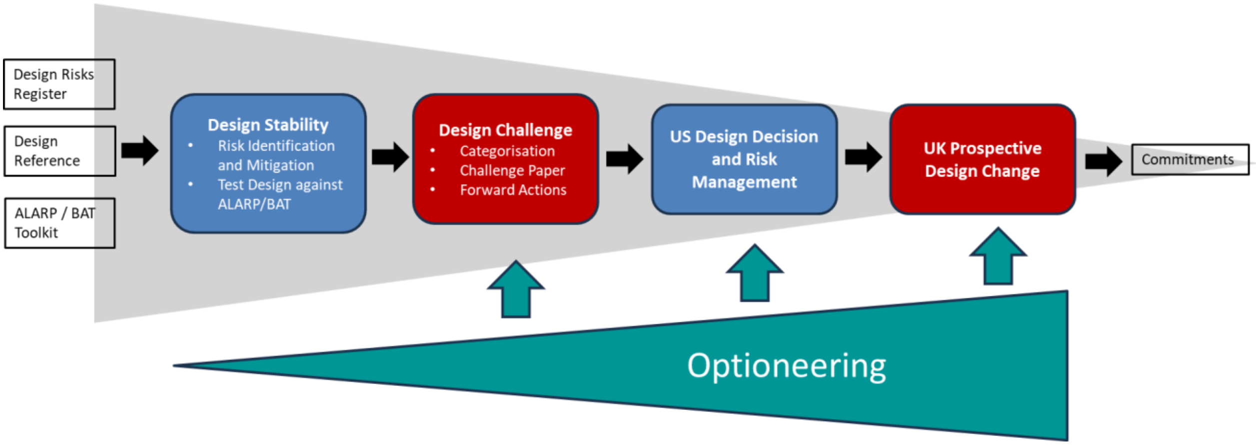

Figure 6: Design Management Process

The ALARP Guidance document [48] provides further discussion on the purpose of each of these parts and their contribution to ALARP.

5.5.3 CAE Summary

This sub-chapter provides an overview of the processes for evaluation of the US design changes and the UK design changes. Prospective design changes are reviewed for the UK design according to the Design Management Process [46], to ensure the change supports continued demonstration that risks can be reduced to ALARP. By applying the process described within this sub-chapter, together with the analysis of numerical targets described in the ToR sub-chapter 5.6, a robust process for ALARP demonstration has been developed for the generic SMR-300 design in support of the GDA and for design changes occurring post-GDA. Claim 1.5 is considered to be adequately demonstrated for the current SMR-300 generic design maturity, recognising that further development of these processes will be required to support UK site licence expectations.

5.6 TOLERABILITY OF RISK

Claim 2.4.2: The safety assessment demonstrates that radiation risk to workers and the public is tolerable and As Low As Reasonably Practicable (ALARP).

Argument: There is confidence that radiation risk to workers and the public risks will be demonstrated as either broadly acceptable or tolerable if ALARP, based on:

- Dose constraints and numerical targets adopted by Holtec at the design stage, in relation to normal operation and accident conditions, to ensure radiological protection for both on-site workers and members of the public,
- Radiological consequence assessments planned to demonstrate that the relevant numerical targets are met and demonstrated as tolerable and ALARP.
- The indicative results from the SMR-160 PSA and associated sensitivity studies for the SMR-300 design, which has an identical release pathway for core radioisotopes involved in accident scenarios.

Evidence:

- **Part B Chapter 10** [7] - This chapter provides a summary of the numerical targets adopted and assessed in Part B of the PSR for normal operations.
- **Part B Chapter 14** [8] **-** presents the available design basis deterministic analysis for the SMR-300 following accident conditions and presents the basis for demonstration that the risk is ALARP in comparison with the numerical targets introduced in Part A Chapter 2 [3], noting that only a limited deterministic assessment is available at GDA Step 2.
- **Part B Chapter 15** [9] - This chapter discusses the analyses of accidents that are beyond the design basis for the generic SMR-300 design. The chapter addresses Severe Accident Analysis (SAA) and emergency preparedness, discussing the preventive and mitigating measures identified.
- **Part B Chapter 16** [10] - This chapter contains the methodology and preliminary findings of the PSA for the SMR-160, together with sensitivity analysis to provide an indicative assessment of its applicability to the generic SMR-300 design.
- **Part B Chapter 21** [51] **-** This chapter contains the identification of external hazards and undertakes a preliminary evaluation of these external hazards for the GDA reference design and GB Generic Site Envelope (GSE) values.
- **Part B Chapter 22** [52] **-** This chapter contains the identification of internal hazards and a preliminary evaluation of internal hazards for the GDA reference design.
- **Preliminary Fault Schedule** [53] **-** The RP has submitted a Preliminary Fault Schedule (PFS) to record a preliminary set of faults and protection systems relevant to the generic Holtec SMR-300 design. The PFS is supported by Design Basis Accident Analysis (DBAA) to investigate each fault and confirm the preliminary categorisation of the functions and the preliminary UK equivalent classification of the systems claimed as delivering those functions. Revision 1 of the PFS covers 'in-reactor' design basis faults, a limited set of Design Extension Condition (DEC) events and external hazards. Further discussion is detailed within the Preliminary Fault Schedule Report [53] which summarises and presents the PFS development work to date.

- **Safety Assessment Handbook** [54] - The Safety Assessment Handbook describes the methodology followed during the safety assessment activities of Step 2 of the GDA.
- **UK DBAA Summary Report** [55] - A limited number of explicit UK DBAA assessments are presented in this document, focusing on a series of typical reactor system faults, to provide confidence in the strategy for fault analysis and demonstrate application of the UK Approach to Fault Studies and ultimately reduce risks to ALARP. The UK DBAA identifies the UK categorisation requirements for safety functions required to mitigate the assessed faults and the UK equivalent classification requirements of the SSCs delivering these functions. While not comprehensive at this stage, there is confidence that the limited set of analysis covers those SSCs most important to safety and the majority of the engineered safety features, thereby reducing the latent risk of not having performed a comprehensive set of design basis fault analysis.
- **UK PSA Sensitivity Studies** [56] - Sensitivity analysis has been undertaken on the SMR-160 Internal Faults PSA to assess the impact of known design changes for the SMR-300, and to address known regulatory expectations regarding claimed reliability of components. This analysis has been undertaken to provide confidence that these changes do not result in significant increases in risk meaning that the overall risk profile remains largely consistent, and that insights drawn from the SMR-160 PSA remain valid.

This sub-chapter provides a summary of the numerical targets assessed, based on the detail presented in Part B of the PSR, for normal operations and accident conditions. At the current design maturity of the SMR-300, a significant proportion of the detailed safety analysis required to demonstrate that these targets are fully met is not yet available. Therefore, the current evidence for Claim 2.4.2 focuses on providing confidence that the numerical criteria will be met by the SMR-300 and identifying the methodologies and work planned to demonstrate this.

The ToR approach introduced in sub-chapter 5.4.2 for normal operations doses and risks from accidents, proposes boundaries between which risks may be regarded as unacceptable, tolerable or broadly acceptable. The ToR framework has been translated into nine numerical targets in ONR's SAPs [5], see Part A Chapter 2 [3], in the form of BSLs and BSOs.

Holtec consider the ToR concept and compliance with numerical targets to be one test of the ALARP demonstration, with the others being compliance with the law, following RGP and the justification of options (see Figure 2).

5.6.1 Doses from Normal Operations

The consideration of normal operations doses to workers and the public contributes to the design development of the generic SMR-300, supporting existing decisions where appropriate or informing improvements to the design.

The SMR-300 has been designed to demonstrate that doses are ALARA [40] and below the defined and justified dose targets and limits. Normal operations cover Level 1 and 2 of the defence-in-depth expected for demonstrating the safety of a nuclear power plant, which are:

- Level 1 – the prevention of abnormal operation and failure by design.
- Level 2 – the prevention and control of abnormal operation and detection of failures.

By looking at risks from radiation exposure directly, the contributions to individual dose from lifetime (stochastic) factors (i.e., the build-up of everyday exposure) make an implied determination of radiological risk and contribute to the demonstration of ALARP. Hence, the risk from normal operations covers the effective dose uptake during the following:

- Reactor operations:
  - Start-up.
  - Shut-down.
  - Full-power.
  - Abnormal.
- Refuelling.
- Examination, Maintenance, Inspection and Testing (EIMT).
- Operations outside of containment:
  - Radioactive source handling operations.
  - Fuel movements.

For normal operations, the dose targets given in Target 1-3 of Part A Chapter 2 [3] are derived from the Ionising Radiation Regulations 2017 (IRR17) [42] for on-site workers and members of the public. The fundamental principles of ALARP in radiological protection in the UK are documented in IRR17, (especially Regulation 9) [42], TAGs (NS-TAST-GD-038 [57] and NS-TAST-GD-043 [58]), TIGs, SAPs and ACOP [43]. Targets 1-3 are presented in Table 4 and Part B Chapter 10 [7] is summarised in sub-chapter 5.8.

5.6.1.1 Normal Operations Dose Results

The Shielding Design Basis [59] presents preliminary dose rate calculations based on defined source terms, preliminary shielding thicknesses and associated material properties. The report determines the maximum dose rate outside containment to be [REDACTED] which is below the limit of 0.5 μSv/h for R0 undesignated areas.

[REDACTED]

The dose rates from the SFP contents are well below background levels and will not contribute significantly to total dose rates inside or outside of the containment.

This work gives confidence that the proposed shielding design can achieve the dose targets. Optimisation of the shielding design will be undertaken in to demonstrate that normal operation dose uptake is ALARP.

SMR-300 Dose Management Strategy [41] and HP-8002-0026, SMR-300 Design Standard for Radiation Protection [40] define the dose constraints and limits, and methods for assessing doses to workers and members of the public during normal operations. They also define the process to be used to undertake Normal Operations Dose Assessment (NODA) and ALARP studies. NODA and ALARP studies have not been undertaken at PSR v1 due to limited design, dose rate and occupancy data, therefore it has not been possible to provide a comparison with SAPs Targets 1-3. However, RGP will be applied when such studies are undertaken to ensure radiological hazards and doses are reduced to ALARP.

5.6.2 Introduction to Accident Risks

The current safety analysis for the Holtec SMR-300 design is based on the US NRC approach contained within 10 CFR 50 regulations [24] and GDC [30], and the NUREG 0800 Standard Review Plan [31]. These codes have been derived from proven technology arising from many decades of experience in the design and operation of PWRs in the US and worldwide. In taking due account of good practice arising from this experience, the design has a sound basis for claiming that the principal requirements of ALARP have been incorporated within the developing design through application of this technology.

The accident analysis developed during GDA is used to support existing decisions where appropriate, the adequacy of defence in depth applied, and identify any relevant changes or additional analysis required for the generic SMR-300.

The risks from accident conditions cover the following:

- Design Basis Accidents (DBA) that could occur within the expected lifetime of the facility. These are covered by UK DBAA (currently for a limited set of faults), which is commensurate with Level 3 of the defence-in-depth expected for demonstrating the safety of a nuclear power plant. Once completed, UK DBAA will address the control of faults within the design basis, including in-reactor design basis faults, additional DEC events, a preliminary set of external hazards, the consolidated fault list, and initial consideration of internal hazards, to protect against escalation of an accident. Numerical Target 4 is applicable to DBA.
- Design Extension Condition (with or without significant core disruption – beyond design basis / severe accidents). The BDBA and SAA are commensurate with Level 4 of the defence in depth expected to address the control of severe plant conditions in which the design basis may be exceeded, including protection against further fault escalation and mitigation of the consequences of severe accidents. SAA (and emergency preparedness) also covers Level 5 of the defence in depth expected, by considering the mitigation of significant releases of radioactive material.
- PSA is a method for analysing all accident conditions and covers levels 1-5 of defence-in-depth. PSA covers both the initiating event frequency and provides a best estimate assessment of the risk associated with the accident occurring and provides results for comparison with Targets 5-9.

