Office for Nuclear Regulation

ONR Assessment Report

Generic Design Assessment of the BWRX-300 – Step 2 Assessment of Human Factors

ONR Assessment Report

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Executive summary

In December 2024, the Office for Nuclear Regulation (ONR), together with the Environment Agency and Natural Resources Wales, began Step 2 of the Generic Design Assessment (GDA) of the BWRX-300 design on behalf of GE-Hitachi Nuclear Energy International LLC (UK Branch), the Requesting Party (RP).

This report presents the outcomes of my Human Factors assessment of the BWRX-300 design as part of Step 2 of the ONR GDA. This assessment is based upon the information presented in the RP's safety, security, safeguards and environment cases (SSSE), the associated revision 3 of the Design Reference Report and supporting documentation.

ONR's GDA process calls for an assessment of the RP's submissions, which increases in detail as the project progresses. The focus of my assessment in this step was to support ONR's decision on the fundamental adequacy of the BWRX-300 design and safety, and the suitability of the methodologies, approaches, codes, standards and philosophies which form the building blocks for the design and generic safety, security and safeguards cases.

I targeted my assessment, in accordance with my assessment plan, at the areas that were fundamental to the acceptability of the design and methods for deployment in Great Britain (GB), benchmarking my regulatory judgements against the expectations of ONR's Safety Assessment Principles (SAPs), Technical Assessment Guides (TAGs) and other guidance which ONR regards as relevant good practice, such as International Atomic Energy Agency (IAEA) safety, security and safeguards standards. Where appropriate, I have also considered how I could use relevant learning and regulatory conclusions from the UK ABWR GDA to inform my assessment of the BWRX-300.

I targeted the following aspects in my assessment of the BWRX-300 Safety Security Safeguards Environment (SSSE) submission:

- safety, security and safeguards case
- defence in Depth (DiD)
- passive safety systems
- modularisation and compact layout
- design assurance
- capability and capacity
- allocation of Function (AoF)
- substantiation of the role of the operator

- substantiation of the Human Factors Engineering (HFE)

Based upon my assessment, I have concluded the following:

- I did not identify any fundamental HF shortfalls that could prevent ONR permissioning the construction of a power station based on the BWRX-300 design, should the design develop in-line with the declared HF requirements and methods;

- I note positively that the design of the BWRX-300 is intended to reduce the significance of human error during normal and fault operations in comparison to older reactor designs. No human intervention is required for the first 72hrs of a DBA, noting only one train of ICS may be left in service following a DBA. In less onerous faults where all 3 ICS trains may be put into service then up to 7 days may be available. For normal plant operations, the design features a high degree of automation. These claims will need to be fully validated as the design and safety case matures;

- I judge that the RP has established an HFE programme that aligns with international good practice, with some minor exceptions. The scope considers all lifecycle phases, all areas of the plant, and all normal and fault operations. It is positive to note that the RP identifies that the current scope does not entirely meet GB regulatory expectations for Environmental, Security and Safeguards functions within its HFE programme and provides forward actions to address these shortfalls;

- I judge that the RP has demonstrated a competent HF capability and an understanding of what is required organisationally to deliver an effective HFE programme. However, a future safety case would need to demonstrate suitable and sufficient resource to deliver the broad scope of HFE on a modern NPP;

- The RP’s HFE methods, requirements and guidance align with international good practices and appear to be being applied in a targeted and proportionate manner. There is a high degree of alignment in method type, and guidance sources, to those methods and guidance applied during previous successful GDAs;

- I judge that the RP has conducted a thorough review of nuclear operational experience, and there is evidence of this being translated into design requirements and guidance;

- The representation of HRA within the PSA is currently immature and lacks suitable representation of Type A and B errors, and errors of commission. The RP notes this and has committed to address this shortfall as a forward action; Further, whilst the RP has conducted task analysis, this has not been submitted for assessment so there is no current formal underpinning for the modelled HEPs. A future safety case would need to substantiate that any HEPs used within the PSA are best estimate, either via qualitative task and error analysis or via simulation;

- The wider HF SSSE case lacks evidence of application of the declared HFE programme to fully support the PSR claims around integration. The HF topic is presented predominantly across two PSR chapters (18 and 15.4), and these chapters contain very little summary evidence of the application of HFE. It was apparent that more evidence exists than was submitted for assessment in this area. However, I do not judge this to be a fundamental shortfall as it is for the RP to determine what evidence is to be submitted for regulatory assessment. I have been able to assess sufficient evidence for Step 2 from the formal submissions and evidence shared for information only, to conclude that: the RP understands the applicable modern standards and scope of HFE, and HF is influencing the design. A future safety case will need to expand upon the presentation of HFE evidence underpinning the claims of HFI. This is an expectation as part of demonstrating that human error risks are reduced ALARP.

