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17.1 INTRODUCTION

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

The Fundamental Purpose is achieved through the Fundamental Objective of the PSR, which is to summarise 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), Holtec SMR-300 GDA PSR Part A Chapter 2 General Design Aspects and Site Characteristics [2].

Part B Chapter 17 of the PSR presents the Claims, Arguments and intended Evidence (CAE) for the Human Factors (HF) topic of the Generic SMR-300.

17.1.1 Purpose and Scope

The Overarching SSEC Claims are presented in Holtec SMR GDA PSR Part A Chapter 3 Claims, Arguments and Evidence [3].

This chapter (Part B Chapter 17) links to the overarching claim through Claims 2.1 and 2.2. The higher level claims HF supports are as follows:

Claim 2.1: The nuclear safety assessment specifies the requirements for safety measures such that safety functions are fulfilled, informs operational and emergency arrangements and demonstrates that risk is tolerable and ALARP.

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.

Human Actions are implied in Claim 2.1, Claim 2.1.7 captures this aspect and is decomposed further to address identification and assessment of safety related actions.

As set out in Part A Chapter 3 [3], Claim 2.2 is further decomposed across several engineering disciplines which are responsible for development of the design of relevant SSCs. This chapter presents the HF engineering aspects for the generic SMR-300 and therefore directly supports a claim focused on the overall design and architecture of civil structures, Claim 2.2.11.

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.

Claim 2.2.8: Human Factors Relevant Good Practice is integrated into the design, operation and maintenance of the Generic Holtec SMR-300.

Further discussion on how the Level 3 claim is broken down into Level 4 claims and how the Level 4 claims are met is provided in subchapter 17.3.

Seven SSCs are covered this chapter, including:

- Main Control Room (MCR), including Plant Control System (PCS) and Plant Safety System (PSS);
- Remote Shutdown Facility (RSF);
- Technical Support Centre (TSC);
- Emergency Operations Facility (EOF);
- Reactor Systems which require human operation, e.g. Primary Sampling System (PSL);
- Mechanical Handling Systems (Cranes);
- Fuel Handling Systems.

These are those areas judged to have the highest levels of human interaction and/or high consequences associated with claims this on system users. This is not an exhaustive list and based on preliminary reviews carried out by members of the HF team for Step 2.

It is also important to note that HF related issues will impact installation, maintenance and decommissioning of all SSCs. For the most part this will be addressed through the application of RGP and appropriate legislation. HF will provide comment on these as required as fully integrated members of the design and safety assessment teams both in the US and in the UK.

This chapter includes the Codes and Standards associated with HF (subchapter 17.5), Human Factors Integration (subchapter 17.4), Design Substantiation (subchapter 17.6), Human Based Safety Claims (subchapter 17.7) and Operational Philosophy and Concept Of Operations (subchapter 17.8). Finally, a summary of considerations against the ALARP principle is provided, together with any forward actions or commitments that have arisen (subchapter 17.9).

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

17.1.2 Assumptions

No assumptions are identified in this revision.

17.1.3 Interfaces with other SSEC Chapters

Most areas of the SMR-300 design, and associated safety justifications make assumptions relating to system users. These assumptions influence design decisions and safety justification. As such it is important that appropriate input is provided by suitably qualified and experienced

(SQEP) HF professionals to ensure these assumptions can be supported. The use of established Human Factors Integration (HFI) approaches helps to manage interfaces with various disciplines.

HF input is required to demonstrate an appropriate level of analysis of human activities and support delivered by HF professionals along with Holtec SMR GDA PSR Part A Chapter 5 Summary of ALARP [4].

Holtec SMR GDA PSR Part B Chapter 4 Control and Instrumentation Systems [5] requires HF input to demonstrate the interface between system users and equipment has been designed in accordance with Relevant Good Practice (RGP) for user interfaces and is incorporated into the design.

HF input is required to ensure operator activities and working arrangements are reflected in the design of the equipment and workspaces for SMR-300 which relates to Holtec SMR GDA PSR Part B Chapter 9 Conduct of Operations [6].

Holtec SMR GDA PSR Part B Chapter 12 Control of Non-Radiological Hazards [7] requires HF input to support claims placed on system users to reduce risks to ALARP as well as to ensure alignment with the application of HF RGP.

HF input is required in Holtec SMR GDA PSR Part B Chapter 14 Design Basis Accident Analysis [8] to support the identification, analysis and modelling of human failures linked to Human Based Safety Claims (HBSCs), in a risk proportionate manner.

HF input is required for Holtec SMR GDA PSR Part B Chapter 15 BDBA, Severe Accidents Analysis and Emergency Preparedness [9] to support the identification, analysis and modelling of human failures linked to HBSCs, in a risk proportionate manner. This will also take account of the design of associated user interfaces, workspaces and proposed tasks.

HF will advise Holtec SMR GDA PSR Part B Chapter 16 Probabilistic Safety Assessment [10] on RGP for modelling and quantifying human failures.

HF input is required to support the identification, analysis and modelling of human failures linked to HBSCs in a risk proportionate manner in Holtec SMR GDA PSR Part B Chapter 21 External Hazards [11].

HF input is required to support the identification, analysis and modelling of human failures linked to HBSCs in a risk proportionate manner as relates to Holtec SMR GDA PSR Part B Chapter 22 Internal Hazards [12].

HF input is required to demonstrate the suitability of the interface between system users and equipment in Holtec SMR GDA PSR Part B Chapter 19 Mechanical Engineering [13], taking account of workspace requirements, ensuring HF RGP has been incorporated into the design. HF is also required to support Examination, Inspection, Maintenance, and Testing (EIMT).

HF input is required to support Holtec SMR GDA PSR Part B Chapter 6 Electrical Engineering [14] to demonstrate the suitability of workplaces to perform tasks and adequacy of the interface between system users and equipment, including consideration of workspace requirements. Ensuring HF RGP has been incorporated into the design. HF is also required to support EIMT.

HF input is required to demonstrate the suitability of workplaces (including the layout of rooms) to perform tasks and incorporated into the design as detailed in Holtec SMR GDA PSR Part B Chapter 20 Civil Engineering [15]. HF is also required to support EIMT.

HF input is required to identify and assess the risk of human failures linked to reactor chemistry as detailed in Holtec SMR GDA PSR Part B Chapter 23 Reactor Chemistry [16].

HF input into Holtec SMR GDA PSR Part B Chapter 25 Construction and Commissioning [17] will support claims on the achievability of human activities and develop user trials.

HF input will be required in Holtec SMR GDA PSR Part B Chapter 18 Structural Integrity [18] to support decisions relating to the suitability of tasks linked to structural integrity (e.g., inspection), taking account of workspaces equipment design, inspection tasks (including new or novel tasks) and competence requirements. HF is also required to support EIMT.

17.2 HUMAN FACTORS OVERVIEW

A key aspect of the licensing of nuclear facilities is demonstrating RGP relating to the discipline of HF has been applied in a systematic manner. For the SMR-300 GDA it is therefore important a clear basis for establishing the human contribution to safety, security and environment is provided across its lifecycle. This helps to ensure Structures, Systems and Components (SSCs) and overall operational philosophy are cognisance for human performance, thus cognisance of the risk of human failure.

The SMR-300 has been designed in accordance with US Nuclear Regulatory Commission's (NRC) Human Factors Engineering (HFE) process, which is applied to the design of all nuclear facilities in the US. Adherence to this process provides some assurance that factors that may negatively impact on human performance have been identified and systematically addressed throughout the design, which is a key part of providing safety assurance.

It is recognised that due to the cross-cutting nature of HF, early involvement is key to support decision making and the successful delivery of support to the project. PSR activities are therefore treated as an essential step towards HF objectives.

The SMR-300 is based on design work carried out for the proposed SMR-160 design. While the SMR-160's design is relatively mature a number of aspects are currently being revisited for SMR-300. As a result, for this PSR emphasis is placed on demonstrating the suitability of the process for integrating HF RGP rather than substantiating detailed aspects of design prepared in support of SMR-160.

17.3 HUMAN FACTORS CLAIMS, ARGUMENTS AND EVIDENCE

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, which is how the Fundamental Purpose of the Safety, Security and Environmental Case (SSEC) (presented in Chapter A1 [1]) is achieved.