The identification of Targets 4-9 is presented in Table 5. The following sub-chapters discuss each analysis technique in further detail.

5.6.3 Design Basis Accident Analysis

The fault analysis process for the SMR-300 has been developed to demonstrate that UK context has been adequately addressed. UK DBAA refers to the full scope of fault analysis, not just operational occurrences and ‘accidents’ within the design basis (i.e. transients, internal events, internal and external hazards), and is a robust demonstration of the fault tolerance of the plant and of the effectiveness of its safety measures.

The fault analysis process requires a systematic and comprehensive identification of the plant initiating events applicable to the reactor design. The Holtec SMR-300 GDA Safety

Assessment Handbook [54] contains the methodology for identification and assessment of fault conditions relevant to the generic SMR-300 design.

At present, the approach taken to develop the list of Potential Initiating Events to be analysed in the deterministic analysis has been limited to those events with the potential to lead to significant off-site radiological consequences originating from within the reactor itself. Part B Chapter 14 recognises that there is a need to further develop the comprehensiveness and scope of the analysis to support future safety reports. In addition, supplementary fault identification techniques such as HAZOP and FMEA have been applied to specific systems, in particular for those novel for UK deployment, in order to identify such initiators.

A PFS has been developed within the two-step GDA to capture the fault and hazard[4] analysis information in a single place aiding transparency of fault management arrangements. Further discussion on this is provided within the Preliminary Fault Schedule Report [53], Part B Chapter 14 [8], Part B Chapter 21 [51] and Part B Chapter 22 [52] .

The initial UK DBAA work is reported in the SMR-300 GDA UK DBAA Summary Report [55]**.** This document is one of the main inputs to Part B Chapter 14 [8], which summarises the key output from the initial UK DBAA. At PSR v1, only a limited set of UK DBAA has been undertaken, due to the maturity of the supporting US Deterministic Safety Analysis (DSA). In a number of instances, the initial UK DBAA results have identified a number of risks against UK context expectations, which have been captured as Design Challenges of GDA Commitments to progress to resolution. These are further discussed in Section 5.6.3.1.

ONR SAP Numerical Target 4 represents criteria for assessing the safety of the plant's design and operation for faults that could have significant radiological consequences, At GDA Step 2, the level of design definition and safety assessment is not sufficient to permit a detailed evaluation of radiological consequences for all faults. Hence, faults identified have been assigned into conservative consequence bands.

GDA Commitment C_Faul_103 includes the need for radiological consequence assessments to be performed for each design basis fault against ONR SAP Numerical Target 4. When available, these results will be reported in the PCSR.

As well as fault conditions arising within the design basis, internal hazards and external hazards require special consideration, as follows.

- External Hazards – Part B Chapter 21 [51] contains the approach and methodologies for identification and evaluation of external hazards for the generic SMR-300 design. This takes into account the Holtec design standards for external events, and how the SMR-300 can be applied on the GB GSE defined in Part A Chapter 2 [3]. Differences in US and UK evaluations have been investigated within Step 2 documentation and a review of the SMR-300 preliminary documentation regarding its design provides confidence that there is sufficient defence in depth for external hazards. As a number

[4] [REDACTED]

of external hazards sources are site specific, it is not possible to deliver a fully mature set of external hazards at this point.

- Internal Hazards – Part B Chapter 22 [52] contains the approach and methodologies for identification and assessment of internal hazards for the generic SMR-300 design. Due to the differing regulatory approaches between the US and UK, differences have been identified and investigated within Step 2 documentation. These differences are summarised within Part B Chapter 22. A review of the SMR-300 preliminary documentation regarding its design provides confidence that there is sufficient defence in depth for internal hazards and a general alignment with RGP.

[REDACTED] Part B Chapter 14 [8], Part B Chapter 21 and Part B Chapter 22 are further summarised in sub-chapter 5.8 of this chapter and support the demonstration that the risks can be reduced ALARP for all faults and hazards within the design basis.

5.6.3.1 UK DBAA Results

Part B Chapter 14 presents UK DBAA for a number of key faults utilising the output from the UK Preliminary Fault Schedule (PFS). The PFS was developed based on US DSA, PWR OPEX and supplemented with consideration of the SMR-300 design.

Although not fully complete, these faults provide good representation of all the major safety systems which act to mitigate the vast majority of faults in the current PFS, so is considered appropriate for a fundamental assessment. Most remaining reactor faults will rely on the same passive systems. Therefore resolving the Design Challenges identified so far is expected to bound similar issues that may arise when the full UK DBAA portfolio is completed after Step 2. Recognition of significant further work to undertake is captured as GDA Commitment C_Faul_103:

Holtec commit to ensuring that the repurposing of the US safety analyses undertaken for the Palisades SMR-300 design also considers and undertakes, as necessary, supplemental safety assessment to appropriately address UK expectations and good practice. This supplemental assessment should incorporate the full scope UK SMR-300 design and will be targeted to ensure a holistic and comprehensive approach across the recognised safety assessment disciplines. Future UK SSEC is therefore expected, as a minimum, to encompass:

- *Completion of the identification of PIEs, within the full scope UK SMR-300 design.*
- *Harmonisation between this initiating event list for use in both deterministic and probabilistic assessments.*
- *Extension of the scope of PSA to assess the SMR-300 design and operation to Level 3 PSA; this will include all sources of radionuclide release and operations (such as the Spent Fuel Pool) and all potential initiating events (e.g. Internal Hazards, External hazards).*
- *Development of a UK-aligned set of design basis faults.*
- *An updated UK Fault and Protection Schedule, which covers all design basis faults for the SMR-300.*
- *UK DBAA studies to: Identify UK aligned expectations for safety function categorisation and SSC classification for each bounding fault; Demonstrate, supported by*

appropriately verified and validated UK DBAA, that the design can safely mitigate all design basis faults; Undertake supporting radiological consequence analysis to demonstrate the residual risks are tolerable and ALARP.

- *UK-aligned Severe Accident studies, informed by the PSA and DBAA, to ensure that the facility can be brought into a long term safe, stable state.*
- *Incorporate Human Factors Engineering analysis (including Human Reliability Analysis*) throughout DBAA/PSA/SAA.

The output of the initial UK DBAA work shows DSA criteria are met but no radiological doses are available yet to demonstrate compliance with SAP Target 4.

The DBAA highlights a number of risks with respect to Classification of SSCs, Single Failure Criteria, and Redundancy, Diversity and Segregation which will be subject to further assessment beyond GDA Step 2. These are discussed further in Part B Chapter 14 but are briefly summarised below.

[REDACTED]

Design challenges have been raised to further progress the prospective risks identified above. These design challenges are listed below, with reference to the current PSR Chapter where more information is presented. A summary of each challenge can be found against the relevant PSR chapter in Appendix B.

- I&C Architecture [DC 01] – Part B Chapter 4.
- Diverse Means of Shutdown [DC 04] – Part B Chapter 1.
- Mechanical SSC Classification [DC 05] – Part B Chapter 19.
- Single Failure Criterion in Passive Safety Systems [DC 12] - Part B Chapter 14.
- HVAC Architecture, Design Codes and Design Basis [DC 13] – Part B Chapter 19.
- Valve Diversity and Motor Operated Valves [DC 25] – Part B Chapter 19.

All design challenges are considered to have credible options available to resolve and will be progressed to completion as per the Design Management Process beyond GDA Step 2.

Further safety assessment will be undertaken post GDA Step 2, including any changes to the design as a result of Design Challenge resolution, in accordance with GDA Commitment C_Faul_103.

On the basis of the above, there is confidence that the SMR-300 design can demonstrate radiological risks are reduced to ALARP and are tolerable (i.e. Target 4 can be met).

5.6.4 Severe Accident Analysis

PSR Part B Chapter 15 [9] discusses the analysis of accidents that are beyond the design basis for the generic SMR-300 design. The chapter addresses SAA and emergency preparedness, discussing the preventive and mitigating measures identified. SAA considers major but very unlikely accidents with potential releases and provides information on their progression, both within the facility and beyond the site boundary.

Within the UK, a DEC systematic analysis is carried out complementary to UK DBAA and PSA. Deterministic analysis of design extension conditions without significant fuel damage (DEC-A) will be considered as part of Part B Chapter 14 due to the similarity of the codes and methods used, while DEC-B type scenarios will be assessed in Part B Chapter 15 as supporting analysis is developed at PCSR.

When developed beyond GDA Step 2, reviews will be undertaken to demonstrate that arrangements within Emergency Operating Procedures (EOPs) and Severe Accident Management Guidelines (SAMGs) have been optimised and can be demonstrated to be ALARP.

5.6.4.1 SAA Results

Part B Chapter 15 outlines the primary US guidance and requirements for severe accidents used in the development of the SMR-300 which are provided by the following:

- US NRC 10 CFR 50.155 Mitigation of beyond-design-basis events.
- HPP-160-3018, Design Standard for Severe Accident Design and Analysis Strategy.

UK expectations require that accidents that have the potential to lead to severe consequences have been systematically analysed, and the analysis is used to identify appropriate preventative and mitigating measures beyond those derived from the UK DBAA. The approach for identifying all BDBA and severe accident phenomena has not been developed for PSR v1, but GDA Commitments **C_SAA_084, C_SAA_085 and C_SAA_086** have been raised to capture this.

5.6.5 Probabilistic Safety Analysis

Part B Chapter 16 [10] contains the methodology and results of the PSA for the SMR-160, which comprises L1 and L2 PSA with calculations of Core Damage Frequency (CDF) and Large Release Frequency (LRF) and addresses At Power and Low Power and Shutdown (LPSD) plant states.

Sensitivity studies were undertaken on the SMR-160 At Power PSA to capture expected design changes for SMR-300 and to address known differences in UK regulatory expectations. This included the following main changes to the SMR-160 model:

[REDACTED]

The results of the SMR-300 PSA Sensitivity Study are discussed in sub-chapter 5.6.5.1.

5.6.5.1 SMR-300 PSA Sensitivity Study Results

The mean value of the CDF due to internal events for a single SMR-160 unit during at power operations, taken from the SMR-160 PSA, is calculated to be [REDACTED] per year, with a breakdown of the dominant initiating events shown in Figure 7. The definition of the initiating events can be found in Table 3.

[REDACTED]

Figure 7: SMR-160 L1 PSA Initiating Event Contributions

The results of the SMR-300 sensitivity study show a [REDACTED] compared to the baseline At Power SMR-160 PSA, with a breakdown of the dominant initiating events shown in Figure 8. The definition of the initiating events can be found in Table 3.

[REDACTED]

Figure 8: SMR-300 L1 PSA Initiating Event Contributions

Table 3: Definition of Initiating Events

ID	Definition
FWLB	Feed Water Line Break
LLOCA	Large Loss of Coolant Accident (LOCA)
LOFW	Loss of Feed Water
LOMW	Loss of Main Feedwater
LOOP	Loss Of Off-Site Power
MLOCA	Medium LOCA
MSLB	Main Line Steam Break
RT/TT/TRANS	Reactor Trip / Turbine Trip
SG/SGTR	Steam Generator Tube Rupture
SLOCA	Small LOCA
VLOCA	Very Large LOCA

[REDACTED]

The results of the limited sensitivity study provides confidence that the CDF for the SMR-300 is likely to be of the same order of magnitude as the CDF for the SMR-160 once the expected design changes have been incorporated into the PSA model.