Overall, based on my assessment to date I have not identified any fundamental shortfalls that could prevent ONR permissioning the construction of a power station based on the generic BWRX-300 design; noting that any decision to permission a BWRX-300 will require further assessment (in either a future Step 3 GDA or during site specific activities) of suitable and sufficient supporting evidence that can substantiate the claims and proposals made in the GDA Step 2 submissions.

List of abbreviations

ALARP	As low as reasonably practicable
ABWR	Advanced Boiler Water Reactor
AOO	Anticipated Operational Occurrences
BTC	Basic Technical Characteristics
BWR	Boiling Water Reactor
CAE	Claim, Argument and Evidence
CNSC	Canadian Nuclear Safety Commission
CRHOA	Habitability and Operability Analysis
DAC	Design Acceptance Confirmation
DEC	Design Extension Conditions
DESNZ	Department of Energy Security and Net Zero
DR	Design Reference
DRP	Design Reference Point
DRR	Design Reference Report
EA	Environment Agency
ESBWR	Economic Simplified Boiling Water Reactor
FAP	Forward Action Plan
FSF	Fundamental Safety Functions
GB	Great Britain
GDA	Generic Design Assessment
GVHA	GE Verona Hitachi Nuclear Energy Americas LLC
GSE	Generic Site Envelope
GSR	Generic Security Report
HBSCs	Human Based Safety Claims
HEDs	Human Engineering Deficiencies
HEPs	Human Error Probabilities
HF	Human Factors
HFE	Human Factors Engineering
HFI	Human Factors Integration
HMI	Human Machine Interface
HRA	Human Reliability Assessment
HSI	Human System Interface
IAEA	International Atomic Energy Agency
ICSO	Isolation Condenser System
LOCA	Loss of Coolant Accident
LTR	Licensing Topical Report
MDSL	Master Document Submission List
NPP	Nuclear Power Plant
NRC	Nuclear Regulatory Commission
NRW	Natural Resources Wales
ONR	Office for Nuclear Regulation
OPEX	Operational Experience
PCSR	Pre-construction Safety Report
PIE	Postulated Initiating Event
PID	Project Initiation Document

PSA	Probabilistic Safety Assessment
PSAR	Preliminary Safety Analysis Report
PSR	Preliminary Safety Report
RGP	Relevant Good Practice
RI	Regulatory Issue
RITE	Risk Informed Targeted Engagement
RO	Regulatory Observation
RP	Requesting Party
RQ	Regulatory Query
SSSE	Safety, Security, Safeguards and Environment Cases
SMR	Small Modular Reactor
SSCs	Structures, Systems and Components
SAP	Safety Assessment Principle(s)
SFAIRP	So far as is reasonably practicable
SSC	Structure, System and Component
TAG	Technical Assessment Guide(s) (ONR)
TSC	Technical Support Contractor
UK	United Kingdom
US	United States of America
WENRA	Western European Nuclear Regulators’ Association

Contents

1. Introduction

1. This report presents the outcome of my Human Factors (HF) assessment of the BWRX-300 design as part of Step 2 of the Office for Nuclear Regulation (ONR) Generic Design Assessment (GDA). My assessment is based upon the information presented in the Safety, security, safeguards and environment cases (SSSE) head document [1], specifically chapters 1, 3, 6, 7, 9B, 12, 13, 15, 16, 17, 18, 19, 21, 27] (refs. [2, 3], [4], [5], [6], [7], [8], [9], [10], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21], [22], [23], [24] the associated revision of the Design Reference Report (DRR) (ref. [25]) and supporting documentation.

2. Assessment was undertaken in accordance with the requirements of ONR's Management System and follows ONR's guidance on the mechanics of assessment, NS-TAST-GD-096 (ref. [26]) and ONR's risk informed, targeted engagements (RITE) guidance (ref. [27]. The ONR Safety Assessment Principles (SAPs) (ref. [28]), together with supporting Technical Assessment Guides (TAGs) (ref. [29]), have been used as the basis for this assessment.

3. This is a Major report as per ONR's guidance on production of reports (NS-TAST-GD-108) (ref. [30]).

1.1. Background

4. The ONR's GDA process (ref. [31]) calls for an assessment of the Requesting Party's (RP) submissions with the assessments increasing in detail as the project progresses. This GDA will be finishing at Step 2 of the GDA process. For the purposes of the GDA, GE Vernova Hitachi Nuclear Energy International LLC, UK Branch, is the RP. GE Vernova Hitachi Nuclear Energy Americas LLC (GVHA) is a provider of advanced reactors and nuclear services and is the designer of the BWRX-300. GVHA is headquartered in Wilmington, North Carolina, United States of America (US).

5. In Step 1, and for the majority of Step 2, the RP was known as GE-Hitachi Nuclear Energy International LLC, UK Branch, and GVHA as GE-Hitachi Nuclear Energy Americas LLC. The entities formally changed names in October 2025 and July 2025 respectively. The majority of the submissions provided by the RP during GDA were produced prior to the name change, and thus the reference titles in Section 6 of this report reflects this.