The Fundamental Purpose follows a golden thread throughout the SSEC to CAE via the objectives of the PSR, Preliminary Environmental Report (PER) and Generic Security Report (GSR). The overarching SSEC claims are presented in Part A Chapter 3 [3].

This chapter contributes directly to Claims 2.1 and 2.2, which are focused on the specification of safety measures and operational and emergency arrangements, and a demonstration that the SSCs that form the design, are developed to ensure they meet the relevant safety requirements and appropriate codes and standards.

Claim 2.1: The nuclear safety assessment specifies the requirements for safety measures such that safety functions are fulfilled, informs operational and emergency arrangements and demonstrates that risk is tolerable and ALARP.

As set out in Part A Chapter 3 [3], Claim 2.1 is further decomposed across several disciplines which are responsible for development of the safety analyses. This chapter presents the aspects for the generic SMR-300 and therefore directly supports claims which focus on how HF inputs to the safety analysis via Human Based Safety Claims (HBSCs), Claim 2.1.7.

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.

Claim 2.1.7 has been further decomposed within Part B Chapter 17, across the design lifecycle, to provide confidence that the relevant requirements will be met during all lifecycle phases.

This has been done by breaking Claim 2.1.7 down into the following sub-claims:

Claim 2.1.7.1 Human failures shall be systematically identified using RGP methodologies.

Claim 2.1.7.2 Human Reliability Assessment shall be undertaken to determine the reliability and effective task performance of human actions.

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.

As set out in Part A Chapter 3 [3], Claim 2.2 is further decomposed across several engineering disciplines which are responsible for development of the design of relevant SSCs. This chapter presents those aspects relevant to the generic SMR-300 and therefore directly supports claims which focus on the application of HFE, Claim 2.2.8.

Claim 2.2.8: A systematic approach to human factors is applied throughout the Generic Holtec SMR-300 lifecycle.

Claim 2.2.8 has been further decomposed within Part B Chapter 17, across the design lifecycle, to provide confidence that the relevant requirements will be met during all lifecycle phases.

This has been done by breaking Claim 2.2.8 down into four further sub-claims:

Claim 2.2.8.1 contributes to design by defining the RGP, including codes and standards, against which applied during design and be used to assess the design against.

Claim 2.2.8.2 is important to design, by ensuring that design of Human Machine Interfaces for SSCs are optimized for human performance the through the application of RPG.

Claim 2.2.8.3 contributes to the design by ensuring that requirements linked to HF RGP are appropriately identified and supported by evidence, developed in a risk proportionate manner.

Claim 2.2.8.4 contributes to the Design and Safety Analyses phases by defining the operating philosophy and the staffing levels required to safely operate the SMR-300 reactor.

Table 1 shows in which chapter of this PSR these claims are met.

Table 1: CAE Chapters

Claim No	Claim	Chapter Section
2.2.8.1	Human factors Relevant Good Practice is appropriately integrated into the Generic Holtec SMR-300 lifecycle.	17.4 HUMAN FACTORS INTEGRATION
2.2.8.2	Human Factors design and assessment shall take cognisance of Relevant Good Practice and Operational Experience.	17.5 CODES AND STANDARDS
2.2.8.3	Requirements relevant to Human Factors are identified and substantiated in a risk proportionate manner.	17.6 DESIGN SUBSTANTIATION
2.1.7.1	Human failures shall be systematically identified using Relevant Good Practice methodologies in a risk proportionate manner.	17.7 HUMAN BASED SAFETY CLAIMS
2.1.7.2	Human Reliability Assessment shall be undertaken to determine the reliability and effective task performance of human actions in a risk proportionate manner.	17.7 HUMAN BASED SAFETY CLAIMS
2.2.8.4	Staffing and qualification requirements are systematically assessed and informed by Human Reliability Assessment	17.8 OPERATIONAL PHILOSOPHY AND CONCEPT OF OPERATIONS

A summary of the current CAE route map for Part B Chapter 17 is provided in Appendix A which is taken from the Generic SMR-300 Overarching SSEC claim route map presented in Appendix A of HI-2240334 Part A Chapter 3 ‘Claims, Arguments & Evidence’ [3]. A further update on claim decomposition, argument development and evidence maturity will be provided in the subsequent update of the Chapter.

17.4 HUMAN FACTORS INTEGRATION

Claim 2.1.8.1: Human factors Relevant Good Practice is appropriately integrated into the Generic Holtec SMR-300 lifecycle.

This subchapter describes how is to be applied to the Generic SMR-300 design.

17.4.1 Overview of Human Factors Engineering Process

The HFE process described in NUREG-0711, Human Factors Engineering Program Review Model [19] provides the framework that has been used to integrate HF RGP into the design of the SMR-300. The approach applied has been considered as part of the Step 1 GDA activities. This has involved high-level discussions during a series of informal workshops with the HFE team based in the US, with examples of HFE documentation. This has provided some assurance that a robust process for HF integration is in place in line with NRC requirements, noting that differences between ONR and NRC expectations are recognised. The key aspects considered are discussed in this section.

The cross-cutting nature of HF means that a systematic process is required to ensure support is delivered to all related disciplines at the appropriate stage in a system's lifecycle. This is key to optimising the design of tasks, workspaces and Human System Interfaces (HSI) for human performance. NUREG 0711 [19] provides a process that delivers HF input to design and assessment of systems in a systematic manner.

An overview of the HFE process covering the full life cycle of the design process for SMR-300, based on NUREG 0711 [19] is presented in Figure 1. This was provided by the Holtec International HFE team and is captured in the HPP-160-1014 HFE Programme Management Plan (PMP) [20].

The application of development of these documents provides a process that helps to ensure HF is delivered in a systematic manner, which is a key part of Claim 2.2.8.1.

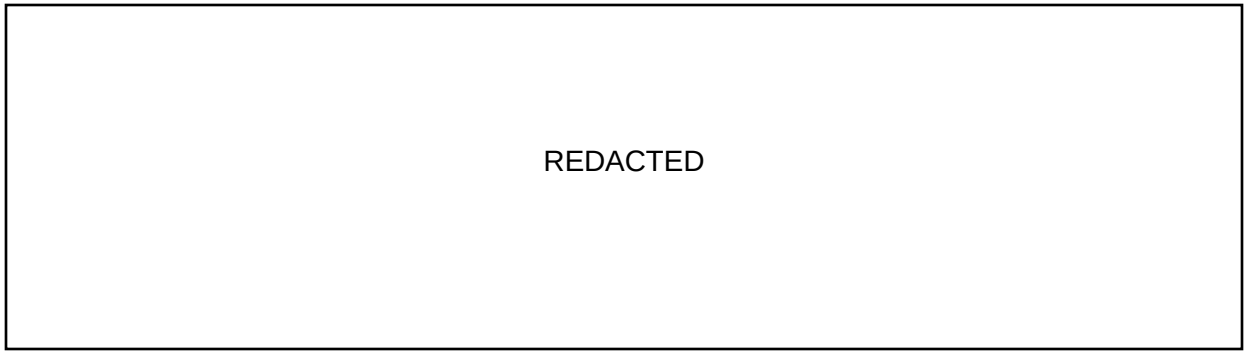

Figure 1: (REDACTED)

The HFE process starts with the development of the HFE PMP [20], which, along with a HF Engineering Integration Road Map [21] provides a framework for the systematic delivery of HFE support. Both documents have been developed for SMR-160 [20] and [21] are expected to be largely unchanged for SMR-300. In the context of the NRC approach to HFE, the PMP [20] and Road Map perform a similar role to a Human Factors Integration Plan (HFIP), which is key to ensuring HF is systematically delivered (see Section 17.5.1.2.1 for further discussion).

The analysis phase begins with a series of Operational Experience Reviews (OERs) which include reviewing sources of information from US nuclear power stations and the World Association of Nuclear Operators (WANO)/Institute of Nuclear Power Operations (INPO) to ensure good practice and lessons learnt from similar facilities are incorporated into the design. Gathering operational experience is a key part of identifying safety related human activities and assessing human reliability, noted in the ONR Safety Assessment Principles for Nuclear Facilities (SAPs) [22] and Technical Assessment Guides (TAGs) (e.g. ONR Technical Assessment Guide (TAG 063 [23]).