[REDACTED]

The SMR-160 L1 and L2 PSA presents overall results in terms of CDF and LRF. Since there is currently no L3 (consequence) analysis available for the SMR-160 these results are not directly comparable with the SAP Risk Targets which are measured in terms of dose band frequency and fatality frequency.

The approach is to use the L1 and L2 PSA results for the SMR-160, supported by the result of the PSA Sensitivity Study [56] (for CDF only) to draw high level conclusions as to the risks against the ONR SAP Targets. Part B Chapter 16 discusses further that the additional L3 PSA work proposed post GDA Step 2 will most likely demonstrate that SMR 300 Plant Risk will be compatible with the SAP risk targets 5-9.

5.6.6 Risk Targets

UK Dose and Risk Targets for the generic SMR-300 are defined in Part A Chapter 2 [3] and summarised in Table 4 (SAP Dose Targets 1-3) and Table 5 (SAP Risk Targets 4-9).

Comparison with the risk targets (5-9) is discussed in this sub-chapter, noting that no normal operations dose assessments have been produced at PSR v1 that would allow comparison with Targets 1-3 and no DBAA consequence assessments have been undertaken that would allow comparison with Target 4.

Preliminary discussion on Targets 5-9 is provided below with further detail presented in PSR Part B Chapter 16.

[REDACTED]

Table 4: Numerical Dose Targets 1-3

Target	Exposed Group	Threshold	Dose Target (mSv)	SMR-300 Dose Constraint [40]
Target 1 - Normal Operations Dose Targets – Individuals on Site	Employee working with ionising radiation	BSL (Legal Limit (LL))	20	10 mSv (outage) 1 mSv (at power)
		BSO	1	
	Other employees on site	BSL	2	0.5 mSv
		BSO	0.1	
Target 2 - Normal Operations Dose Targets – Groups on Site	Any group on site	BSL	10	2 mSv
		BSO	0.5	
Target 3 - Normal Operations Dose Targets – Any Person off Site	Any person off site	BSL (LL)	1	0.02 mSv
		BSO	0.02	

Table 5: Numerical Risk Targets 4-9

Target	Exposed Group	Threshold	Frequency (per annum)	Dose Target (mSv)	SMR-300 Dose Target [40]
Target 4 – Design Basis Fault Sequences – Any Person	On-site	BSL	>10-3	20	-
			10-3 – 10-4	200	=
			10-4 – 10-5	500	-
		BSO	-	0.1	-
	Off-site	BSL	>10-3	1	1 mSv
			10-3 – 10-4	10	10 mSv
			10-4 – 10-5	100	100 mSv
		BSO	-	0.01	-
Target 5 - Individual Risk of Death from Accidents – Any Person on the Site	Any person on site	BSL	10-4	-	-
		BSO	10-6	-	-
Target 6 - Frequency Dose Targets for any Single Accident – Any Person on the Site	Any person on site	BSL	10-1	2-20	-
			10-2	20-200	-
			10-3	200-2000	-
			10-4	>2000	-
		BSO	10-3	2-20	-
			10-4	20-200	-
			10-5	200-2000	-
			10-6	>2000	-
Target 7 - Individual Risk to People off the Site from Accidents	Any person off site	BSL	10-4	-	-
		BSO	10-6	-	-
Target 8 - Frequency Dose Targets for Accidents on an Individual Facility – Any Person off the Site	Any person off site	BSL	1	0.1-1	-
			10-1	1-10	-
			10-2	10-100	-
			10-3	100-1000	-
			10-4	>1000	-
		BSO	10-2	0.1-1	-
			10-3	1-10	-

Target	Exposed Group	Threshold	Frequency (per annum)	Dose Target (mSv)	SMR-300 Dose Target [40]
			10-4	10-100	-
			10-5	100-1000	-
			10-6	>1000	-
Target 9 - Total risk of 100 or more fatalities	Any person off site	BSL	10-5	-	-
		BSO	10-7	-	-

5.6.7 CAE Summary

This sub-chapter summarises the results of the safety assessment, with the aim of demonstrating that the risk to workers and the public meets numerical targets and is reduced to a level which is tolerable and ALARP. At the current design maturity of the SMR-300, a significant proportion of the detailed safety analysis required to demonstrate that these targets are fully met is not yet available. Therefore, the current evidence for Claim 2.4.2 focuses on providing confidence that the numerical criteria will be met by the SMR-300 and identifying the methodologies and work planned to demonstrate this.

The confidence Claim 2.4.2 can be demonstrated at future safety reports is based upon:

- The adoption of defence-in-depth in the fundamental design principles of the SMR-300, which is applied across the development of the design.
- Dose constraints and numerical targets adopted by Holtec at the design stage, in relation to normal operation and accident conditions, to ensure radiological protection of both on-site workers and members of the public.
- The application of good practice in the development of the design, particularly regarding compliance with ALARA for normal operations doses.
- A commitment to undertake a robust demonstration of the fault tolerance of the plant and of the effectiveness of its safety measures, by application of a UK context approach to hazard identification and fault assessment.
- The development of a PFS to identify the bounding reactor faults and the relevant lines of protection available within the current SMR-300 design, at the various levels of defence-in-depth.
- The output of the initial UK DBAA work, supported by US DSA and focused on a selection of key reactor faults.
- The Design Challenges being progressed to address any significant risks resulting from the DBAA work, as reported in Sub-chapter 5.8.
- Planned radiological consequence assessments to demonstrate that the relevant numerical targets are met and demonstrated as tolerable and ALARP.
- The indicative results from the SMR-160 PSA and associated sensitivity studies for the SMR-300 design.

Based on the summary above, there is recognition that full demonstration of Claim 2.4.2 is not yet possible. However, there are a clear set of safety analysis activities planned to support PCSR, which will further strengthen demonstration of Claim 2.4.2. In addition, a number of Design Challenges have been raised as a result of the DBAA work to date, which will be progressed to resolution, with design changes or supplemental analysis produced, to ensure a robust ALARP demonstration can be made, Consequently, there is considered to be sufficient evidence to judge that Holtec is proceeding with a design which will be able to support the demonstration of risks being tolerable and reduced to ALARP.

5.7 OPTIONS CONSIDERED TO FURTHER REDUCE RISK

Claim 2.4.3: Consideration is given to implement options to reduce risk, with a focus on issues that make a more significant contribution to risk, such that no further reasonably practicable options are identified.

Argument: A process exists to identify and assess credible options for prospective design changes that is compliant with the requirements expected to reduce risks to ALARP for optioneering and for the application and demonstration of BAT. The assessment of options includes considerations of safety, security, safeguards, and environmental criteria, as well as novelty, complexity, and the reduction of margins.

Evidence:

- **ALARP Guidance Document** [48] - This document includes the regulatory principles of ALARP and provides an optioneering methodology for undertaking ALARP assessment.
- **RSR-BAT Guidance** [60] - This guidance document details Holtec Britain's proportionate approach to demonstrating how the SMR-300 design complies with RSR environmental permit conditions regarding the use of BAT. This guidance also incorporates the BAT optioneering process.
- **Design Management Process** [46] - This process sets out a gated process which has the potential to identify design challenges and prospective design changes, which will be identified as commitments to be addressed post-GDA. The Design Management Process will be used to help identify where proportionate optioneering is required to support design challenges and prospective design changes.
- **Design Challenges** - A summary of the design challenges is presented for each PSR Part B Chapter in the ALARP Summary Table (Appendix B).

This sub-chapter discusses the optioneering process which will be used on the prospective design changes to the GDA reference design, so they can be evaluated for their risk contribution and against the test of gross disproportion required to demonstrate risk are ALARP.

The procedural application of ALARP is constructed around an optioneering process. Reducing risks to ALARP involves weighting the risk of a hazard causing harm to people against the money, time or trouble needed to control it. Optioneering is a key project activity which ultimately supports the demonstration that risks are ALARP and is defined as follows.

'Optioneering' is the term used to describe the process of identifying and developing various potentially viable options to address the given problem.

The optioneering process looks at specific risks, providing further evidence that a range of options have been considered and there are good reasons for choosing a particular option. The optioneering should be proportionate to the scale of the project and the safety significance of the issue being considered, covering the intended lifecycle [18].

Optimisation (in the context of the generic Holtec SMR-300) is the process whereby an operator selects the technical or management option that best meets the full range of relevant health, safety, environmental, security and safeguards objectives, taking into account factors such as social and economic considerations.

There is a synergy between optioneering for the demonstration of ALARP and optimisation for the demonstration of BAT. To support the Design Management Process described in sub-chapter 5.5, where design decisions are significant to safety and/or the environment, Holtec will apply proportionate optioneering, following the methodology described in the ALARP Guidance Document [48] and RSR-BAT Guidance [60].

The Design Management Process utilises this proportionate optioneering to compare credible options, consider a holistic approach which balances risks and ensure that design modifications to be applied to any future UK deployed design will continue to ensure risks are ALARP and demonstrate BAT.

In evaluating the prospective design changes, the ALARP Guidance Document [48] and RSR-BAT Guidance [60] provide guidance on optioneering and optimisation for ALARP and BAT in the following steps.

1. Option identification.
2. Screening of potential options.
3. Option assessment – including statement of benefits/disbenefits applied.
4. Identification and justification of preferred option(s) – including explanation of qualitative/quantitative ranking process applied.

Each stage should be completed and clearly evidenced to ensure that the optioneering assessment can be easily traced and understood. This will ensure that decisions made remain justifiable at later stages within the design lifecycle can be identified and understood.

Conventional safety hazards (associated with design methods), radiological safety hazards, environmental impacts, safeguards and security will be considered in parallel in an optimised manner during optioneering studies and in the categorisation, process outlined in the Design Management Process [46]. Early consultation with stakeholders in these disciplines should be undertaken prior to optioneering, to help develop the options assessment to be suitable for all relevant areas and avoid nugatory/duplication of work.

5.7.1 CAE Summary

This sub-chapter summarises the guidance which supports the Design Management Process, to identify and assess credible options to inform design decisions and ensure the selected option continues to reduce risks to ALARP and demonstrate application of BAT.

The ALARP and BAT guidance align with UK expectations to ensure assessment of options includes considerations of safety, security, safeguards, and environmental criteria, as well as novelty, complexity, and the reduction of margins. The test for gross disproportionality is included within the ALARP and BAT guidance. These processes and their application in GDA support the demonstration of Claim 2.4.3 to a maturity considered appropriate for the design development of the SMR-300.

Holtec are applying these processes, in a proportionate manner, to all design challenges and prospective design changes applicable to the GDA reference design. Outputs of the process are discussed within individual PSR Part B Chapters, with key contributions to the demonstration of ALARP discussed in Sub-chapter 5.8.

5.8 CONCLUSION ON THE FUNDAMENTAL OBJECTIVE OF THE PSR

PSR Fundamental Objective: The PSR summarises the safety standards and criteria, safety management and organisation, claims, arguments and intended evidence to demonstrate that the Generic Holtec SMR-300 design risks to people are likely to be tolerable and As Low As Reasonably Practicable (ALARP).

This sub-chapter aims to demonstrate that the Fundamental Objective of the PSR is met based upon the body of evidence provided against Claim 1 and Claim 2 presented below.

5.8.1 Technical Summary of Claim 1

Claim 1: The generic Holtec SMR-300 design, and safety case are developed for a GB-context generic site using integrated project, quality and safety management arrangements that take cognisance of relevant good practice and adopt appropriate codes and standards in the context of the UK regulatory regime.