6. In the UK, the RP has been supported by its supply chain partner, Amentum, who has assisted the RP in the development of the UK-specific chapters of the Safety, Security, Safeguards and Environment cases (SSSE), and other technical documents for the GDA.

7. In January 2024 ONR, together with the Environment Agency and Natural Resources Wales began Step 1 of this two-Step GDA for the generic BWRX-300 design.

8. Step 1 is the preparatory part of the design assessment process and is mainly associated with initiation of the project and preparation for technical assessment in Step 2. Step 1 completed in December 2024. Step 2 is the first substantive technical assessment step, and began in December 2024 and will complete in December 2025.

9. The RP has stated that at this time it has no plans to undertake Step 3 of GDA and obtain a Design Acceptance Confirmation (DAC). It anticipates that any further assessment by the UK regulators of the BWRX-300 design will be on site-specific basis and with a future licensee.

10. The focus of ONR's assessment in Step 2 was:

- The fundamental adequacy of the design and safety, security and safeguards cases; and
- The suitability of the methodologies, approaches, codes, standards and philosophies which form the building blocks for the design and cases.

11. The objective is to undertake an assessment of the design against regulatory expectations to identify any fundamental safety, security or safeguards shortfalls that could prevent ONR permissioning the construction of a power station based on the design.

12. Prior to the start of Step 2 I prepared a detailed Assessment Plan for HF (ref. [32]). This has formed the basis of my assessment and was also shared with the RP to maximise openness and transparency.

13. This report is one of a series of assessments which support ONR's overall judgements at the end of Step 2 which are recorded in the Step 2 Summary Report (ref. [33]) and published on the regulators' website.

1.2. Scope

14. The assessment documented in this report is based upon the SSSE for the BWRX-300 (refs. [1], [2], [3], [4], [34], [35], [5], [6], [36], [37], [7], [38], [39], [8], [9], [10], [11], [40], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21], [22], [23], [41], [42], [43], [44], [45], [46], [47], [24], [48]).

15. The RP's GDA scope has been agreed between the regulators and the RP during Step 1. This is documented in an overall Scope of Generic Design Assessment report (ref. [49]). This is further supported by its DRR (ref. [25]) and the master document submission list (MDSL) (ref. [50]). The GDA scope report documents the submissions which were provided in each topic area during Step 2 and provides a brief overview of the physical and functional scope of the NPP that is proposed for consideration in the GDA. The DRR provides a list of the systems, structures and components (SSCs) which are included in the scope of the GDA, and their relevant GDA reference design documents.

16. The RP has stated it does not have any current plans to undertake GDA beyond Step 2. This has defined the boundaries of the GDA and therefore of my own assessment.

17. The GDA scope includes the Power Block (comprising the Reactor Building, Turbine Building, Control Building, Radwaste Building, Service Building, Reactor Auxiliary Structures) and Protected Areas (PA) as well as the balance of plant. It includes all modes of operation.

18. The regulatory conclusions from GDA apply to everything that is within the GDA scope. However, ONR does not assess everything within it or all matters to the same level of detail. This applies equally to my own assessment, and I have followed ONR's guidance on the mechanics of assessment, NS-TAST-GD-096 [26] and ONR's guidance on Risk Informed, Targeted Engagements [27].

19. As appropriate for Step 2 of the GDA, information has not been submitted for all aspects within the GDA Scope during Step 2. The following aspects of the SSSE are therefore out of scope of this assessment:

20. Whilst I have assessed whether the RP has included the full SSSE case within its HFI scope, I have only considered the application of HF with respect to nuclear safety in this assessment report. The role of the human in Conventional Health Safety, Environment, Security and Safeguards is within scope of those assessment reports:

- Conventional Health Safety (ref. [51])
- Security (refs. [52] and [53])
- Safeguards (ref. [54])

21. My assessment has considered the following aspects:

- The adequacy of the HF Integration (HFI) on the project;
- The concept of operations;
- The suitability of the Allocation of nuclear safety Functions (AoF) between the human and technology;
- The adequacy of HF Engineering (HFE) programme;
- The adequacy of the RP's approach to the identification, analysis and substantiation of Human Based Safety Claims (HBSCs); and
- The adequacy of the HF safety case and design analysis submissions.

2. Assessment standards and interfaces

22. The primary goal of the GDA Step 2 assessment is to reach an independent and informed judgment on the adequacy of the RP's SSSE for the reactor technology being assessed.

23. ONR has a range of internal guidance to enable Inspectors to undertake a proportionate and consistent assessment of such cases. This section identifies the standards which have been considered in this assessment. This section also identifies the key interfaces with other technical topic areas.