Task analysis and Functional Requirements Analysis are then carried out using information from the OERs and associated reference documents including System Design Description (SDD), Piping and Instrumentation Diagram (P&ID), & Control System Description (CSD). This is used to decompose human activities and to assess and present functional requirements in a systematic manner. Information from these reviews feeds into the HSI and workspace design, development of Staffing and Qualification arrangements, procedure development and Treatment of Important Human Actions (TIHAs) as part of ongoing interaction between the HFE team and other disciplines. ONR guidance (e.g. TAG 063 [23])) highlights the importance of gathering information from a range of sources such as these.

NRC HFE processes specify the approach used for task analysis and functional requirements analysis in a manner that is more prescriptive than the ONR, who allow more flexibility to choose the optimal approach for a project to gather this information. However, at a high-level, the approach in NUREG 0711 [19], which the HFE PMP [20] is based on, delivers evidence of this information being gathered and applied in a systematic manner.

(REDACTED)

(REDACTED)

The work conducted for SMR-160 in all of these areas is relatively mature and while many documents will need to be re-assessed for SMR-300, most are expected to remain largely unchanged. A key part of ongoing HF activities will be liaising with the HFE team to identify which material will be available to support GDA.

The HFE approach used for designs in the US is based on RGP, however, it is also recognised that elements of this are not directly applicable to the UK. This includes differences in design conventions, operational environments and user expectations. As such additional steps will be required to demonstrate and incorporate UK RGP. A UK-developed HFIP will be developed for

GDA and subsequent phases to provide a strategy for identifying and incorporating this RGP so that HF integration can be achieved for the SMR-300 within a UK context.

17.4.2 Scope of the Human Factors Engineering Programme Management Plan

A HFE PMP [20] has been issued for SMR-160, The HFE PMP [20] includes the following information:

- HFE program goals and scope.
- HFE team, including member qualifications, and organisation.
- HFE process and procedures.
- HFE issues tracking system.
- HFE technical program elements effectively incorporated into the design of HSI, procedures, and training.

The scope of the SMR-160 HFE program focuses primarily on the MCR and RSF, and the systems that will be operated within these facilities. The MCR HSIs will be developed in line with the activities listed in the HFE program. The RSF HSI will provide the same function as the MCR HSI, as such, the TSC and EOF are also included, however, as they offer only read only access to plant data and have no control functions will receive lower levels of HFE input.

The EOF and TSC will follow guidance in NUREG-0696, Functional Criteria for Emergency Response Facilities [24]. The HSI of the TSC, EOF, and RSF are based on the MCR HSI and comply with the HSI style guide.

The HFE PMP [20] is applicable from the start of the design cycle through completion of initial plant startup test program.

The latest version of the HFE PMP [20], for SMR-160, was issued in January 2023, with activities being carried out in all areas relevant to the current phase (i.e. Operational Experience Reviews, Task Analysis, Functional Requirements Analysis, TIHA and HSI design).

To date OERs, Functional Requirements Analysis (FRAs) and Task Analysis have been carried out for the key systems, the Staffing Goal has been identified with several investigations into the proposed staffing arrangements, TIHAs have been reviewed by the team in the US and so far no IHAs have been identified, and drafts of the HSI are complete to allow simulator set up. A revised version will be issued for SMR-300, although the core activities are expected to remain largely unchanged. HSI Style Guides have also been developed and Human Reliability Assessment (HRA) carried out in support of the Probabilistic Safety Assessment (PSA) and Deterministic Safety Assessment (DSA).

Additional documentation currently under development to support the design process includes:

- Human System Interface Style Guide (safety) [25].
- Human System Interface Style Guide (non-safety) [26].
- HF Engineering Design Implementation Procedure [27]
- HF Engineering Verification and Validation (V&V) Implementation Plan [28].

These documents address activities in the NR-GDA-GD-007 GDA Technical Guidance [29] and Safety Assessment Principles for Nuclear Facilities [22].

Prior to performance of an element, an Implementation Plan (IP) is developed and followed until the element is completed. Results Summary Reports (RSR) are prepared on the completion of these activities and issued to the relevant stakeholders. For the NRC construction application, IPs or RSRs can be submitted. For the operating license application, RSRs must be submitted. Outstanding issues are recorded in a HFE Issues Tracking System (HITS). Those available will be reviewed to determine if associated resolutions will be appropriate for the context.

The scope of the HFE PMP is assumed to not meet all UK requirements but has been reviewed as part of GDA Step 1 and any gaps will be mitigated in the UK GDA HFIP Step 2 deliverable. The UK scope, which is articulated within the GDA HFIP, will consider differences in regulatory expectations between US and UK approaches, and differences in the responsibilities assigned to the HF topic and other safety assurance/design substantiation topics.

17.4.3 The Human Factors Engineering Team

The SMR-160 HFE Team is not a separate organisation or group but is comprised of team members within the disciplines described in the NUREG 0711 [19]. These team members are from other various groups in the SMR-160 design team. They do not directly report to the HFE Team Lead but contribute on an as needed basis and take direction from the HFE Team lead.

The HFE elements are described in the PMP [20]. Each HFE element is executed by team members based on their discipline and qualifications, so the composition of the HFE team for any one element may vary. The team members are selected from other discipline work groups as needed to perform the HFE activities along with their other duties. The generic roles for each HFE element are:

(REDACTED)

(REDACTED)

The I&C Manager is involved in the design of the human system interaction development with MELCO, the I&C development of the system controls, and owner of the HITS database as well as providing oversight of the HFE program.

The HFE PMP [20] provides further detail on the competence requirements. Individuals are required to perform the following roles to implement the HFE PMP [20] activities:

(REDACTED)

These individuals are not required to have qualifications in HF related subjects but are required to have an appropriate understanding of HFE relating to their area of responsibility. Currently Holtec International do not employ staff with HF related qualifications but are considering employing contractor resource with these skills. It is also noted that Holtec Britain and Mott MacDonald have HF professionals, with the required qualifications and experience supporting the GDA process and sharing knowledge and experience.

The role of HF to influence the SMR-300 is recognised as a critical factor to ensure safety and security aspects for the SMR-300. The HFE team will possess sufficient mandate within the project to influence decision making and will be fully integrated into the project lifecycle. The importance of SQEP HF professionals with an understanding of UK context towards achievement of HF objectives is fully recognised, and it is expected that UK HF professionals will make up a significant portion of the integrated HFE team for the SMR-300.

17.4.4 Tracking Human Factors Issues and Assumptions

HFE issues are identified and recorded in the HITS, which is a web-based database available on the SMR-160 SharePoint. Where practical, issues will be addressed immediately, however if the issue cannot be immediately addressed, it will be added to the HITS. This process is equivalent to a Human Factors Issues and Assumptions Register (HFIAR) or a Risks, Assumptions, Issues, Dependencies and Opportunities (RAIDO) register used in the UK. To capture issues relevant to the GDA process a separate project risk register with a dedicated HF section, overseen by the HF team based in the UK has been developed. The output from this will be shared with the Holtec International team.

17.4.5 Claims Arguments Evidence Summary

The application of a robust approach to HFE, that is inline with RGP and ensures the delivery of appropriate design criteria in a systematic manner, is key to Claim 2.2.8.1. The delivery of this is key to all HF related claims. The NRC approach to HFE provides such a methodology and there is evidence of this being applied to the design of Holtec SMR-300. It is recognised that there are some differences in approach between the UK and US (e.g. support for the development of a fault schedule) and that there are some differences in the characteristics of the system users. Therefore, the majority of the HF work in the UK will focus on assessing these differences and demonstrating the suitability of the design for use in the UK in a systematic and risk proportionate manner, which is discussed in the subsequent sections.

17.5 CODES AND STANDARDS

2.2.8.2. Human Factors design and assessment shall take cognisance of Relevant Good Practice and Operational Experience.

This subchapter outlines the UK HF and US HFE guidance applicable to the SMR-300 design. It addresses the following:

- Standards and Guidance used in the SMR-300 Design.
- HF Consideration in Generic Design Assessment.

17.5.1 Standards and Guidance used in the SMR-300 Design

17.5.1.1 United States Nuclear Regulatory Commission Nuclear Regulations

The primary Nuclear Regulations (NUREGs) that relate to HFE considered in the SMR-300 design are captured in Table 2.