Claim 1 is broken down into five Level 2 claims. Evidence that these Level 2 claims have been met to a maturity appropriate for a PSR is provided below.

Claim 1.1: The US Reference SMR-300 Plant design is derived from US design and International good practice to demonstrate compliance with US NRC requirements.

Claim 1.1 supports Claim 1 by demonstrating that the design principles, codes and standards used in the design of the SMR-300 have been selected to meet the stringent requirements of the US NRC. These mature and established US codes and standards are internationally recognised and are commensurate with the importance of the safety functions being delivered. The codes and standards applied to the design of nuclear safety related SSCs of the SMR-300 are nuclear specific, many of them are from existing practices adopted on UK nuclear licensed sites and / or application in earlier successful GDAs.

The evidence that the codes and standards are chosen to meet US NRC requirements can be found in the Holtec SMR-300 Safety, Security and Safeguards Principles Alignment Review [22]. This highlights the suite of Holtec International documents that provide the evidence that the US NRC requirements, as codified by the 10 CFR Part 50, Appendix A General Design Criteria (GDC), Electric Power Research Institute (EPRI) User Requirements Document, NUREG 0800 Standard Review Plan for the Review of Safety Analysis Reports and other NRC requirements of Title 10 CFR are met.

Claim 1.2: The Generic SMR-300 design is developing to ensure compliance with UK nuclear safety and design principles while minimising the impact on the design stability of the global fleet.

Claim 1.2 supports Claim 1 by showing that the design and safety principles being used to develop the US SMR-300 Reference Plant broadly align with UK-context expectations in order to provide assurance to a future licensee, that it will ultimately be able to demonstrate the generic SMR-300 design against its own safety and design principles. The Holtec SMR-300

Safety, Security and Safeguards Principles Alignment Review [22] presents the results of a review of the respective UK and US regulatory expectations that are relevant to the SMR 300 design. The report identifies areas where, in Holtec's judgement, there is broad alignment between the US SMR-300 design and safety principles and the ONR SAPs [96].

Claim 1.2 also demonstrates that the SSEC has assessed the generic SMR-300 design and demonstrated the equivalency of the codes and standards utilised in the design of the US SMR-300 reference plant and UK codes and standards. This is further evidenced through the Part B chapters, which justify individual design codes and standards selected. The codes and standards used in the design of the SMR-300 have been selected to meet the stringent requirements of the US NRC. Many of them represent good practice adopted on UK nuclear licensed sites and / or application in earlier successful GDAs. Where any risks are identified, either in principle alignment or selection of appropriate codes and standards, these are raised as Design Challenges and are discussed further in Appendix B on a Chapter by Chapter basis.

Claim 1.3: An appropriately conservative and bounding GB-context generic site envelope is derived for the Generic SMR-300 GDA.

Claim 1.3 supports Claim 1 by defining the GB GSE for the generic SMR-300. A comprehensive hazard identification and screening has been undertaken in accordance with RGP to identify credible External Hazards that are relevant to the deployment of the generic SMR-300. The identified External Hazards have then been characterised following appropriate codes and standards, taking cognisance of RGP and OPEX, to establish the GB GSE Parameters. This is presented in the Generic Site Envelope Report for SMR-300 UK GDA [61].

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 the environment throughout its lifecycle.

Claim 1.4 supports Claim 1 by defining the project, quality, design and safety management arrangements that have been adopted to deliver a UK SMR-300. The evidence that demonstrates this claim is met is provided by PSR Part A Chapter 4 Lifecycle Management of Safety and Quality Assurance [4] which provides the following information for the SMR-300 Project:

- Quality Management arrangements.
- Project Management arrangements.
- Design Management arrangements.
- Safety, Security and Environment Case management arrangements.
- Arrangements for future lifecycle phases.

Holtec's design arrangements are considered to be sufficient against US NRC requirements to deliver the SMR-300 design, at this stage of project maturity. This is evidenced through the SMR-300 Design Control Process [62] which ensure 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). Part A Chapter 4 raises

[Not UK Export Controlled]
[Not Part 810 Export Controlled]

GDA Commitments where additional work is required to demonstrate satisfactory implementation of arrangements. Holtec has established a design management approach that does not foreclose options and enables future UK-specific design development to meet the ALARP principle.

Claim 1.5: An appropriate ALARP methodology is applied to the design change process, to ensure ongoing design decisions support the reduction of risks to ALARP.

An ALARP process exists to identify and assess credible options for prospective design changes that is compliant with the requirements expected to reduce risks to ALARP for optioneering and for the application and demonstration of BAT. The assessment of options includes considerations of safety, security, safeguards, and environmental criteria, as well as novelty, complexity, and the reduction of margins. Evidence of the ALARP process can be found in the following documentation:

- ALARP Guidance Document [48] - This document includes the regulatory principles of ALARP and provides an optioneering methodology for undertaking ALARP assessment.
- RSR-BAT Guidance [60] - This guidance document details Holtec Britain's proportionate approach to demonstrating how the SMR-300 design complies with RSR environmental permit conditions regarding the use of BAT. This guidance also incorporates the BAT optioneering process.
- Design Management Process [46] - This process sets out a gated process which has the potential to identify design challenges and prospective design changes, which will be identified as commitments to be addressed post-GDA. The Design Management Process will be used to help identify where proportionate optioneering is required to support design challenges and prospective design changes.

5.8.2 Technical Summary of Claim 2

Claim 2: The design and safety assessment shows that the generic Holtec SMR-300 can be constructed, commissioned, operated, and decommissioned on a generic site in the UK with risks that are tolerable and As Low As Reasonably Practicable (ALARP).

Claim 2 is broken down into four Level 2 claims. A high level summary of the evidence that these Level 2 claims have been met to a maturity appropriate for a PSR is provided below.

5.8.3 Technical Summary of Claim 2.1

Claim 2.1: The nuclear safety assessment identifies plant initiating events and specifies the requirements for safety measures such that safety functions are fulfilled, informs operational and emergency arrangements and demonstrates that risk is tolerable and As Low As Reasonably Practicable (ALARP).

Claim 2.1 is broken down into seven Level 3 claims as shown in Table 6. A high level summary of the evidence that those Level 3 claims have been met is provided below.

Table 6: Claim 2.1 - L3 Claims

No.	Claim	SSEC Chapter
2.1.1	Radiological Protection requirements are identified such that effective doses to workers and public during normal operations are below legal limits, defined justified dose targets and constraints and are As Low As Reasonably Practicable.	B10
2.1.2	The design basis analysis demonstrates that the risk from design basis faults associated with the operation of the Generic Holtec SMR-300 are tolerable and As Low As Reasonably Practicable (ALARP).	B14
2.1.3	Beyond design basis faults and severe accidents are appropriately identified and risk assessed to be tolerable and As Low As Reasonably Practicable (ALARP).	B15
2.1.4	The probabilistic safety assessment (PSA) demonstrates that the design of the Generic Holtec SMR-300 is balanced such that risk is tolerable and As Low As Reasonably Practicable (ALARP).	B16
2.1.5	Risks from External Hazards and their combinations have been demonstrated to be tolerable and ALARP.	B21
2.1.6	Risks from Internal Hazards and their combinations have been demonstrated to be tolerable and ALARP.	B22
2.1.7	Human actions important to safety and factors likely to influence human performance are systematically identified and their reliability and effective task performance is considered to be achievable.	B17

Claim 2.1.1: Radiological Protection requirements are identified such that effective doses to workers and public during normal operations are below legal limits, defined justified dose targets and constraints and are As Low As Reasonably Practicable.

This claim is addressed in Part B Chapter 10 and a summary of the radiological protection work undertaken to meet this claim is provided in sub-chapter 5.6.1.1.

Claim 2.1.2: The design basis analysis demonstrates that the risk from design basis faults associated with the operation of the Generic Holtec SMR-300 are tolerable and As Low As Reasonably Practicable (ALARP).

This claim is addressed in Part B Chapter 14 and a summary of the UK DBAA work undertaken to meet this claim is provided in sub-chapter 5.6.3.1.

Claim 2.1.3: Beyond design basis faults and severe accidents are appropriately identified and risk assessed to be tolerable and As Low As Reasonably Practicable (ALARP).

This claim is addressed in Part B Chapter 15 and a summary of the SAA work undertaken to meet this claim is provided in sub-chapter 5.6.4.1.

Claim 2.1.4: The probabilistic safety assessment (PSA) demonstrates that the design of the Generic Holtec SMR-300 is balanced such that risk is tolerable and As Low As Reasonably Practicable (ALARP).

This claim is addressed in Part B Chapter 16 and a summary of the PSA work undertaken to meet this claim is provided in sub-chapter 5.6.5.1.

Claim 2.1.5: Risks from External Hazards and their combinations have been demonstrated to be tolerable and ALARP.

A preliminary evaluation of the GDA Reference Design was undertaken for each of the identified External Hazards in PSR Part B Chapter 21. This preliminary evaluation demonstrated that for many of the identified External Hazards there was significant margin present between the GDA Reference Design parameters and the GB GSE Parameters providing confidence in the robustness of the generic SMR-300 in the context of a UK deployment. This evaluation also identified hazards which require further investigation at the site-specific stage which are discussed in the External Hazards US-UK Gap Analysis Report [63].

Claim 2.1.6: Risks from Internal Hazards and their combinations have been demonstrated to be tolerable and ALARP.

Internal Hazards relevant to SMR-300 have been defined based on a review of ONR and IAEA guidance and previous UK GDA submissions as presented in Appendix B, RGP and Extant Internal Hazards Review of Part B Chapter 22. Due to the lack of design information at Step 2 GDA only hazard methodologies have been defined which are presented in the following Step 2 reports:

- HI-2241281, Internal Hazard Methodology and Alignment Report defines assessment methodologies for individual Internal Hazards in accordance with UK expectations, excluding impact, dropped loads and pipe whip.
- HI-2241055, B22 Impact Hazard Assessment and HI-2241235, B22 Impact Hazard Substantiation Methodologies covers Pipe Whip and Jet Impact, Dropped Loads and Flooding and pipe break from moderate energy pipework in accordance with UK expectations.
- HI-2241054, Internal Hazards and External Hazards Combined Hazards Methodology covers combined and consequential hazards in accordance with UK expectations.

Commitment C_Inte_095 has been raised relating to the difference in approach between the US and UK with respect to internal flooding, [REDACTED]. Commitment C_Inte_096 has been raised relating to regulatory expectations related to dropped loads as they differ between the US and the UK, [REDACTED]. Commitment C_Inte_117 has been raised relating to risks to the SMR-300 design against UK expectations on the level of segregation for a new reactor design.

Claim 2.1.7: Human actions important to safety and factors likely to influence human performance are systematically identified and their reliability and effective task performance is considered to be achievable.

This claim is addressed in Part B Chapter 17 which describes how the Holtec process for reviewing Human Actions (HAs) and identifying those important to nuclear safety has been reviewed against ONR expectations for this PSR. In line with expectations for a PSR and GDA Step 2, the process has been considered at a fundamental level, with examples of its application. GDA Commitment C_Huma_003 was raised in Part B Chapter 17 to develop a Human Reliability Assessment (HRA) Strategy for the UK SMR-300 design:

5.8.3.1 Summary of Demonstration Claim 2.1

The evidence that Claim 2.1 is broadly met, to a maturity appropriate for a PSR, is provided by the discussion under the Normal Operations, UK DBAA, SAA and PSA sections in sub-chapter 5.6 which provides some preliminary risk quantification. The risks from Internal and External Hazards and their combinations have not been quantified for PSR v1 but evidence is presented that there is significant margin in the SMR-300 design against External Hazards and for Internal Hazards, appropriate methodologies have been derived that will allow them to be assessed at PCSR stage.