2.1. Standards

24. The ONR Safety Assessment Principles (SAPs) (ref. [28]) constitute the regulatory principles against which the RP's case is judged. Consequently, the SAPs are the basis for ONR's assessment and have therefore been used for the Step 2 assessment of the BWRX-300.

25. The International Atomic Energy Agency (IAEA) safety standards (ref. [55]) and nuclear security series (ref. [56]) are a cornerstone of the global nuclear safety and security regime. They provide a framework of fundamental principles, requirements and guidance. They are applicable, as relevant, throughout the entire lifetime of facilities and activities.

26. Furthermore, ONR is a member of the Western European Nuclear Regulators Association (WENRA). WENRA has developed Reference Levels [57], which represent good practices for existing nuclear power plants, and Safety Objectives for new reactors (ref. [58]).

27. The relevant SAPs, IAEA standards and WENRA reference levels are embodied and expanded on in the TAGs (ref. [29]). The TAGs provide the principal means for assessing the HF aspects in practice.

28. The key guidance is identified below and referenced where appropriate within Section 4 of this report. Relevant good practice, where applicable, has also been cited within the body of this report.

2.1.1. Safety Assessment Principles (SAPs)

29. The key SAPs applied within my assessment are:

- EHF.1 Integration within design, assessment and management
- EHF.2 Allocation of safety actions
- EHF.3 Identification of actions impacting safety
- EHF.5 Task analysis

- EHF.6 Workspace design
- EHF.7 User interfaces
- EHF.10 Human reliability
- EHF.11 Staffing levels
- MS.2 Capable organisation
- ECS.2 Safety classification of structures, systems and components
- ESS.8 Automatic initiation
- ESS.13 Confirmation to operating personnel
- SC.4 Safety case characteristics

30. A list of the SAPs used in this assessment is recorded in Appendix 1.

2.1.2. Technical Assessment Guides (TAGs)

31. The following TAGs have been used as part of this assessment:

- NS-TAST-GD-096 - Guidance on Mechanics of Assessment (ref. [59])
- NS-TAST-GD-005 – Regulating duties to reduce risks As Low As Reasonably Practicable (ALARP) (ref. [60])
- NS-TAST-GD-051 – The purpose, scope and content of safety cases (ref. [61])
- NS-TAST-GD-058 - Human Factors Integration (ref. [62])
- NS-TAST-GD-059 - Human Machine Interfaces (ref. [63])
- NS-TAST-GD-062 - Workplaces and Work Environment (ref. [64])
- NS-TAST-GD-063 - Human Reliability Analysis (ref. [65])
- NS-TAST-GD-064 - Allocation of Function Between Human and Engineered Systems (ref. [66])

2.1.3. National and international standards and guidance

32. The following international standards and guidance have been used as part of this assessment:

- IAEA SSR-2/1 – Safety of Nuclear Power Plants: Design (ref. [67])
    - Requirement 32: Design for Optimal Human Performance

- IAEA SSG-2 - Deterministic Safety Analysis for Nuclear Power Plants (ref. [68])
- IAEA SSG-61 – Format and Content of the Safety Analysis Report for Nuclear Power Plants (ref. [69]):
  - Chapter 7 - Instrumentation and Control
  - Chapter 13 - Conduct of operations
  - Chapter 18 - Human Factors Engineering
- IAEA TECHDOC-1936 – Applicability of design safety requirements to small modular reactor technologies intended for near term deployment (ref. [70]).
- IAEA, Commissioning and Operation of Nuclear Power Plants SSR 2/2 (Rev. 1) (ref [71]):
  - Requirement 4. Staffing of the operating organisation
- IAEA, Safety Assessment for Facilities and Activities. GSR Part 4 (Rev. 1) (ref. [72]):
  - Requirement 11: Assessment of human factors
- IAEA, Human Factors Engineering in the Design of Nuclear Power Plants, IAEA Safety Standards Series No. SSG-51 (ref. [73])
- WENRA safety reference levels for existing reactor 2020 (ref. [74])
- WENRA Safety of New NPP designs (ref. [75])
- WENRA Applicability of the Safety Objectives to SMRs (ref. [76])

2.2. Integration with other assessment topics

33. To deliver the assessment scope described above I have worked closely with several other topic leads to inform my assessment. Similarly, other assessors sought input from my assessment. These interactions are key to the success of GDA to prevent or mitigate any gaps, duplications or inconsistencies in ONR’s assessment.

34. The key interactions with other topic areas were:

- Probabilistic Safety Analysis – To assess the scope and maturity of the Human Reliability Assessment (HRA);
- Fault Studies – To assess the treatment of human actions within the deterministic analysis;

- Control and Instrumentation – To assess the adequacy of the key Human Machine Interfaces;
- Mechanical Engineering – To assess the habitability of the Main Control Room (MCR) / Secondary Control Room (SCR);
- Civil Engineering – To assess the implications of the chosen MCR / SCR locations; and
- Conventional Health and Safety – To manage the risk of assessment duplication.