Table 2: NUREG's Applicable to Human Factors

Label	Title	Revisions
NUREG 0700.	Human-System Interface Design Review Guidelines [30]	Rev. 3
NUREG 0711.	Human Factors Engineering Program Review Model [19].	Rev. 3
NUREG 0800. Chapter 18.	Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plans: LWR Edition. Human Factors Engineering [31].	Rev. 3
NUREG/CR 01278.	Handbook of Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications [32].	August 1983
NUREG 2199. Vol 1.	Integrated Human Event Analysis System (IDHEAS) [33].	March 2017
NUREG 6400.	Human Factors Engineering Insights for Advanced Reactors Based Upon Operating Experience (NUREG/CR-6400) [34].	January 1997
NUREG-0696.	Functional Criteria for Emergency Response Facilities [10].	Feb. 1981

NUREG 0711 [19] provides a framework for the delivery of HFE and contains the following sections, all of which are being considered in the design of the SMR-300:

- HFE Program Management.
- Operating Experience Review.
- Task Analysis.
- Functional Requirements Analysis and Function Allocation.
- Staffing and qualifications.
- Treatment of Important Human Actions.
- Human System Interface Design.
- Procedure development.
- Training Program Development.
- HF Verification and Validation.
- Design Implementation.
- Human Performance Monitoring.

Compliance with these NUREGs, including a strategy for addressing each of the sections in NUREG 0711 [19] from the early stages of design, is part of the US NRC licensing process. The SMR-300 is being designed in line with this process to allow it to be licensed in the US. The process for integration of HF into the design of SMR-300, including the use of this standard, is discussed further in Section 17.4.

17.5.1.2 Office of Nuclear Regulation Safety Assessment Principles

The UK ONR SAPs [22] provide a framework to assess UK licensees against which includes the application of HF related RGP. All are applicable to the design of the SMR-300 and provide a baseline that has been used to compare the SMR-300 approach to HFE (based on NRC guidance) with the ONR expectations.

17.5.1.2.1 Human Factors Safety Assessment Principles

The ONR SAPs [22] directly linked to HF are listed below:

- EHF01 - Integration within design, assessment and management.
- EHF02 - Allocation of safety actions.
- EHF03 - Identification of actions impacting safety.
- EHF04 - Identification of administrative controls.
- EHF05 - Task analysis.
- EHF06 - Workspace design.
- EHF07 - User interfaces.
- EHF08 - Personnel competence.
- EHF09 - Procedures.
- EHF010 - Human Reliability.
- EHF011 - Staffing Levels.
- EHF012 - Fitness for Duty.

It should be noted that for GDA emphasis will be placed on EHF 01 to 07, 10 and 11. Personnel competence, procedures and Fitness for duty are all important aspects, but will be largely addressed through the PSR Chapter B12 [7], with HF input provided as necessary.

17.5.1.2.2 Safety Assessment Principles related to Human Factors

The following section summarises related SAPs [22] from other disciplines, highlighting where further engagement with HF will be required.

Engineering Principles – Safety Measures and Safety Functions

Analysis of activities supporting safety functions and safety measures, including the use of task analysis to assess associated human activities and processes to identify and substantiate human claims (EHF 1 to 5) is an important consideration for the definition and substantiation of safety functions and safety measures. The process for deriving and substantiating Safety Functions (EKP 4) and Safety Measures (EKP 5) will therefore consider the associated HF SAPs [22].

Reliability Claims

Analysis and substantiation of the human activities linked to safety measures must be carried out in accordance with related HF SAPs [22] including EHF 1 to 5. This is linked to SAPs [22] for Engineered Safety Measures (ERL 3) and use of automatic initiation (ESS 8). Again, the approach used by the design teams to demonstrate the applicability of these processes will take this guidance into account.

Layout

The layout of workspaces will be key to the successful completion of safety significant tasks. The analysis of these activities needs to be developed using a task focused approach and be compliant with RGP for workspace design. As such EHF 5 and 6 considered when determining the suitability of the workspace layout and available Access (ELO 1), which is also linked to HF input to EIMT. Both of these are issues that are also considered by nuclear site health and safety, fire safety and Mechanical Teams.

Safety classification and standards

There will be safety functions delivered or supported by human actions. These human actions must be identified and classified on the basis of those functions and their significance to safety, taking account of EHF 01 to 05. These SAPs [22] are directly linked to Safety classification of SSCs (ECS 2).

Safety Systems

Assumptions relating to safety must be supported by appropriate levels of analysis, including the Allocation of Function and user interfaces design. This includes links to EHF 01 to 05 to identify and assess those tasks with safety related implications and 07 to consider good practice in user interface design. These SAPs [22] support the following:

- ESS. 3. Monitoring of Plant Safety.
- ESS. 8. Automatic Initiation.
- ESS. 9. Time for human intervention.
- ESS. 11. Demonstration of adequacy.
- ESS. 13. Confirmation to operating personnel.
- ESS. 26. Maintenance and testing.

Engineering Principles: control and instrumentation of safety related systems.

Application of appropriate guidance relating to the design of user interfaces captured in EHF 07 and guidance for assessing safety related tasks must be considered in the following:

- ESR. 1. Provision in control rooms and other locations.
- ESR. 4. Minimum operational equipment.
- ESR. 7. Communications systems.

Fault Analysis

Human actions captured in fault sequences must be identified, assessed, defined and fully substantiated in line with RGP captured in SAPs EHF 1 to 5 [22]. This is applicable to defining and representing the following:

- FA.5. Initiating faults.
- FA 6. Fault Sequences.
- FA 13. Adequate representation (human errors that lead to initiating faults).

Leadership and Management for Safety

Organisational factors have historical basis as playing a key role the delivery of safety across the system lifecycle. HF provides significant contribution to these aspects, and more recent formal definitions of HF extend to Human and Organisational Factors (HOF) to acknowledge this contribution. This is applicable to the following:

- MS.1: Leadership.
- MS.2: Capable Organisation.
- MS.3: Decision Making.
- MS.4: Learning from Experience.

Assurance of Validity of data and models

Quantitative data used to support the development of PSA must be demonstrated to be applicable to the UK, which is linked to SAPs [22] relating to the use of data (AV. 3).

17.5.1.1 Office of Nuclear Regulation Security Assessment Guides

The role of HF in supporting security is also considered important. The ONR Fundamental Security Assessment Principles (FSyPs) refer to ensuring the design of security systems are optimised for human performance through the use of HF RGP. The FSyPs relevant to HF for GDA are listed below:

FSyP 3 Management of Human Performance

- FSyP 3.1. Identification and Analysis of Security Tasks and Roles
- FSyP 3.2. Sufficiency and Competence of Persons Delivering Security
- FSyP 3.3. Suitability and Sufficient Workspaces, Equipment and user interfaces
- FSyP 3.4. Suitable and Sufficient Procedures and Administrative Controls

17.5.1.1 Environment Agency Engineering: generic developed principles

The Environment Agency (EA) Engineering Generic Developed Principles also recommend the application of HF RGP in design. As with security HF RGP can be used to inform a number of aspects of EA guidance however Engineering Design Principle (ENDP) 5 specifically refers to consideration of HF and is considered to be the most relevant to GDA.

17.5.1.2 Office of Nuclear Regulation Inspections Guides

The following ONR technical inspection guides that are directly applicable to HF have also been considered:

Table 3: Office of Nuclear Regulation Technical Assessment Guides directly relevant to Human Factors

Label	Title	Revisions
NS-TAST-GD-058	Human Factors Integration [35].	Issue 5.2
NS-TAST-GD-059	Human Machine Interface (HMI) [36]	Issue 5.2
NS-TAST-GD-060	Procedure Design and Administrative Controls [37].	Issue 5
NS-TAST-GD-061	Staffing Levels and Task Organisation [38]	Issue 5
NS-TAST-GD-062	Workplaces and Work Environment [39].	Issue 4.2
NS-TAST-GD-063	Human Reliability Analysis [23].	Issue 6
NS-TAST-GD-064	Allocation of Function between Human and Engineered Systems [40].	Issue 5
NS-TAST-GD-065	Function and Content of the Nuclear Baseline [41]	Issue 5

Table 4: Office of Nuclear Regulation Technical Assessment Guides related to Human

Label	Title	Revisions
NS-TAST-GD-005	Guidance on the demonstration of ALARP [42].	Issue 11.2
NS-TAST-GD-027	Training and assuring personnel competence [43].	Issue 7
NS-TAST-GD-046	Computer Based Safety Systems [44].	Issue 7
NS-TAST-GD-093	Guidance for undertaking Leadership and Management for Safety Reviews [45].	Issue 2
NS-TAST-GD-103	Emergency Power Generation [46].	Issue 1.1
NS-TAST-GD-107	Safety Leadership [47].	Issue 1.2

Appendix B presents the initial comparison of the RGP used in the UK and that used in the US carried out in the early stages to GDA Step 1 to highlight significant gaps. This has helped to demonstrate that the processes are largely aligned at a high-level, covering similar aspects of HF at a similar level of detail.