5.8.4 Technical Summary of Claim 2.2

Claim 2.2: The design of the systems and associated processes have been developed taking cognisance of relevant good practice and substantiated to achieve their safety and non-safety functional requirements.

Claim 2.2 is broken down into eighteen Level 3 claims as shown in Table 7. A high level summary of the evidence that those Level 3 claims have been met is provided below.

Table 7: Claim 2.2 - L3 Claims

No.	Claim	SSEC Chapter
2.2.1	Adequate provision for the control of reactivity is incorporated into the design of the reactor systems, engineered safety features and fuel and core design.	B1, B2, B4, B5
2.2.2	Adequate provision for the removal of heat from the reactor core and spent fuel pool is incorporated into the design of the reactor systems, engineered safety features and fuel and core design.	B1, B2
2.2.3	Adequate provision for the control of radiation exposure and control of release of radioactive material is incorporated into the design of the reactor systems, supporting facilities, engineered safety features, and fuel and core design.	B1, B2, B5, B10, B18, B20
2.2.4	The Reactor Coolant System and Connected Systems are designed to ensure they deliver relevant safety features, supported by substantiation which is suitably mature.	B1
2.2.5	The Engineered Safety Features are designed to ensure they deliver relevant safety features, supported by substantiation which is suitably mature.	B1
2.2.6	The overall design and architecture of I&C SSCs ensures that safety functions and non-safety functions are delivered and faults arising from failures of the SSCs are minimised.	B4
2.2.7	The overall design and architecture of Electrical SSCs ensures that safety functions and non-safety functions are delivered and faults arising from failures of the SSCs are minimised.	B6
2.2.8	Human factors requirements are integrated into the design, operation and maintenance of the Generic Holtec SMR-300.	B17
2.2.9	Higher Reliability SSCs have been justified using appropriate methods, demonstrating that risk is tolerable and As Low As Reasonably Practicable (ALARP).	B18

No.	Claim	SSEC Chapter
2.2.10	The overall design and architecture of Mechanical SSCs ensures that safety functions and non-safety functions are delivered and faults arising from failures of the SSCs are minimised.	B19
2.2.11	The overall design and architecture of Civil SSCs ensures that safety functions and non-safety functions are delivered and faults arising from failures of the SSCs are minimised.	B20
2.2.12	The objective of preventing damage to the fuel and core components is appropriately accounted for within their design and safety function.	B2
2.2.13	The Reactor Supporting Facilities are designed to ensure they deliver relevant safety features, supported by substantiation which is suitably mature.	B5
2.2.14	The SMR-300 chemistry regime and systems reduce chemistry-related risks during all normal operating modes and accident conditions for all phases of the lifecycle.	B23
2.2.15	SSCs are designed to meet Radiological Protection requirements and minimise exposures.	B10
2.2.16	SSCs which support the safe management and storage of radioactive waste are designed to ensure safety functions and measures are delivered and radiation exposure and release of radioactive material are minimised ALARP.	B13
2.2.17	SSCs which support operational fuel activities are designed to ensure safety functions and measures are delivered and radiation exposure and release of radioactivity are minimised ALARP.	B24
2.2.18	The overall design and architecture of heating, ventilation and air conditioning SSCs ensure that safety functions and non-safety functions are delivered and faults arising from failures of the SSCs are minimised.	B5

Claim 2.2.1: Adequate provision for the control of reactivity is incorporated into the design of the reactor systems, engineered safety features and fuel and core design.

Part B Chapters 1, 2, 4 and 5 explain the design and safety features used for control of reactivity during normal operations and fault conditions. Reactivity is managed and controlled by the following:

- Shutdown margin of the core (Part B Chapter 2).
- Control Rod Control (CRC) System (Part B Chapter 4).
- Control of the boron concentration in the reactor coolant by the Chemical and Volume Control (CVC) System (Part B Chapter 5).
- Plant Safety System and Instrumentation (Part B Chapter 4) that monitors the neutron population and shuts the reactor down, via the Control Rod Control System, if it exceeds limits.
- Two independent means of shutdown, one by control rods (Part B Chapter 2), the other by boron injection via the PCM accumulators (Part B Chapter 1 [64]). Further defence-in-depth can also be provided, in certain fault scenarios, by boron injection using the CVC System (Part B Chapter 5).

The Nuclear Design Basis Report [65] provides evidence that reactivity can be suitably controlled during all operating modes. The SMR-300 CRA Nuclear Analysis [66] defines the required SMR-300 soluble boron concentration needed to maintain the shutdown margin requirement.

Claim 2.2.2: Adequate provision for the removal of heat from the reactor core and spent fuel pool is incorporated into the design of the reactor systems, engineered safety features and fuel and core design.

Part B Chapters 1 and 2 explain the design and safety features used for removal of heat from the reactor core and spent fuel pool during normal operations and fault conditions. Heat removal is provided by the following:

- RCS (Part B Chapter 1), which includes RPV, RCPs, SGE and PZR, which provides the primary coolant flow through the reactor and the means of pressure control by pressuriser heaters, spray control and relief valves.
- Reactor (Part B Chapter 2), where the core design ensures that it is always maintained in a coolable geometry.
- Passive Core Cooling System (PCC) (Part B Chapter 1), which includes the PDH, SDH, ADS and PCM:
    - The PDH and SDH provide primary protection in the form of emergency decay heat removal when the normal heat rejection path is lost. Each decay heat removal system is capable of removing core decay heat and bringing the plant to a safe shutdown condition.
    - The ADS and PCM provide primary protection in the form of controlled depressurisation and safety injection, respectively, for DBAs resulting in loss of reactor coolant. The PCM and ADS will ensure sufficient RCS inventory to prevent fuel failure during the event and remove decay heat for the first 72 hours with no operator action required.

The Main Steam System (MSS), Residual Heat Removal System (RHR) and Spent Fuel Cooling System (SFC) also provide heat removal but this is currently classified as a US non-safety function of these systems. These systems are addressed under claim 2.2.13, below.

Claim 2.2.3: Adequate provision for the control of radiation exposure and control of release of radioactive material is incorporated into the design of the reactor systems, supporting facilities, engineered safety features, and fuel and core design.

Part B Chapters 1, 2, 5, 10, 18 and 20 explain the design and safety features used to control radiation exposure and control of release of radioactive material during normal operations and fault conditions.

Radiation exposure is controlled by the following:

- Shielding (Part B Chapter 10) designed to ensure that dose rates within the CS and outside the CES are within targets.

Control of release of radioactive material is provided by the following barriers to radiation release:

- Integrity of fuel rod cladding (Part B Chapter 2).
- Integrity of the RCS pressure boundary (Part B Chapter 1) and higher reliability components, e.g. RPV, pressuriser, etc (Part B Chapter 18).

- Contribution to the integrity of the CS (Part B Chapter 1 and Part B Chapter 20), the Passive Containment Heat Removal System (PCH) (Part B Chapter 1), the Containment Isolation System (CIS) (Part B Chapter 1), Auxiliary Systems (Part B Chapter 5), and Steam and Feed Systems (Part B Chapter 5), that contribute to maintaining the containment boundary.

Further discussion on the containment structures and systems can be found in the Containment Structure Systems Based View document [67] and within Part B Chapter 20 [68].

Front-line Systems Engineering Claims 2.2.4, 2.2.5, 2.2.6, 2.2.9, 2.2.12

The Reactor Coolant System and Connected Systems are designed to ensure they deliver relevant safety features, supported by substantiation which is suitably mature.

The Front-line Systems include the SSCs directly required to fulfil a safety function and comprise:

- Reactor Coolant System (2.2.4) which is designed and substantiated in Part B Chapter 1.
- Engineered Safety Features (ESF) (2.2.5) which are designed and substantiated in Part B Chapter 1.
- Instrumentation and Control (I&C) (2.2.6) which is designed and substantiated in Part B Chapter 4.
- Higher Reliability Components (2.2.9) which are designed and substantiated in Part B Chapter 18.
- Reactor (2.2.12) which is designed and substantiated in Part B Chapter 2.

The evidence that these systems meet their claims is provided by the following:

- Designed based on US codes and standards (GDC and EPRI requirements) and OPEX from the world-wide PWR fleet.
- Compared with RGP to highlight any risks in meeting UK expectation and associated codes and standards. Where risks are identified, Design Challenges have been raised to address these.
- Substantiation techniques between US and UK are shown to be broadly equivalent with certain exceptions.

Support Systems Engineering Claims 2.2.7, 2.2.11, 2.2.13, 2.2.16, 2.2.17, 2.2.18

The Support Systems include the SSCs which enable the Front-line systems to fulfil their safety function and comprise:

- Electrical Systems (2.2.7) which are designed and substantiated in Part B Chapter 6.
- Civil SSCs (2.2.11) which are designed and substantiated in Part B Chapter 20.
- Reactor Supporting Facilities (2.2.13) which are designed and substantiated in Part B Chapter 5. These systems include:
    - Main Steam System (MSS), which provides the secondary heatsink during normal reactor operation.

  - Residual Heat Removal System (RHR), which provides decay heat removal from the reactor core and the RCS during normal shutdown/refuelling operations.
  - Spent Fuel Cooling System (SFC), which provides decay heat removal from the Spent Fuel Pool.
- Radioactive Waste Management (2.2.16) which is designed and substantiated in Part B Chapter 13.
- Fuel Transport and Storage (2.2.17) which is designed and substantiated in Part B Chapter 24.
- HVAC (2.2.18) which is designed and substantiated in Part B Chapter 5.

The evidence that these systems meet their claims is provided by the following:

- Designed based on US codes and standards (GDC and EPRI requirements) and OPEX from the world-wide PWR fleet.
- Compared with RGP to highlight any risks in meeting UK expectation and associated codes and standards. Where risks are identified, Design Challenges and Commitments have been raised to address these.
- Substantiation techniques between US and UK are shown to be broadly equivalent.

Claim 2.2.8: Human factors requirements are integrated into the design, operation and maintenance of the Generic Holtec SMR-300.

Part B Chapter 17 explains how human factors requirements are integrated into the design and safety assessment during normal operations and fault conditions. Human factors input is provided by the following:

- Systematic Integration of Human Factors (HF) into the SMR-300 lifecycle.
- Qualitative HF design and analysis, taking cognisance of RGP & OPEX.
- Identification and substantiation of HF related requirements.
- Staffing and Qualification requirements assessed and informed by HRA.

The Passive Systems Report [69] describes the passive safety features incorporated in the SMR-300 design. These passive safety features are designed to eliminate the reliance on operator actions for a period of 72 hours post fault initiation. The demonstration that the design and operation of passive safety features reduces the risks to ALARP, assuming no operator actions, will be demonstrated as part of the Deterministic and Probabilistic Safety Assessments undertaken at PCSR.

Claim 2.2.15: SSCs are designed to meet Radiological Protection requirements and minimise exposures.

Part B Chapter 10 explains how radiological protection requirements are integrated into the design and safety assessment during normal operations and fault conditions to minimise exposures. Radiological protection input is provided by the following:

- Radiological protection targets for dose rate and normal operation dose uptake for collective and average/maximum individual dose.

- Designation of areas for contamination and dose rate.
- Shielding Design Basis that specifies the radiological inventory, geometry data, materials data, flux-to-dose conversion factors and assessment criteria. It also presents preliminary dose rate calculations for the reactor and SFP.
- ALARP Guidance Document [48] which provides guidance on ALARP optioneering.