2.3. Use of technical support contractors

35. I have not engaged Technical Support Contractors (TSCs) to support my assessment of the Human Factors aspects of the BWRX-300 GDA.

3. Requesting Party's submission

36. The RP submitted the SSSE at the start of Step 2 in four volumes that integrate environmental protection, safety, security, and safeguards. This was accompanied by a head document (ref. [1]), which presents the integrated GDA environmental, safety, security, and safeguards case for the BWRX-300 design.

37. All four volumes were subsequently consolidated to incorporate any commitments and clarifications identified in regulatory engagements, regulatory queries and regulatory observations, and were resubmitted in July 2025. This consolidated revision is the basis of the regulatory judgements reached in Step 2.

38. This section presents a summary of the RP's safety case for HF. It also identifies the documents submitted by the RP which have formed the basis of my Step 2 assessment of the BWRX-300 design.

3.1. Summary of the BWRX-300 Design

39. The BWRX-300 is a single unit, direct-cycle, natural circulation, boiling water reactor with a power of ~870 MW (thermal) and a generating capacity of ~ 300 MW (electrical) and is designed to have an operational life of 60 years. The RP claims the design is at an advanced concept stage of development and is being further developed during the GDA in parallel with the RP's SSSE.

40. The BWRX-300 is the tenth generation of the boiling water reactor (BWR) designed by GVHA and its predecessor organisations. The BWRX-300 design builds upon technology and methodologies used in its earlier designs, including the Advanced Boiling Water Reactor (ABWR), Simplified Boiling Water Reactor (SBWR) and the Economic Simplified Boiling Water Reactor (ESBWR). The ABWR has been licensed, constructed and is currently in operation in Japan, and a UK version of the design was assessed in a previous GDA with a view to potential deployment at the Wylfa Newydd site. Neither the SBWR or ESBWR have been built or operated.

41. The BWRX-300 reactor core houses 240 fuel assemblies and 57 control rods inside a steel reactor pressure vessel (RPV). It uses fuel assemblies (GNF2) that are already currently widely used globally (ref. [34]).

42. The reactor is equipped with several supporting systems for normal operations, and a range of safety measures are present in the design to provide cooling, control criticality and contain radioactivity under fault conditions. The BWRX-300 utilises natural circulation and passive cooling rather than active components, reflecting the RP's design philosophy.

43. The design basis includes two notable top-level claims relating to HF (ref. [77]) that the design de-emphasises the role of the operator during faults.

44. For any PIE (Postulated Initiating Event) or event sequence in the Anticipated Operational Occurrences or Design Basis Analysis event categories, fundamental safety functions can be performed and maintained for 72 hours without operator action. This claim is substantiated using conservative analysis techniques; and

45. For any PIE or event sequence within the scope of the Coping Capability Sequence Selection process, the fundamental safety functions can be performed and maintained for 7 days without operator action. This claim is substantiated using best estimate or realistic analysis technique.

3.2. BWRX-300 Case Approach and Structure

46. The RP has submitted information on its strategy and intentions regarding the development of the SSSE (refs [77], [78], [79], [80]). This was submitted to ONR during Step 1.

47. The RP has submitted a SSSE for the BWRX-300 that claims to demonstrate that the standard BWRX-300 can be constructed, operated, and decommissioned on a generic site in GB such that a future licensee will be able to fulfil its legal duties for activities to be safe, secure and will protect people and the environment. The SSSE comprises a Preliminary Safety Report (PSR) which also includes information on its approach to safeguards and security, a security assessment, a Preliminary Environment Report (PER), and their supporting documents.

48. The format and structure of the PSR largely aligns with the IAEA guidance for safety cases, SSG-61 (ref. [69]), supplemented to include UK specific chapters such as Structural Integrity and Chemistry. The RP has also provided a chapter on As Low as Reasonably Practicable (ALARP), which is applicable to all safety chapters. The RP has stated that the design and analysis referenced in the PSR is consistent with the March 2024 Preliminary Safety Analysis Report (PSAR) submitted to the US Nuclear Regulatory Commission (NRC). The Security Assessment and PER are for the same March 2024 design but have more limited links to any US or Canadian submissions.

3.3. Summary of the RP’s case for Human Factors

49. The aspects covered by the BWRX-300 safety case in HF can be broadly grouped under 3 headings which are summarised as follows:

3.3.1. All Functions Identified and Substantiated

50. The RP makes the following sub-claims and arguments in relation to demonstrating that “all functions have been derived and substantiated taking

into account RGP and OPEX, and processes are in place to maintain these through-life." (ref. [22]):

- *The design of the system has been substantiated to achieve the safety functions in all relevant operating modes*. This is supported by task analysis, testing and evaluation as part of the HFE process, and formal verification and validation.