17.5.1.3 Relevant Engineering Guidance

17.5.1.3.1 Design of Control Rooms and Associated User Interfaces

Demonstrating the application of RGP, such as that captured in British Standards and other related guidance is a key part of developing the safety case for the facility. In the UK the following provide good practice approach for designing control rooms and associated user interfaces.

Table 5: Engineering Guidance Relevant to SMR-300 Human System Interface Design

Label	Title	Revisions
BS EN IEC 60964:2019	Nuclear power plants. Control rooms. Design [48].	2019
BS EN 60965: 2016	Nuclear power plants. Control rooms. Supplementary control room for reactor shutdown without access to the main control room [49].	2016
BS EN 61227:2016	Nuclear power plants. Control rooms. Operator controls [50].	2016
BS EN 61839:2014	Nuclear power plants. Design of control rooms. Functional analysis and assignment [51].	2014
BS EN 62241:2015	Nuclear power plants. Main control room. Alarm functions and presentation [52].	2015
BS IEC 62954:2019	Nuclear power plants. Control rooms. Requirements for emergency response facilities [53].	2019
BS EN IEC 62646:2019	Nuclear power plants. Control rooms. Computer-based procedures [54].	2019
EEMUA 191	Alarm systems – A guide to design, management and procurement [55].	2013
EEMUA 201	Control Rooms: A Guide to their specification, design, commissioning and operation [56].	2019

The NRC provide prescriptive guidance for the design of control rooms and user interfaces in NUREG 0700 [30], applicable to all US nuclear facilities. This provides comprehensive design criteria, however, should UK specific criteria need to be referred to, this guidance will be considered (noting that this level of detail is not anticipated for Step 1 GDA).

17.5.1.3.2 General Human Factors Guidance

The following documents provide HF related guidance applicable to all industries in the UK. Some of these are also referred to in NUREG 0700 [30], which the SMR-300 is based on and as such the associated criteria will be directly applicable.

Table 6: Engineering Guidance Relevant to Human Factors

Label	Title	Revisions
BS EN ISO 9241- (All Parts).	Ergonomics of human-system interaction [57].	N/A
BS EN ISO 11064 (All Parts).	Ergonomic design of control centres [58].	N/A
BS EN ISO 6385.	Ergonomic principles in the design of work systems [59].	2016
ISO/TS 18152.	Ergonomics of human-system interaction — Specification for the process assessment of human-system issues [60].	2010
CDM Regulations	The Construction (Design and Management) Regulations 2015 [61]	2015

17.5.2 Human Factors Consideration in Generic Design Assessment

ONR technical guidance for GDA [29] recognises the importance of an established framework for HFI and includes advice based on lessons learnt from previous GDAs. This also highlights the need for the operational philosophy to be justified as well as ensuring Human Based Safety Claims (HBSCs) are identified and assessed.

The GDA Technical Guidance [29] and previous GDAs have also been reviewed as part of the Step 1 activities. Those areas that were considered relevant to the SMR-300 GDA are listed below:

- Development of a HFIP and HFI guidance documents, the need for early input to ensure a balanced design is also recognised. For SMR-300 has been managed through the HFE PMP [20].
- An operational philosophy and justification of the Allocation of Function are required. This has already formed a key part of the work carried out on the SMR-160 design, which includes reduced staffing levels both in the MCR and on plant. The operational experience and functional allocation reviews consider these aspects.
- Task and error analysis reports must be available. Task analysis is part of the HFE process and is used to inform design decisions. The level of detail available for GDA will be dependent on safety significance and the maturity of the design. NUREG 0711 [19] requires this to be completed for licensing. Where available and where appropriate, data from these reviews will be used to support GDA.
- The PSA also includes human error analysis to derive HEPs for Pre (Type A) and Post (Type C) initiators as well as HEPs that occur during normal operations (Type B). These have been developed in accordance with good practice outlined in NUREGs.
- Fault Schedules capturing HBSCs are also recognised as being an important part of the safety justification. The NRC HFE process requires the identification of IHAs. While these are not directly equivalent to HBSCs (or at least derived in a different manner), they perform a similar function (i.e., define actions important to safety) linking safety functions, safety measures and human actions. This will include the consideration of the ability of the operator to take appropriate and timely action.

- Consideration of operational experience from the US and internal sources of information as part of the OERs, along with input from subject matter experts will help to ensure a sound understanding of operational processes linked fault scenarios and the associated implications for nuclear safety.
- Design Aspects relating to a range of plant SSCs have also been considered and are informed by RGP primarily in NUREG 0700 [30]. Evidence of this will be used to explicitly justify why the design meets the requirements of the assessment in appropriate design substantiation documentation (e.g., RSRs).

All of these aspects of the SMR-300 design will be considered in conjunction with the relevant disciplines leads from other areas to ensure consistency.

17.5.3 Claims Arguments Evidence Summary

The SMR-300 design and assessment has been undertaken using good practice nuclear industry codes and standards and RGP from recent UK GDA submissions. These codes and standards include guidance and expectations from the USNRC, as well as consideration of ONR expectations and British Standards. This is a key aspect of Claim 2.2.8.2.

Differences between the US and UK guidance are recognised, Section 17.6 discusses the steps taken to demonstrate its applicability to the UK in a risk proportionate manner (Claim 2.2.8.3). Section 17.4 discusses how this guidance will be delivered (Claim 2.2.8.1)

Advice based on lessons learnt from previous GDAs has also been taken into consideration.

17.6 DESIGN SUBSTANTIATION

Claim 2.2.8.3: Requirements relevant to Human Factors are identified and substantiated in a risk proportionate manner.

This subchapter describes the approach for delivery of HF RGP to the design of SMR-300 and associated approach for design substantiation. This includes the design criteria relating to HF and how it is used to demonstrate the suitability of the HSI and workspaces.

17.6.1 Allocation of Function Review

A review of AoF processes applied to the US-based HFE programme is being undertaken by Holtec International. In addition to this review sampled assessment will be carried out using UK-derived criteria for Step 2. This information will provide evidence that the SMR 300 design does not place undue reliance on the human, and that safety functions are delivered optimally using human-automation teamwork. This will consider a range of modes and contexts. The sampled assessment of functions will consider both risk significance (to nuclear safety, security and environmental protection), novelty, and the potential for design decisions on functions to be finalised by design maturity.

The SMR-300 will have some novel aspects associated with it, including a greater reliance on passive safety systems and digital control systems, as well as changes in the design and location of plant, when compared to traditional nuclear power plants. This is already being considered by the Holtec International team and will be considered for the UK context.

17.6.2 Review of HF-Related Design Decisions

Design decision papers have been produced in the US to document significant design decisions. These will be reviewed to provide comment on any that have potential issues that may significantly impact on human performance, thus helping to ensure designs support credible expectations on operators, are aligned with RGP, and managed in accordance with the ALARP principle.

17.6.3 Target Audience Description

A Target Audience Description (TAD) will be produced to provide a summary of the working population for the SMR-300 in the UK. This will provide a point of reference for the project and a baseline to compare any guidance based on a US specific population against. If significant gaps are identified, they will be addressed or provided with an action plan for resolution in early detailed design.

There is no requirement to produce a TAD as part of the NRC NUREG 0711 [19]. This is a relatively minor gap as the SMR-160 style guides are based on prescriptive criteria derived from US PWR working populations. Also, a more thorough analysis of staffing and qualification requirements is required at a later stage as part of HFE PMP [20].