The Shielding Design Basis [59] determines the maximum dose rate outside containment to be [REDACTED] μSv/h which is below the limit of [REDACTED] for R0 undesignated areas. The dose rates from the SFP contents are well below background and will not contribute significantly to total dose rates inside or outside of the containment. This work gives confidence that the proposed shielding design can achieve the dose targets.

No Normal Operations Dose Assessment (NODA) has been undertaken at PSR v1 due to the lack of details on occupancy and manning levels. It is not therefore possible to demonstrate that normal operations dose uptake meets targets and can be shown to be ALARP.

Claim 2.2.14: The SMR-300 chemistry regime and systems reduce chemistry-related risks during all normal operating modes and accident conditions for all phases of the lifecycle.

Part B Chapter 23 explains the design and safety features used to control primary and secondary chemistry during normal operations and fault conditions. The key aspects of chemistry control are:

- Chemistry Support to Fuel Reactivity through the use of a soluble neutron absorber to control core reactivity.
- Chemistry Support to Fuel Heat Removal by chemistry control to reduce the risk of channel blockage and the generation of fuel crud.
- Chemistry Support to Fuel Heat Removal by reducing the risk of blockages due to physical debris or chemical species created following a LOCA type accident.
- Chemistry Support to Structural Material integrity and Confinement of Radioactivity by controlling the oxygen, hydrogen and impurities in the RCS coolant and pH control via the addition of Lithium Hydroxide.
- Chemistry Support to Radioactive Source Term
- Chemistry Monitoring and Control, including sampling
- Chemistry Support to Integrity of Structural Materials and Confinement of Radioactivity Within the Secondary Circuit
- Secondary Chemistry Monitoring and Control

5.8.4.1 Summary of Demonstration Claim 2.2

Claim 2.2 has been broadly demonstrated as met, to a maturity appropriate for a PSR, by presenting evidence from the eighteen Level 3 claims that comprise Claim 2.2. In general, the evidence that the SSCs within the scope of Claim 2.2 meet their claims is demonstrated by the following:

- Designed based on US codes and standards (GDC and EPRI requirements) and OPEX from the world-wide PWR fleet.

- Compared with RGP to highlight any risks in meeting UK expectations and appropriate codes and standards. Where risks are identified, Design Challenges and GDA Commitments have been raised to address these.
- Substantiated based on common US/UK techniques that are shown to be broadly equivalent, unless highlighted otherwise.

5.8.5 Technical Summary of Claim 2.3

Claim 2.3: The design and safety assessment of the Generic Holtec SMR-300 considers the entire reactor lifecycle.

Claim 2.3 is broken down into six Level 3 claims as shown in Table 8. A high level summary of the evidence that those Level 3 claims have been met is provided below.

Table 8: Claim 2.3 - L3 Claims

No.	Claim	SSEC Chapter
2.3.1	Operations: Appropriate arrangements to safely manage people and plant during the operation of the generic SMR-300 are suitably mature.	B9
2.3.2	Decommissioning: The Generic Holtec SMR-300 can be safely decommissioned.	B26
2.3.3	Radioactive waste will be safely managed throughout the entire reactor lifecycle.	B13
2.3.4	Spent fuel will be safely managed throughout the entire reactor lifecycle.	B24
2.3.5	Nuclear site health and safety and fire safety: Nuclear site health and safety and conventional fire safety are managed to ensure that the conventional health and safety risks, and fire safety risks to workers and the public are reduced so far as is reasonably practicable.	B12
2.3.6	Construction and Commissioning: Appropriate arrangements are developed to safely manage people and plant during the construction and commissioning of the Generic Holtec SMR-300.	B25

Part B Chapter 9 describes the arrangements to safely manage people and plant during the operation of the generic SMR-300 and are demonstrated to an expected maturity appropriate for a PSR.

Part B Chapter 26 describes the proposed arrangements to safely decommission the SMR-300 and are demonstrated to an expected maturity appropriate at PSR, noting the need to progress GDA Commitments to provide a comparative assessment of the preferred prompt strategy against a deferred strategy.

Part B Chapter 13 explains how the safe management and storage of radioactive waste will be undertaken throughout the entire reactor lifecycle and are demonstrated to an expected maturity appropriate at PSR, noting that information dependent on site-specific factors will be required to meet regulatory expectations in establishing the strategies for ILW and LLW facilities.

Part B Chapter 24 explains how spent fuel will be safely managed throughout the entire reactor lifecycle and are demonstrated to an expected maturity appropriate at PSR.

Part B Chapter 12 describes the arrangements for nuclear site health and safety and conventional fire safety are demonstrated to an expected maturity appropriate at PSR, noting the GDA Commitments relating to means of escape and firefighting in the CS and RAB. In addition, the need to further demonstrate compliance with CDM 2015 Designer duties during the Detailed Design phase and subsequent phases.

Part B Chapter 25 describes the proposed arrangements to safely manage people and plant during construction and commissioning and are demonstrated to an expected maturity appropriate at PSR.

5.8.5.1 Summary of Demonstration Claim 2.3

Claim 2.3 has been broadly demonstrated, to a maturity appropriate for a PSR, by referencing the PSR Chapters that present the evidence that the six Level 3 claims that comprise Claim 2.3 are met. In general, the evidence that the entire lifecycle has been addressed is demonstrated by the description of the arrangements presented in the relevant PSR Chapter.

5.8.6 Technical Summary of Claim 2.4

Claim 2.4: The risk to workers and the public is tolerable and is as low as reasonably practicable, for the design, construction, commissioning, operation and decommissioning of the generic Holtec SMR-300.

Claim 2.4 is covered in this Chapter and is broken down into three Level 3 claims as set out in Section 5.3. A high level technical summary that those Level 3 claims have been met is provided below.

Claim 2.4.1: The design of the SMR-300 and planned activities are developed to meet legislative requirements and adopt relevant good practice.

Sub-chapter 5.4 shows how good practice is recognised in the SMR-300 design and how OPEX has been considered extensively in the design development process. Holtec International has used sound and historically successful engineering principles to develop the SMR-300 design in the US, using codes and standards that are, in many instances, recognised as RGP in the UK.

In many instances there is good alignment between adopted codes, standards and methodologies for the generic SMR-300 design and UK context expectations of good practice. However, in several instances further work is still required to fully demonstrate Claim 2.4.1. Where additional evidence is needed to demonstrate meeting UK expectations, Design Challenges have been raised within Step 2. For Design Challenges that cannot be closed within Step 2, GDA commitments have been raised to ensure closeout beyond GDA.

Claim 2.4.2: The safety assessment demonstrates that radiation risk to workers and the public is tolerable and As Low As Reasonably Practicable (ALARP).

Sub-chapter 5.6 summarises the results of the safety assessment, with the aim of demonstrating that the risk to workers and the public meets numerical targets and is reduced to a level which is tolerable and ALARP. At the current design maturity of the SMR-300, a significant proportion of the detailed safety analysis required to demonstrate these targets are fully met is not yet available. Therefore, the current evidence for Claim 2.4.2 focuses on providing confidence that the numerical criteria will be met by the SMR-300 and identifying the methodologies and work planned to demonstrate this.

The confidence Claim 2.4.2 can be demonstrated at future safety reports is based upon:

- The adoption of defence-in-depth in the fundamental design principles of the SMR-300, which is applied across the development of the design.
- Dose constraints and numerical targets adopted by Holtec at the design stage, in relation to normal operation and accident conditions, to ensure radiological protection of both on-site workers and members of the public.
- The application of good practice in the development of the design, particularly regarding compliance with ALARA for normal operations doses.
- A commitment to undertake a robust demonstration of the fault tolerance of the plant and of the effectiveness of its safety measures, by application of a UK context approach to hazard identification and fault assessment.
- The development of a PFS to identify the bounding reactor faults and the relevant lines of protection available within the current SMR-300 design, at the various levels of defence-in-depth.
- The output of the initial UK DBAA work, supported by US DSA and focused on a selection of key reactor faults.
- The Design Challenges being progressed to address any significant risks resulting from the UK DBAA work, as reported in Sub-chapter 5.6.3.1.
- Planned radiological consequence assessments to demonstrate that the relevant numerical targets are met and demonstrated as tolerable and ALARP.
- The indicative results from the SMR-160 PSA and associated sensitivity studies for the SMR-300 design.

Consequently, there is considered to be sufficient evidence to judge that Holtec is proceeding with a design which will be able to support the demonstration of risks being tolerable and reduced to ALARP.

Claim 2.4.3: Consideration is given to implement options to reduce risk, with a focus on issues that make a more significant contribution to risk, such that no further reasonably practicable options are identified.

Sub-chapter 5.7 summarises the guidance which supports the Design Management Process, to identify and assess credible options to inform design decisions and ensure the selected option continues to reduce risks to ALARP and demonstrate application of BAT.

The ALARP and BAT guidance align with UK expectations to ensure assessment of options includes considerations of safety, security, safeguards, and environmental criteria, as well as novelty, complexity, and the reduction of margins. The test for gross disproportionality is included within the ALARP and BAT guidance. These processes and their application in GDA, support demonstration of Claim 2.4.3 to a maturity considered appropriate for the design development of the SMR-300.

Holtec are applying these processes, in a proportionate manner, to all design challenges and prospective design changes applicable to the GDA reference design. Outputs of the process are discussed within individual PSR Part B Chapters, with key contributions to the demonstration of ALARP discussed in Sub-chapter 5.8.

5.8.6.1 Summary of Demonstration Claim 2.4

PSR Part A Chapter 5 (this report) presents a summary of the evidence, to a maturity appropriate for a PSR, that the SMR-300 has been designed against RGP and that risks from normal operations and accidents are understood. Safety significant design challenges have been identified during GDA, for those areas of highest risk, to support the future demonstration of ALARP. Holtec will ensure these design challenges are resolved and any consequent design changes incorporated into the future UK SMR-300 design. The iterative approach to safety analysis and design development, as set out in Part A Chapter 4, will ensure design development continues to drive down nuclear safety risks, with further design challenges raised as necessary for safety significant issues identified subsequent to GDA Step 2.

5.8.7 GDA Commitments

At Revision 1 there are no GDA commitments identified for PSR Part A Chapter 5.

A comprehensive list of GDA commitments across the PSR have been formally captured in the CAR process [6] and are defined against the relevant PSR Part B Chapter in the ALARP Summary Table (Appendix B). Further details of the CAR process are provided in Part A Chapter 4 [4].

5.8.8 Summary of Meeting the Fundamental Objective of the PSR

PSR Fundamental Objective: The PSR summarises the safety standards and criteria, safety management and organisation, claims, arguments and intended evidence to demonstrate that the Generic Holtec SMR-300 design risks to people are likely to be tolerable and As Low As Reasonably Practicable (ALARP).

The technical summaries for Claims 1 and 2 present the high-level arguments and evidence that each respective claim is met, with much greater detail presented in relevant PSR Chapters.

For Claim 1, a summary of the evidence is presented that the generic SMR-300 is designed to US codes and standards, meets UK design and safety principles, meets the requirements of the generic UK site and will be designed, constructed, commissioned, operated and decommissioned in accordance with a robust safety management system, and that a robust methodology will demonstrate that the design has been optimised and risks are ALARP.

For Claim 2, a summary of the evidence is presented that the generic SMR-300 design and its associated safety features meet the UK requirements for control of reactivity, decay heat removal and maintaining confinement of nuclear material by the provision of robust independent and diverse engineered safety features and by suitably trained operators. It also includes a shielding related function to protect against the effects of direct radiation exposures.