- *The system design has been undertaken in accordance with relevant design codes and standards (RGP) and design safety principles and takes account of OPEX to support reducing risks ALARP.* This is supported by the general HFE programme inlcuding control room and plant layout designs. The plant is designed to meet the anthropometric range of 5th percentile female to 95th percentile male.

- *The BWRX-300 will be designed, and is intended to be operated, so that it can be decommissioned safely, using current available technologies, and with minimal impact on the environment and people.* The HFE programme requires HFE principles to be applied throughout the project lifecycle. This includes specific analysis and substantiation of layout to demonstrate the accommodation of people and equipment through life. Within scope are those components that will be replaced during the design life of the plant.

3.3.2. Suitable and Sufficient Safety Analysis

51. The RP makes the following sub-claims and arguments in relation to demonstrating that "A suitable and sufficient safety analysis[1] has been undertaken which presents a comprehensive fault and hazard analysis that specifies the requirements on the safety measures and informs emergency arrangements (Safety Analysis)" (ref. [22]):

- Human Factors assessments have been appropriately integrated into the design, safety assessments and management arrangements, to meet the relevant safety requirements. The RP argues that a modern standards Allocation of Function (AoF) programme has been followed, supplemented by the application of a graded (proportionate) approach to both HFE and identification and substantiation of HBSCs.

3.3.3. ALARP

52. The RP makes the following sub-claims and arguments in relation to demonstrating that "*Safety risks have been reduced as low as reasonably practicable*" (ref. [22]):

[1] It should be noted that the treatment of HF in security, safeguards, and environment lags that of safety, but the RP does note its requirements and assigns a number of forward actions to address the omissions

- *Relevant Good Practice (RGP) has been taken into account across all disciplines.* The RP argues that the applied methods and standards meet RGP and align with international nuclear standards and other national regulatory requirements.

- *Operating Experience (OPEX) and Learning from Experience (LFE) has been taken into account across all disciplines.* The RP argues that OPEX and LFE have are incorporated within its HFE design requirements and therefore inform the BWRX-300 design.

- *Optioneering (all reasonably practicable measures have been implemented to reduce risk).* The RP argues that the BWRX-300 has been subject to optioneering activities that include allocation of function and HFE trade-off evaluations.

3.4. Basis of assessment: RP's documentation

53. The principal documents that have formed the basis of my HF assessment of the SSSE are:

- *BWRX-300 UK GDA Chapter 18 Human Factors Engineering* (ref. [22]). This submission summarises the HF elements of the SSSE.

- *BWRX-300 UK GDA Chapter 15.4 - Safety Analysis - Human Action* (ref. [14]). This submission summarises the approaches to substantiating the role of the operator.

- *BWRX-300 Human Factors Engineering Program Plan* (ref. [81]). This submission summarises the scope and approach of the HFE programme.

- *BWRX-300 Human Factors Engineering Concept of Operations* (ref. [82]This submission summarises the high-level operational philosophies and some provides some user characteristics.

3.5. Design Maturity

54. My assessment is based on revision 3 of the DRR (ref. [25]). The design reference report presents the baseline design for GDA Step 2, outlining the physical system descriptions and requirements that form the design at that point in time. For security, this also includes the Protected Area (PA) boundary and the PA access building.

55. The reactor building and the turbine building, along with the majority of the significant structures, systems and components (SSCs) are housed with the 'power block'. The power block also includes the radwaste building, the control building and a plant services building.

56. The GDA Scope Report (ref. [49]) describes the RP's design process that extends from baseline (BL) 0 (where functional requirements are defined) up to BL 3 (where the design is ready for construction).

57. In the March 2024 design reference, SSCs in the power block are stated to be at BL1. BL1 is defined as:

- System interfaces established;
- (included) in an integrated 3D model;
- Instrumentation and control aspects have been modelled;
- Deterministic and probabilistic analysis has been undertaken; and
- System descriptions developed for the primary systems.

58. The balance of plant remains at BL0 for which only plant requirements have been established, and SSC design remains at a high concept level.

4. ONR assessment

4.1. Assessment strategy

59. The objective of my GDA Step 2 assessment was to reach an independent regulatory judgement on the fundamental aspects of the BWRX-300 design, relevant to HF as described in sections 1 and 3 of this report. My assessment strategy is set out in this section and defines how I have chosen which matters to target for assessment. My assessment is consistent with the delivery strategy for the BWRX-300 GDA [83].

60. GVHA is currently engaging with regulators internationally, including the Nuclear Regulatory Commission in the US (US NRC) and the Canadian Nuclear Safety Commission in Canada (CNSC). It is proposing a standard BWRX-300 design for global deployment with minimal design variations from country to country. My assessment takes cognisance of work undertaken by overseas regulators where appropriate.