17.6.4 Design Basis Review

Style guides and design guidance reports have been produced for SMR-160 based on US design criteria and are currently being used to inform design decisions made by the Holtec design team based in the US. Differences with UK context are expected to include specific design conventions, such as design stereotypes applied to the US populations, as well as the way delivery of HF support is provided. For the most part these differences are assumed to be minor but could have potential to impact on design decisions both inside and outside the MCR, particularly assumptions made for EIMT. This will be considered for the UK context early in the subsequent project phases which will be defined in the GDA HFIP, which will be available for PSR Version 1.

The design basis report will include a review of the approach to designing Human System Interfaces (HSIs) and workspaces, including a review of design criteria to provide evidence that RGP for workspaces and human system interfaces has been applied in design and factors with potential to impact on human performance are adequately managed. This will include the criteria in relevant style guides and guidance reports.

17.6.5 Claims Arguments Evidence Summary

The NRC approach to HFE is recognised as RGP, which is key to claim 2.2.8.3. The differences between approaches used in the US and those used in the UK has been noted in Section 17.5. A review of the proposed design and decisions made relating to the role of the operator will be carried out to demonstrate RGP for design has been considered in a risk proportionate manner with appropriate evidence.

17.7 HUMAN BASED SAFETY CLAIMS

Claim 2.1.7.1. Human failures shall be systematically identified using Relevant Good Practice methodologies in a risk proportionate manner.

Claim 2.1.7.2. Human Reliability Assessment shall be undertaken to determine the reliability and effective task performance of human actions in a risk proportionate manner.

This subchapter outlines the approach to HRA to be used for the Generic SMR-300 Reactor. It considers:

- HRA Strategy.
- HRA methodology.
- Summary of Operator Claims.
- HRA Position Statement.

17.7.1 Human Reliability Assessment Strategy

The HRA strategy will set out the plan to validate existing Holtec International HRA work. To provide the capability (through development of processes and methods) to identify and assess emergent issues during GDA scope and beyond, including the selection of qualitative and quantitative methods. As an activity that interfaces with a variety of HF sub-topics, the strategy will be produced and presented as part of the overall HFIP. The HRA strategy will be supported by a gap analysis between US and UK expectations for HRA, in terms of qualitative and quantitative processes.

Available evidence from the US-based HFE programme is expected to include HRA methodologies, Operational Experience Reviews, Functional Requirements Analysis, Task Analysis and TIHA.

17.7.2 Human Reliability Assessment Methodology

A methodology document will be produced for UK-based HF assessors to provide consistent guidance on the validation of US-based evidence, generation of supplementary evidence to align with UK context, and where necessary, the process to undertake new analysis. The methodology will aim to ensure that assessments are reflective of a single, unified approach to qualitative and quantitative assessment, and therefore will aim to positively influence the UK programme.

17.7.3 Human Reliability Assessment Summary of Claims

All operator claims that have been identified will be presented in a summary document as evidence for PSR Version 1, which will eventually form the basis for an Operational Schedule to manage claims over the lifetime of the SMR-300. The summary document will provide relevant information for each operator claim including the type, class, faults/hazards in which actions are claimed, level of substantiation and associated HEPs.

It is not anticipated that any HEPs will be developed in support of the PSR (Version 0 or 1), however HEPs have been developed in support of the SMR-160 PSA to inform the PSR. It is recognised that the error quantification methodologies used in the US are not validated for use in the UK, therefore the HRA methodology will produce a strategy for the use and modelling of operator actions.

17.7.4 Human Reliability Assessment Generic Design Assessment Position Statement

The HRA programme in support of PSR will be summarised in a position statement available for PSR Version 1, which will demonstrate that significant risks (operator claims) have been identified. It will also show that the human contribution to risk is understood and that the necessary strategies and processes have been developed to support identification and assessment of claims. This will be performed in support of the PCSR delivery and will be dependent on the maturity of evidence from other areas.

17.7.5 Claims, Arguments, Evidence Summary

The methodology for identifying and assessing safety related claims placed on operators is being delivered in a systematic manner in line with established methodologies used in the US. This will be informed by safety case activities to ensure the HF support is risk proportionate. This is a key part of Claims 2.1.7.1 and 2.1.7.2.

17.8 OPERATIONAL PHILOSOPHY AND CONCEPT OF OPERATIONS

Claim 2.2.8.4: Staffing and qualification requirements are systematically assessed and informed by Human Reliability Assessment

This subchapter discusses the proposed operational philosophy to be used for the SMR-300 Reactor and considerations for GDA. It includes discussion on:

- Operational Philosophy.
- Concept of Operations.
- Main Control Room Staffing Levels.
- Staffing and Qualifications Review.
- Target Audience Description.

17.8.1 Operational Philosophy

The operational philosophy for SMR-300 includes a number of novel aspects, not just for power stations in the UK but also in the US. This includes the use of software-based systems and a greater reliance on automated safety systems. Both features could influence human performance and subsequently the risk of human failure, as such they require further analysis. Currently there is work conducted in the US, (REDACTED), to investigate the user needs of software-based user interfaces. The use of this type of interface will be considered by the HF team for PSR Version 1 and will require further consideration of this work.

The functional allocation reviews have also investigated the overall operational philosophy for different scenarios. However, this is captured in multiple documents which will need to be reviewed as part of subsequent input and consolidated to provide comment for GDA.

For PSR Revision 1, the Operational Philosophy for SMR-300 will be summarized to provide that proposed arrangements support a fundamentally safe design.

17.8.2 Concept of Operations

A Concept of Operations (Con Ops) report is listed as a deliverable in the HFE PMP [20], this will address the following six topics:

- Plant Goals (or Missions).
- Agents' Roles and Responsibilities.
- Staffing, Qualifications, and Training.
- Management of Normal Operations.
- Management of Off-normal Conditions and Emergencies.
- Management of Maintenance and Modifications.

This will be produced at a later stage in the design process for SMR-300, after GDA. Information that would be contained in such a document is available in other documentation, but in the UK,

there is an expectation by the ONR a Con Ops or equivalent document will be produced early in the design to inform design decisions. As a result, there will need to be a review of this associated documentation, and work that has been conducted so far in support of the Con Ops. This will be investigated further as part of activities in support of PSR 1 and will determine where this information is available and how it will be used to support the design. This will include the design team examining how new or novel aspects of the design.

17.8.3 Main Control Room Staffing Levels

(REDACTED)

(REDACTED)

Justifying the staffing levels for the full range of activities, including abnormal and emergency scenarios, is an important consideration in the proposed operating philosophy and forms a key part of the assumptions for the allocation of function reviews. In the event of the MCR is unavailable, there will be a remote shutdown facility (RSF) that contains all the required controls to shutdown and maintain safe shutdown of the reactor. The TSC and EOF provide technical support to the operations crew not to control the plant.

Studies have already been conducted to justify these staffing levels, however, the final justification for this will not be completed before the end of GDA. As a result, the justification on which the operational philosophy is based will need to be reviewed along with the proposed activities to be performed as part of GDA Step 2, making use of existing documentation, to ensure they provide adequate levels of justification for use in the UK.

Staffing levels are also an important part of design, to ensure workspaces are sized appropriately, before finalising the design. The basic layout of the MCR has been considered by the HFE team as part of GDA Step 1. The ‘footprint’ of the MCR has yet to be finalised, however, the proposed space for SMR-160, which will be staffed by 1 RO and 1 SRO does not meet the requirements (minimum of 11m^3 per person). Staffing levels remain the same for SMR-300, the space has been doubled, allowing for staffing levels to be doubled (i.e., 1 RO and 1 SRO for each unit). The design decisions linked to this are currently being informed by the HFE team.

17.8.4 Staffing and Qualifications Review

The SMR-160 HFE program includes a staffing and qualification analysis, the purpose of which is to determine the required number and necessary qualifications of personnel to complete tasks allocated to people, while meeting all regulations. The staffing analysis includes the full range of plant operating modes such as startup, normal operations, shutdown, abnormal conditions, and emergency conditions. The scope of personnel included in the evaluation is limited to licensed control room operators. The NRC do not require detailed analysis of other staff until later in the development of the facility. The requirements for non-licenced operators are provided in NUREG 0800 Chapter 13 [31].

The basis for this review will also be discussed further in PSR Version 1.