The preliminary reactor shielding design will ensure dose rates in and outside containment, subject to the development of further shielding around the reactor, can meet dose rate targets.

These low dose rates give confidence that normal operation doses to operators and other site workers will ultimately be able to be demonstrated ALARP.

The design is underpinned by a Preliminary Fault Schedule that identifies for each fault the Safety Function Category based on frequency/unmitigated consequence and designates the Principal and Secondary safety systems required to deliver the safety function, together with a UK equivalent classification. UK DBAA of selected faults demonstrates adequate provision of safety systems in the design, subject to a commitment C_Faul_103 and relevant Design Challenges, which require supplemental safety assessment to appropriately address UK expectations and good practice.

On the basis of the information presented in this sub-chapter, it is considered that the evidence presented supports the argument that the fundamental purpose of the PSR has been met as far as possible, given the design maturity at the end of Step 2 GDA.

5.9 CONCLUSION ON THE FUNDAMENTAL OBJECTIVES OF THE PER, GSR AND PSGR

The PSR, PER, PSgR and GSR developed throughout GDA together contribute to the fulfilment of the Fundamental Purpose. This sub-chapter discusses the interface of the PSR with other disciplines, including BAT, security threats and proliferation risks.

5.9.1 Conclusion on the Fundamental Objective of the PER

The PER has been developed in support of the environmental objectives that underpin the environmental case for the generic SMR-300. The Fundamental Objective for the environmental case is presented in sub-chapter 0. The PER Fundamental Objective for the environment case will be achieved for the generic SMR-300 GDA through the demonstration of SSEC Claim 3 and Claim 4, as well as the relevant sub-claims 3.1, 3.2, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6 and 4.7. These claims are associated with the environmental chapters, which at this stage consist of:

- Holtec SMR GDA PER Chapter 1 - Radioactive Waste Management Arrangements [70].
- Holtec SMR GDA PER Chapter 2 - Quantification of Effluent Discharges and Limits [71].
- Holtec SMR GDA PER Chapter 3 - Radiological Impact Assessment [72].
- Holtec SMR GDA PER Chapter 4 - Conventional Impact Assessment [73].
- Holtec SMR GDA Approach and Application of the Demonstration of BAT [74].
- Holtec SMR GDA PER Chapter 5 – Approach to Monitoring and Sampling [75].
- Holtec SMR GDA PER Chapter 6 – Demonstration of BAT [76].

The PER chapters, as well as all relevant PSR Chapters (mainly including A2 [3], A3 [2], A4 [4], B1 [64], B2 [77], B5 [78], B10 [7], B11 [79], B13 [80], B19 [81], B20 [68], B23 [82], B24 [83] and B26 [14]) will collectively contribute to the development of the environment case within the GDA process. The substantiation of the environmental claims Claim 3 and Claim 4 is presented in PER Chapter 6 Demonstration of BAT [76]. The demonstration of BAT for generic SMR-300 provides the arguments and available evidence on the generic SMR-300 design in line with Approach and Application of the Demonstration of BAT [74] to substantiate the environmental claims, which indicate how radioactive waste will be prevented and minimised to reduce the impacts on the members of the public and environment to ALARA.

The environment case of the generic SMR-300 has been developed based on GDA guidance, as well as SMR-300 design information, the summary of environment case is described in PSR Part B Chapter 11 [79]. The use of RGP is central to the demonstration of both BAT and ALARP for health and safety, nuclear and environmental law. The application does vary slightly for each legal space, but the overall purpose is the same. The EA definition of RGP, although slightly different to that of the ONR, achieves the same purpose. To meet the claims and demonstrate RGP is being followed in compliance with the Fundamental Objective of the PER, further work needs to be done as part of the design challenges identified via the Design Management Process [46]. GDA Commitments relevant to the PER are presented in PSR Part B Chapter 11 [79]. Further evidence to develop the environment case of the generic SMR-300 and demonstrate BAT is identified across the PER Chapters.

A detailed compliance analysis of the GDA guidance for RPs against the SMR-300 GDA submission has been undertaken to demonstrate that the information requirements are considered and / or addressed appropriately in the development of the environment case, alongside the safety case. The RSR principles, other written and OPEX, standards, and working practices are considered in the development of environment case, more details are presented in the PER chapters 1 [70], 2 [71], 3 [72], 4 [73], 5 [75] and 6 [76] and BAT demonstration approach report [74].

In the development of the environment case, the RP has continued to identify design challenges and manage these according to the Design Management Process [46]. This includes a robust consideration of RRM options and a categorisation of any design change taking account of safety, security, safeguards and environmental criteria. The management of environmental protection in the design requires consideration of BAT. The RSR-BAT Guidance [60] provides guidance on how BAT has been, and will be, applied proportionally to the generic SMR-300 design. Situations can occur where the approach in the demonstration of BAT will need to integrate ALARP principles to ensure an overall optimised measure in safety and environmental protection performance. The balance of BAT and ALARP is considered appropriately to yield the most practicable option through risk-informed decision-making process. Further discussion on this is provided in sub-chapters 5.5 and 5.7.

On the basis of the information presented, it is considered that by compliance with UK RGP (ACOP, Regulatory Guidance, RSR Principles, OPEX etc.), recommendations fed through the Design Management Process, and appropriate closure of any identified GDA Commitments, supports the argument that the fundamental purpose of the PER has been met as far as possible given the design maturity within GDA.

5.9.2 Conclusion on the Fundamental Objective of the GSR

The Fundamental Objective for the security case is presented in sub-chapter 0. The Fundamental Objective is supported by seven high-level SyC, which are being progressed by the SMR-300 security case as it has evolved from the Preliminary Security Report (PSyR) issued during Step 1, into the GSR at the end of Step 2 and to the Nuclear Site Security Plan (NSSP) beyond GDA timescales. To progress the SyCs, work has been done during GDA Step 2. This includes the development of UK-specific security methodologies for the SMR-300, security studies to trial the methodologies and security-inform the design, and the production of associated documentation. The seven SyCs are decomposed into sub-claims, arguments and evidence (as possible and proportionate with the GDA Reference Design maturity) during GDA Step 2.

The security submissions have drawn upon RGP. In addition to examples of RGP outlined by ONR's TAGs, TIGs, other RGP has been identified through: security submissions from current and previous GDAs, ONR summary reports and feedback on previous GDAs, information and guidance from industry bodies and associations such as the IAEA, National Protective Security Authority (NPSA) and National Cyber Security Centre (NCSC). The security methodologies developed by Holtec during GDA Step 2 have considered RGP identified from UK and international sources in areas such as Vital Area identification, cyber security risk assessment, secure by design and the development of conceptual security arrangements.

RGP from security submissions to international regulators including, for example to the CNSC's Vendor Design Review (VDR) process has been considered. In developing the SMR-300 security case for the UK, Holtec will have drawn upon, and learnt lessons from, the development of security arrangements for the SMR-300 in international markets, including feedback from the US NRC licensing process.

5.9.2.1 Secure by Design

The SMR-300 aims to deliver an inherently secure design by seeking to eliminate or reduce, security vulnerabilities during the design process rather than address these later in the development lifecycle by retrospectively adding protective or mitigative security measures. Hence an approach is adopted for the SMR-300 which aims to eliminate, or minimise, the need for security measures which are costly to install, operate and maintain throughout the lifetime of the plant by building in robustness in the SMR-300 design during the design development stage. The secure by design principle is adopted throughout the lifecycle of the nuclear security case. This approach has been developed and recorded during GDA Step 2.

A secure by design hierarchy of risk control is applied when considering key design decisions or assessing modifications to the plant during the GDA programme and helps guide the design firstly towards 'designing out' security vulnerabilities or otherwise providing passive protection (e.g., plant robustness), in preference to adding active security features such as access control or a response force.

The security by design hierarchy of risk control is illustrated by Figure 9 below:

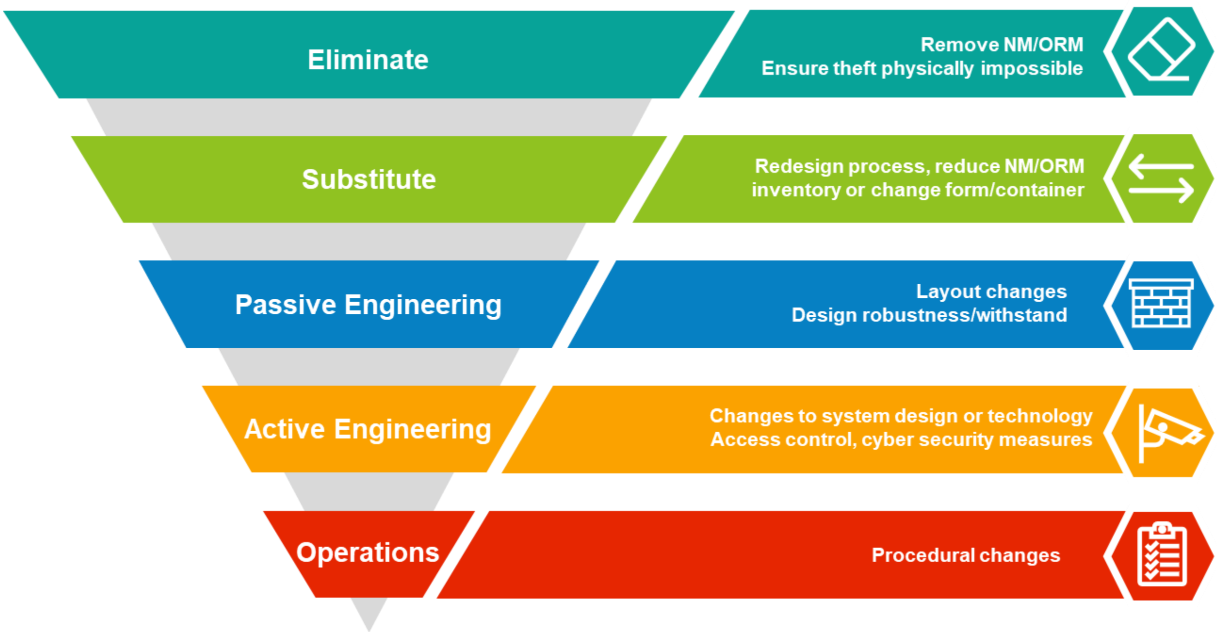

Figure 9: Secure by Design Hierarchy of Risk Controls

This hierarchy recognises that the most effective means of reducing security vulnerability and achieving an inherently secure design are through elimination of vulnerabilities, substitution of processes or through passive engineering. Furthermore, making appropriate design decisions provides for a long-term reduction in the capital and operational costs of providing physical security at the facility because of the reduction in the need for, and reliance on, protective security systems.

The defence in depth principle ensures that the integrated security solution is composed of multiple layers and approaches which together ensure that an adversary would need to overcome several independent barriers to achieve its objective. In line with the above philosophy and principles mentioned, nuclear security for the SMR-300 plant will be delivered via a series of activities, which, taken together, provide a structured, clear, and logical approach to the development of the conceptual security arrangements for the SMR-300.

On the basis of the information presented in the GDA submissions, it is considered that by compliance with UK RGP, secure by design and defence in depth considerations, recommendations fed through the GDA Design Management Process and the Step 2 scope of work have provided confidence that the fundamental purpose of the GSR will be met.