61. Whilst there is no operating BWR plant in the UK, ONR has previously performed a four-step GDA on the Hitachi-GE UK ABWR (ref. [84]). I have taken learning from this previous activity, targeting my assessment on those aspects of the BWRX-300 which are novel or specific to this design. I have not looked to reassess inherent aspects of BWR technology which were considered in significant detail for the UK ABWR and judged to be acceptable.

62. My assessment strategy has been informed by:

- ONR's RITE principles;
- The fact that this design is an evolution (iteration 10) of the RP's BWR reactor design, a version of which was previously assessed during the UK ABWR GDA;
- Methodologies used by previous GDA requesting parties, where ONR has already judged them to be capable of delivering suitable and sufficient output to support reactor design and safety analysis;
- The most safety significant hazards or where they appear least well controlled in the context of the design and SSSE;
- Factors such as novelty, or uncertainty;
- Any differences between the standards selected by the RP and established Relevant Good Practice (RGP);

- Where there is a risk that the fundamental aspect being assessed cannot be substantiated or will not meet regulatory expectations should the design be taken forward to a site-specific phase.

- Where attention is needed on a fundamental aspect of the design or safety case that may prevent construction and operation of the BWRX-300 in GB; and

- Items identified during Step 1 for follow-up.

4.2. Assessment Scope

63. My assessment scope and the areas I have chosen to target for my assessment are set out in this section. This section also outlines the submissions that I have sampled, the standards and criteria that I will judge against and how I have interacted with the RP and other assessment Topics.

64. My assessment scope is consistent with the GDA scope agreed between the regulators and the RP during Step 1 and detailed in Section 1.2 of this report. I have targeted my assessment within this scope.

65. In line with the objectives for Step 2, I have undertaken a broad review of the highest level, fundamental claims and supporting arguments related to HF. To support this, I have sampled a targeted set of the claims or arguments as set out below. Where applicable, I have also sampled the evidence available to support any claims and arguments including both formally submitted documentation and that made available for information only via the RP's online document viewing platform – the "reading room". I have not undertaken an assessment of material within the "reading room", however I have used it to gain regulatory confidence in the breadth and depth of the assessment undertaken by the RP (ref. [85]).

66. To fulfil the aims for the Step 2 assessment of the BWRX-300, I have assessed (and taken account of information provided for information only) the following items, which I consider important to enable an overall judgement on fundamental adequacy to be made:

- The Safety, security and safeguards case;
  I targeted my assessment on the presentation of the HF case with respect to whether it is cogent and coherent, and sufficiently complete to offer regulatory judgements on the fundamental adequacy of the design.

- Defence in depth;
  I considered whether the role of the human has been optimised via suitable analytical methods to determine the appropriate balance of engineered and human based protection.

- Passive safety systems;
  I considered whether the fundamental role of the human in ensuring the functioning of passive safety systems has been adequately considered.

- Modularisation and compact layout;
  I considered the human reliability implications of modularisation and the compact layout.

- Design assurance
  I considered the efficacy of the RP's approach to HF related Verification and Validation (V&V).

- Capability and Capacity;
  I considered whether the capacity and capability of the RP's HF team, and codes, methods and standards are suitable and sufficient to deliver against the requirements of GDA.

- Allocation of Function (AoF).
  I considered whether the RP's AoF outputs have led to a fundamentally balanced socio-technical design. This is the only area where I specifically considered Security, Safeguards, and Environment – confirmation that the AoF process considered Environment, Safety, Security and Safeguards at the holistic level to ensure that competing functional requirements are identified and can be resolved and optimised.

- Substantiation of the role of the operator (HRA).
  I had intended to sample the substantiation of a selection of operator claims to judge whether they are fundamentally credible. The RP did not submit any qualitative substantiation of discrete HBSCs, so my assessment considered the role of the operator more holistically.

- Substantiation of the engineering design (HFE).
  I assessed the RP's scope of HFE and how it was implementing it across the design of the BWRX-300, to confirm that SSCs important for safety are being optimised for human reliability.

4.3. Assessment

4.3.1. Human Factors Integration

67. This section presents my assessment of the enabling factors necessary to deliver an integrated programme of HF work in support of the development of the BWRX-300 design and SSSE analysis.

68. ONR's SAP EHF.1 sets the expectation that there should be a systematic approach to integrating HF within the design, assessment and management of systems and processes applied throughout the facility's lifecycle. Similar expectations are established in IAEA requirements, i.e., requirement 32: design for optimal operator performance (ref. [67])

69. Fundamental to the effective and proportionate consideration of the limitations and capabilities of the human within the design, is a HFI programme. It ensures that HF is properly considered and hence contributes to the principle of ALARP. Throughout my assessment, I place significant reliance on the efficacy of the HFI process as it gives confidence that HF is being (or will be) appropriately considered throughout the design.