17.8.5 Claims Arguments Evidence Summary

The operational philosophy and proposed staffing levels are a key part of Claim 2.2.8.4. This is being considered by the US based HFE team and the UK based HF team as part of the HFE activities performed for SMR-300. The status of this will be considered by the HF team for GDA, including the systematic nature and suitability for the UK context.

17.9 CHAPTER SUMMARY AND CONTRIBUTION TO ALARP

This sub-chapter summarises the HF contribution to the PSR and how HF contributes to the overall demonstration of ALARP for the generic SMR-300. Part A Chapter 5 [4] sets out the overall approach for demonstration of ALARP and how contributions from individual Chapters are consolidated.

This subchapter provides a summary of the following elements:

- Technical Summary.
- ALARP Summary.
    - Review against Relevant RGP.
    - Demonstration Against Risk Targets (evaluation of risk).
    - Risk Reduction Options.
    - GDA Commitments and Forward Actions.
- Conclusion.

17.9.1 Technical Summary

PSR Chapter B Part 17, Revision 0 demonstrates that the assessment within the scope of this report will meet the high-level Claims of the SSEC and that the SSC have been appropriate considered for the Pre-Construction Safety Report (PCSR) stage. This is demonstrated through the following sub-claims:

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.

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

- Demonstration that the process for HFE applied to the SMR-300 is aligned with ONR expectations for HF integration in the UK.
- Demonstration of the extent to which guidance applied to the design of the SMR-300 in the US is applicable to the UK, with significant differences assessed to ensure that the design is proven to be fundamentally safe for the UK context.
- Demonstration that the Operational Philosophy and proposed staffing levels are feasible and broadly suitable (i.e. that no significant issues are identified) and that there are on-going activities to assess this in a systematic manner as the design develops.
- Demonstration that the processes for identifying and assessing HBSCs is systematic, comprehensive, and appropriate for the UK context.
- Developed a broad understanding of the human-risk contribution to the SMR-300 and determine an action plan to mitigate key risks prior to finalising the design.

17.9.2 ALARP Summary

17.9.2.1 Demonstration of Relevant Good Practice

The RGP considered in the design of the SMR-300 has been compared with the RGP used in the design of UK nuclear facilities along with previous HF work for GDAs. The approach to HFE used for the SMR-300 is closely aligned, which means the associated HF analyses is relevant for the use of the Generic SMR-300 in the UK, subject to approval from the UK based HF team. Many of these documents will require additional input to provide UK context, however, a significant amount the analysis required to support ONR HF expectations has already being performed in the US.

The Step 1 activities have focused on RGP, with some consideration of potential risk linked to novel aspects of the design. The delivery of HF support to the design of the SSCs and working arrangements for SMR-300 is based on the HFE approach defined in NUREG 0711 [19] and associated documents, which are considered to be RGP. The activities listed in the Holtec SMR-160 HFE PMP [20], along with HRA documentation, style guides and design guidance demonstrate that this is being applied. There are differences between the HFE approach used in the UK and that used in the US, however, both processes are based on similar concepts with the same overall objective of optimising designs for human performance through the application of RGP.

There are some novel aspects to the operation of the SMR-300 which could increase the risk of human failures. It is noted that many of these are not unique to the UK and analysis has already been carried out of has been proposed, in the US to support the case for the SMR-300. This will be examined during subsequent phases of the project lifecycle and will involve targeted reviews of this documentation to further support GDA.

Provided the associated differences are clearly defined and any gaps managed, the approach used is considered to be good practice and additional effort required to ensure alignment is considered to reduce risk in line with the ALARP principle.

17.9.2.2 Demonstration Against Risk Targets

The numerical targets against which the demonstration of ALARP is considered can be found in PSR Part A Chapter 2 [2]. SSCs associated with HBSCs will contribute to the demonstration of ALARP by comparison against the risk targets in two ways:

- By fulfilling safety functions for normal operations (e.g., reduction of normal operation dose uptake by minimising the time operators spend in high dose rate areas), and thereby contributing to achieving Targets 1-3;
- By achieving the target value linked to the associated HBSC they will contribute to the achievement of accident risk, Targets 4-9.

Risks below the Basic Safety Objectives (BSOs) are considered broadly acceptable, , however, consideration will be given to reducing risks in a proportionate manner where appropriate. Risks between the BSOs and Basic Safety Levels (BSLs) require a consideration of risk reduction options. Risks above the BSLs are not acceptable.

It should be noted that numerical targets have not been assessed for PSR Revision 1.

17.9.2.2.1 Evaluation of Risk

Evaluation of risk is captured in Part B Chapter 16 [10]. Human Reliability Analysis and error quantification will be required for the PSA to calculate HEPs that will form part of the overall comparison against the risk targets.

At this time, the evaluation of the normal operations and accident risks against Targets 1-9 has not been provided. This information will be presented in Holtec SMR GDA PSR Part B Chapter 10 Radiological Protection [62] for normal operations, and PSR Chapters B14 [8], B15 [9] B16 [10] for accident conditions.

17.9.2.3 Risk Reduction Options

Position Papers and Design Decision Papers linked to HF will be identified and reviewed with a view to demonstrate which option(s) is/are ALARP.

This will summarise those option evaluations, and it will briefly explore if other risk reduction options have or could be considered and either:

- Present the ALARP argument for why those options have not been implemented.
- Present the ALARP argument for why those options will be implemented in future.
- Create a Forward Action to consider the option(s) at some future point (noting this still must be a point where a meaningful design improvement could be made).

The process for the assessment of risk reduction options is presented in HPP-3295-0017-R0, Holtec SMR-300 Generic Design Assessment Reference Design Process and GDA Prospective Design Change Register [63]. Part A Chapter 5 of this PSR ‘ALARP Summary’ [4] considers the holistic risk-reduction process for the Generic SMR-300.

17.9.2.4 GDA Commitments and Forward Actions

There are no GDA commitments identified for Chapter B17.

Forward Actions have been collated and are managed via the process described in Hotec SMR GDA PSR Part A Chapter 4 Lifecycle Management of Safety and Quality Assurance (MSQA) [64]. PSR Chapter A5 ‘ALARP Summary’ [4] describes the contribution of the forward actions to the ALARP argument.

17.9.3 Conclusion

The Claims identified in this chapter have been sufficient met for the maturity of the preliminary safety report. Further claims, arguments and evidence will be presented in due course as the design develops.

The SMR-300 HFE programme includes the design and evaluation for the SMR-300 the design.

The AoF and HRA will take credit for work carried out as part of the Holtec International processes, that have been developed in accordance with NRC expectations. This will establish processes to identify new/modified functions, and to feed back HRA outputs back into AoF. This will also provide information to demonstrate sequences of operator actions claimed against risk significant faults are achievable and represent optimal allocation.

Chapter A5 of this PSR [4] will provide a demonstration that the Generic SMR-300 reduces risks to ALARP and that the Fundamental Purpose of the SSEC has been fulfilled.

Gaps associated with HF that have been identified as part of this review, are summarized and a forward action plan created. The delivery of the forward action plan will address the gaps identified.

17.10 REFERENCES

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[2] “Holtec Britain, "HI-2240333, Holtec SMR GDA PSR Part A Chapter 2 General Design Aspects and Site Characteristics," Revision 0, August 2024”.

[3] “Holtec Britain, "HI-2240334, Holtec SMR GDA PSR Part A Chapter 3 Claims, Arguments and Evidence," Revision 0, August 2024”.

[4] Holtec Britain, "HI-2240336, Holtec SMR GDA PSR Part A Chapter 5 Summary of ALARP," Revision 0, August 2024.

[5] Holtec Britain, "HI-2240338, Holtec SMR GDA PSR Part B Chapter 4 Control and Instrumentation Systems," Revision 0, August 2024.

[6] “Holtec Britain, "HI-2240340, Holtec SMR GDA PSR Part B Chapter 9 Conduct of Operations," Revision 0, August 2024”.

[7] Holtec Britain, "HI-2240343, Holtec SMR GDA PSR Part B Chapter 12 Control of Non-Radiological Hazards," Revision 0, August 2024.

[8] Holtec Britain, "HI-2240345, Holtec SMR GDA PSR Part B Chapter 14 Design Basis Accident Analysis," Revision 0, August 2024.