5.9.3 Conclusion on the Fundamental Objective of the PSgR

The generic SMR-300 safeguards case integrates with the SMR-300 SSEC via the SMR-300 Fundamental Purpose. The PSgR supports the safeguards submission in support of Step 1 and Step 2. In Step 1, this document adequately demonstrated Holtec's understanding of the safeguards requirement at the generic (international and UK level) and how they will be accommodated in the generic design of the SMR-300, providing ONR with the confidence that a meaningful assessment of the safeguards topic during Step 2 has been carried out. The SMR-300 GDA Step 2 Preliminary Safeguards Report [41] is an evolution of the Step 1 PSgR to reflect the developments of the design and layout of the SMR-300 and the associated safeguards arrangements, In particular, it presents:

- Holtec's understanding of the safeguards requirement at the generic (international and UK domestic) level and RGP.
- An outline at a high level the SMR-300 safeguards programme, i.e. how the safeguards requirements will be delivered for the SMR-300 through all phases of its lifecycle, and progress in its implementation during Step 2.
- An outline of the SMR-300 safeguards case and the main safeguards claims, showing how these claims integrate with the SMR-300 SSEC, and progress on the development of the safeguards case.
- The basis for the accommodation of safeguards requirement in the generic SMR-300 design, including information on the development of the safeguards design objective, safeguards design principles, and progress in the implementation of safeguards by design.

The overall aim of the Step 2 PSgR is to demonstrate that there are no fundamental safeguards shortfalls that could prevent granting permission for the construction of a power station based on the generic SMR-300 design information, provided for GDA.

To meet the high-level safeguards claims (SgC1 and SgC2) delivered by the SMR-300 safeguards case, further work needs to be done as part of the future work identified. A holistic approach is used in the SMR-300 safeguards programme to deliver SgC1, throughout the SMR-300 project lifecycle. This will involve a combination of design measures, procedural measures, deterrence, nuclear material accounting and reporting, inspection and independent verification which is decomposed into three safeguard sub-claims. The three sub-claims form the basis for the SMR-300 general safeguards design principles as tabulated in Table 3 of the PSgR. The SMR-300 safeguards programme will include reporting arrangements to meet the requirements of AP, as prescribed by the ONR to meet SgC2.

The key ONR safeguards regulatory guidance documents identified in Table 2 of the PSgR Step 2 submission together with the documents identified in Section 4 represent RGP for the delivery of the safeguards requirements in the UK. Specific safeguards RGP for design development, licensing and GDA of new reactors in the UK is currently limited. However, RGP on safeguards during the design development and licensing of a new reactor plant in the UK can be inferred from publicly available ONR safeguards assessment reports for existing nuclear power plants such as Hinkley Point C and previous GDAs such as the Rolls Royce SMR Step 2 safeguards submission as well International RGP and safeguards frameworks.

5.9.3.1 Safeguards by Design

The safeguards by design process makes a significant contribution to the SMR-300 safeguards programme and safeguards case throughout the SMR-300 project lifecycle. Safeguards by design is the process by which it is ensured ‘that safeguards requirements are fully integrated into the design process stages (design, construction, commissioning, operation and decommissioning) and the project management structure from project inception.

International safeguards experience has shown that integrating safeguards into the design process from project inception delivers a cost-effective and efficient safeguards solution. This is in contrast with the traditional approach to considering safeguards retrospectively when the design and layout has been frozen, which in some cases had ‘resulted in costly redesign and project delays and had reduced the efficiency and effectiveness of safeguards implementation’.

The key elements of the generic SMR-300 safeguards by design process is illustrated in Figure 10 below and an overview is given within the PSgR.

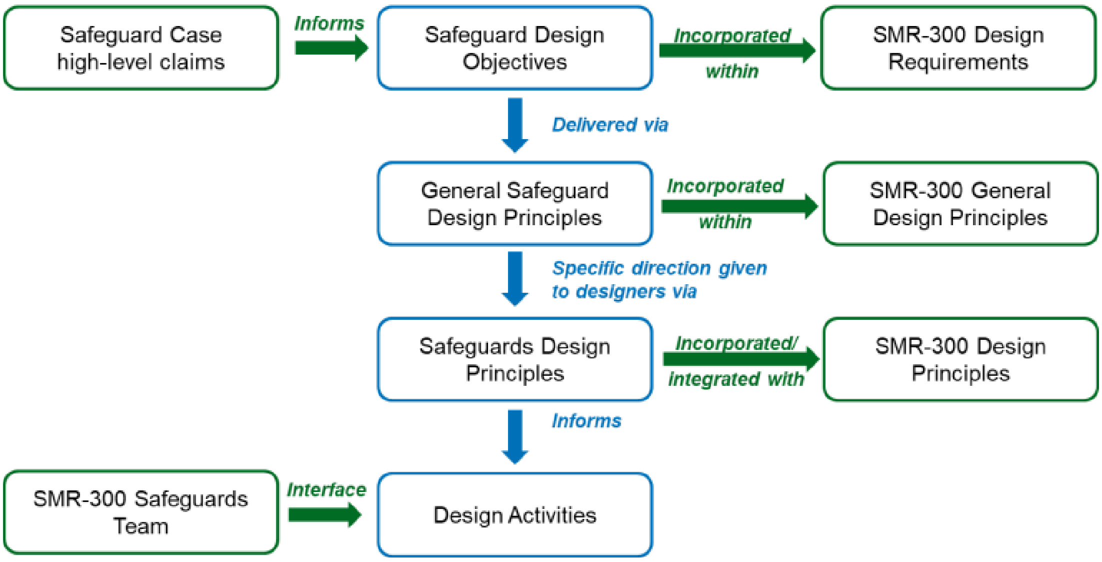

Figure 10: SMR-300 Safeguards by Design Process

A safeguards by design hierarchy of control, adapted from the ONR security hierarchy of control, is used to guide the development of the SMR-300 safeguards by design principles and the subsequent design solutions where appropriate. This is illustrated in Figure 11 below.

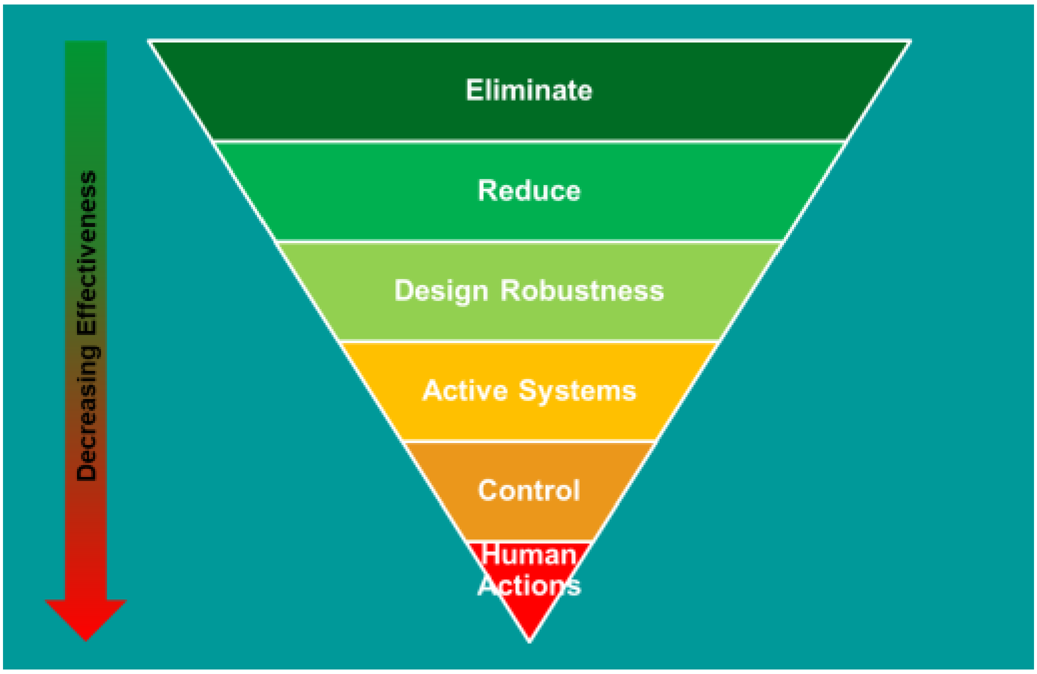

Figure 11: Safeguards by Design Hierarchy of Control

The aims of the SMR-300 Step 2 safeguards submission is to demonstrate to ONR that safeguards by design is being implemented in the evolving generic SMR-300, that safeguards is informing the design and layout, and that the UK safeguards regulatory framework and expectations are being accommodated.

For Safeguards, the Step 2 PgSR and The Safeguards by Design Basic Technical Characteristics Document have been issued in Step 2. In line with the above philosophy and principles mentioned, including an illustration of the key elements of the SMR-300 safeguards programme and the associated regulatory, safeguards by design for the SMR-300 which is the focus of the programme during design development and that a robust safeguards management system and supportive culture are required at all stages of the project lifecycle to ensure a successful cost-effective and efficient delivery.

The SMR-300 safeguards programme starts during design development. International safeguards experience shows that considering safeguards as an integral part of the design process rather than retrospectively offers many benefits to all stakeholders. The key steps of this approach and activities during the SMR-300 design process are outlined within the PgSR. The Step 2 PSgR will evolve into the overarching SMR-300 Safeguards submission for nuclear site licensing in the UK. It is expected that there will be a number of submissions of the overarching Safeguards Report to coincide with the main SSEC development phases and submissions during site specific design and site licensing. On the basis of the information presented, it is considered that by compliance with UK RGP, secure by design and defence in depth considerations, recommendations fed through the Design Management Process and appropriate closure of further work identified will allow the fundamental purpose of the PgSR to be met in the future.

5.10 OVERALL SSEC CONCLUSION ON THE FUNDAMENTAL PURPOSE

The fundamental purpose of the SSEC is repeated here.

SSEC Fundamental Purpose: *To demonstrate that the generic SMR-300 can be constructed, operated, and decommissioned on a generic site in the UK to fulfil the future licensee's legal duties to be safe, secure and protect people and the environment.'*

The SSEC Fundamental Purpose can be achieved as a combination of the PSR Fundamental Objective together with the PER Fundamental Objective, the GSR Fundamental Objective and the PSgR Fundamental Objective.

The SSEC has been written for all stakeholders, which include:

- The RP and its partners.
- The future licensee.
- The public.
- The ONR, the EA and NRW.
- The UK Government.

Other stakeholders will be involved in the future (e.g., local authorities) when a specific site for the generic SMR-300 is chosen.

The future licensee's legal requirements have been considered in the individual SSEC reports. While it is recognised that there are differences between the US and UK legal requirements, particularly in the design and safety report development processes, it is noted that both regulatory regimes are well established and mature and have taken account of (and have influenced) extensive international co-operation on the design of light-water reactors and safety, security, safeguards and environmental protection. As a result, it would be expected that a reactor designed to meet US legal requirements would adopt similar engineering solutions for a given technical problem, hence, it is reasonable to claim that following sound and well-established engineering practice in the US should imply good engineering practice in the UK context.

Nevertheless, some risks exist in meeting UK expectations and therefore the demonstration of the future licensee's legal duties. However, Design Challenges and GDA Commitments have been identified for completion beyond GDA for the individual SSEC reports, so that the PCSR at site-specific stage, will be able to say, with confidence, that they are likely to be met.

Holtec have founded the SMR-300 design on principles for safe operation. The GDA process has contributed to developing what was already a high standard of design in the interests of the people who will operate it, the people who will work on the site and the people who will live near to the eventual UK site. These people and the environment surrounding the generic SMR-300 will benefit from safe, clean energy for 80-plus years.

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5.12 LIST OF APPENDICES

Appendix A PSR Part A Chapter 5 CAE Route Map

Table 9: PSR Part A Chapter 5 CAE Route Map

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Appendix B ALARP Summary Table

Table 10: ALARP Summary Table

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