[9] Holtec Britain, "HI-2240346, Holtec SMR GDA PSR Part B Chapter 15 BDBA, Severe Accidents Analysis and Emergency Preparedness," Revision 0, August 2024.

[10] Holtec Britain, "HI-2240347, Holtec SMR GDA PSR Part B Chapter 16 Probabilistic Safety Assessment," Revision 0, August 2024.

[11] Holtec Britain, "HI-2240350, Holtec SMR GDA PSR Part B Chapter 21 External Hazards," Revision 0, August 2024.

[12] Holtec Britain, "HI-2240351, Holtec SMR GDA PSR Part B Chapter 22 Internal Hazards," Revision 0, August 2024.

[13] Holtec Britain, "HI-2240356, Holtec SMR GDA PSR Part B Chapter 19 Mechanical Engineering," Revision 0, August 2024.

[14] Holtec Britain, "HI-2240339, Holtec SMR GDA PSR Part B Chapter 6 Electrical Engineering," Revision 0, August 2024.

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[17] Holtec Britain, "HI-2240354, Holtec SMR GDA PSR Part B Chapter 25 Construction and Commissioning," Revision 0, August 2024.

[18] Holtec Britain, "HI-2240349, Holtec SMR GDA PSR Part B Chapter 18 Structural Integrity," Revision 0, August 2024.

[19] US NRC, "NUREG-0711, Human Factors Engineering Program Review Model," Revision 3, 2012.

[20] “Holtec International, "HPP-160-1014, SMR-160 Human Factors Engineering Program Mangement Plan," Revision 2, January 2023”.

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17.11 LIST OF APPENDICES

Appendix A Human Factors CAE Route Map

Table 7: Chapter B17 Claims, Arguments and Evidence Relevant Route Map

Overarching SSEC Claim	Chapter Claim/s	Chapter Sub-claim	Chapter Section
Claim 2.1 – Nuclear Safety The nuclear safety assessment specifies the requirements for safety measures such that safety functions are fulfilled, informs operational and emergency arrangements and demonstrates that risk is tolerable and ALARP.	**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. .	**Claim 2.1.7.1** Human failures shall be systematically identified using Relevant Good Practice methodologies in a risk proportionate manner.	**17.7 Human based Safety Claims**
		Claim 2.1.7.2. Human Reliability Assessment shall be undertaken to determine the reliability and effective task performance of human actions in a risk proportionate manner.	**17.7 Human based Safety Claims**
Claim 2.2 – System / Process Design and Substantiation 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 2.2.8** HF requirements are integrated into the design, operation and maintenance of the Generic Holtec SMR-300.	**Sub-claim 2.2.8.1** Human factors Relevant Good Practice is appropriately integrated into the Generic Holtec SMR-300 lifecycle.	**17.4 Human Factor integration**
		Sub-claim 2.2.8.2 Human Factors design and assessment shall take cognisance of Relevant Good Practice and Operational Experience.	**17.5 Codes and Standards**
		Sub-claim 2.2.8.3 Requirements relevant to Human Factors are identified and substantiated in a risk proportionate manner.	**17.6 Design Substantiation**
		Sub-claim 2.2.8.4. Staffing and qualification requirements are systematically assessed and informed by Human Reliability Assessment	**17.8 Operational Philosophy and Conduct of Operations**

Appendix B Comparison of ONR and NRC HF Guidance

Table 8: Comparison of NUREG 0711 and Office of Nuclear Regulation Safety Assessment Principles Relevant to Human Factors

ONR SAPs	SAPs supported by Human Factors	GDA Requirements	Relevant NRC information	Relevant Holtec Information	Observations
EHF01 - Integration within design, assessment and management	ECS. 2 Safety classification of structures, systems and components ESS. 3. Monitoring of Plant Safety ESS. 8. Automatic Initiation ESS. 9. Time for human intervention ESS. 11. Demonstration of adequacy ESS. 13. Confirmation to operating personnel ESS. 26 Maintenance and testing	HFIP and HFI Guidance	**NUREG 0711** Section 2. HFE Program Management Section 11. Verification and Validation Section 12. Design Implementation Section 13. Human Performance Monitoring	PMP Road Map Style Guide	Alignment with the UK

ONR SAPs	SAPs supported by Human Factors	GDA Requirements	Relevant NRC information	Relevant Holtec Information	Observations
EHF02 - Allocation of safety actions	ECS. 2 Safety classification of structures, systems and components ESS. 3. Monitoring of Plant Safety ESS. 8. Automatic Initiation ESS. 9, Time for human intervention ESS. 11, Demonstration of adequacy ESS. 13, Confirmation to operating personnel ESS. 26 Maintenance and testing	Operating Philosophy and Allocation of Function	**NUREG 0711** Section 4. Functional Requirements Analysis and Function Allocation Section 6. Staffing and qualifications Section 7. Treatment of Important Human Actions	Operational Experience Reviews Functional Requirements Analysis/Allocation of Function Task Analysis Staffing & Qualification (identifying staffing goal)	Assumptions on which Allocation of Function is based need to be demonstrated to be applicable to the UK context
EHF03 - Identification of actions impacting safety	ECS.2. Safety Classification of structures systems and components FA 13. Fault Sequence PSA. Adequate representation	Task and Error Analysis reports	**NUREG 0711** Section 3. OER review Section 5. Task Analysis Section 7. Treatment of Important Human Actions	Operational Experience Reviews Functional Requirements Analysis/Allocation of Function Task Analysis	Task analysis will be based on the approach outlined in NUREG 0711 Probabilistic and Deterministic Analysis will be based on the approach in the NUREG, with additional information for the UK context where necessary.

ONR SAPs	SAPs supported by Human Factors	GDA Requirements	Relevant NRC information	Relevant Holtec Information	Observations
EHF04 - Identification of administrative controls		Task and error analysis Fault Schedules capturing HBSCs	**NUREG 0711** Section 3. OER review Section 5. Task Analysis Section 7. Treatment of Important Human Actions	Operational Experience Reviews Functional Requirements Analysis/Allocation of Function Task Analysis	
EHF05 - Task analysis	FA.5. Initiating faults. FA 6, Fault Sequences FA 13. Adequate representation (human errors that lead to initiating faults	Task and Error Analysis reports	**NUREG 0711** Section 3. OER Section 5. Task Analysis	Task Analysis	Support use of task analysis
EHF06 - Workspace design	ESR. 1. Provision in control rooms and other locations. ESR, 4. Minimum operational equipment ESR. 7. Communications systems	Design aspects relating to a range of plant, systems, structures and components	**NUREG 0711** Section 5. Task Analysis **NUREG 0700** Sections 11, 12, 13	Task Analysis (preliminary workplace for MCR, RSS and EOF)	Review of the applicability of UK standards
EHF07 - User interfaces	ESS. 13. confirmation to operating personnel ESR. 1. Provision in control rooms and other locations	Design aspects relating to a range of plant, systems, structures and components	**NUREG 0711** Section 8 Human-System Interface Design **NUREG 0700** Sections 1 to 11	HIS Design (draft for initial simulator set up)	Review of style guide
EHF08 - Personnel competence	N/A	Concept of Operations and Operating Philosophy	**NUREG 0711** Section 10	N/A	N/A

ONR SAPs	SAPs supported by Human Factors	GDA Requirements	Relevant NRC information	Relevant Holtec Information	Observations
EHF09 - Procedures	N/A for Step 1	N/A for Step 1	**NUREG 0711** Section 9	N/A	N/A
EHF011 - Staffing Levels	MS. 2. Capable organisation	The Operating Philosophy and Allocation of Function	**Section 6** Staffing and qualifications	Staffing and Qualifications (identified staffing goal)	Applicability of UK standards
EHF012 - Fitness for Duty	N/A for Step 1	N/A for Step 1	**NUREG 0711** Section 10 Section 7. Treatment of Important Human Actions	N/A	Not considered in detail for GDA
EHF010 - Human Reliability	AV.3. Use of data	Fault Schedules capturing HBSCs HRA supporting analyses Verification and validation of HF claims and criteria	**NUREG 0800** Chapter 18 **NUREG 0700** OER Review Task Analysis Functional Allocation review	Operational Experience Reviews Functional Requirements Analysis/Allocation of Function Task Analysis Staffing & Qualification (identifying staffing goal)	