70. ONR's expectations for the integration of HF in nuclear safety are set out within NS-TAST-GD-058 (Rev 4) Human Factors Integration (ref. [62]). I recognise that there are other requirements for the consideration of HF in other areas such as Environment, Security and Safeguards, but these are not considered in detail within this assessment report as, if judged necessary for Step 2, would be covered by other regulators and ONR disciplines. I have, however, attempted to confirm consideration of these areas within the RP's wider HFI programme.

71. The HFI expectations (ref. [62]) can be summarised as the RP demonstrating suitable and sufficient processes and arrangements in the following areas. The bracketed numbers indicate which section of this report they are assessed in.

- The capability and capacity of the HF organisation (Section 4.3.1.1)
- The scope of HFI (Section 4.3.1.2)
- Managing issues and assumptions (Section 4.3.1.3)
- Operational experience (Section 4.3.1.4)
- Standards, codes, methods, and guidance (Section 4.3.1.5)
- Concept of Operations (4.3.2)
- Allocation of Function and Substantiation of Human Actions (Section 4.3.3)

- Human Factors Engineering (Section 4.3.4)

4.3.1.1. The capability and capacity of the HF organisation

72. ONR's SAPs, EHF.8 and EHF.11 set the expectation that there will be sufficient SQEP HF resource delivering the relevant HFE and safety analysis work. SAP MS.2 also sets the expectation that organisations should have the capability to secure and maintain the safety of their undertakings.

73. The efficacy of the HF capability within an RP organisation is predicated on several enabling factors. These include:

    - Sufficient agency to effect necessary design modifications to ensure that human error is reduced ALARP;
    - Sufficient personnel to support the HFE and SSSE analysis programmes; and
    - Suitably SQEP individuals.

74. The RP describes the GVH HF organisation within the BWRX-300 Human Factors Engineering Program Plan (ref. [81]). It describes the HF team having decision making parity with the other engineering and analysis disciplines, which I consider to be a positive enabler for HFI. However, I was unable to test this claim during Step 2 as the RP did not submit evidence to support it. A future safety case would need to demonstrate that the HF team has sufficient agency to ensure that HF considerations are suitably weighted against engineering ones.

75. The core HFE team comprises a Technical Lead and two specialist HFE roles: HF Engineer and HFE Operations/Maintenance. Supporting these two key roles are additional specialist staff from relevant cross-cutting disciplines, such as ex-operators or Control and Instrumentation (C&I) specialists (ref. [81]). Total available resource is ~ 25 personnel. The RP has also sought specialist GB specific advice from its supply chain partner to tailor its submission for GDA.

76. Reference [81], sets out the SQEP requirements and responsibilities for each of the employee roles, which align with what I would expect in GB dutyholders. The only noteworthy difference from GB practice, is that the HRA function sits within the PSA specialism. Whilst this is not necessarily problematic, such a separation can increase the potential for siloed working and misalignment between qualitative data developed by the HFE team, and quantified data in the form of Human Error Probabilities (HEPs) provided by the PSA specialism. There was insufficient HRA and HF analysis submitted to verify that integration between the qualitative and quantitative data was occurring effectively as the HEPs at this stage are still largely conservative screening numbers. However, GDA learning has shown that the integration needs to be carefully managed to ensure that the qualitative data fully underpins the HEPs. As such, any future safety case would need to

demonstrate that the qualitative data from the HFE work is directly underpinning HRA.

77. I consider the RP has demonstrated that it clearly understands the organisational factors necessary to support an effective HFI programme and the competency requirements. This is sufficient for Step 2. A future HFE programme would need to demonstrate that sufficient capacity is available to implement the expanded HFI scope (a consequence of addressing the forward actions and ONR's regulatory observations).

4.3.1.2. The Scope of HFI

78. ONR's SAP, EHF.1 sets the expectation that there will be a systematic approach to integrating human factors within the design, assessment and management of systems and processes and that this should be applied throughout the facility's lifecycle.

79. I therefore expect an HFI scope to be targeted and risk informed, and to be inclusive of:

- All aspects of the SSSE case;
- All project phases, including: design; construction; commissioning; operation (e.g. reactor and fuelling operations); and decommissioning;
- All the major risk important Human Machine Interfaces (HMIs) and environments;
- Normal, fault, and emergency operations; and
- An appropriate range of stakeholders.

80. I consider the RP to have established an HFI scope that mostly meets GB regulatory expectations. Reference x *BWRX-300 Human Factors Engineering Program Plan* establishes a scope that comprises all phases of the product lifecycle from construction to decommissioning, all operational plant states, and includes the key areas of the plant where operators may have risk important interactions. It also acknowledges that task identification processes will also inform this selection.

81. However, I found that the treatment of HF in security is not as well developed as HF in safety.

82. Additionally, safeguards and environment are also not included within the HFE programme.

83. This does not meet Requirement 8: Interfaces of safety with security and safeguards. Safety measures, nuclear security measures and arrangements for the State system of accounting for, and control of, nuclear material for a

nuclear power plant shall be designed and implemented in an integrated manner so that they do not compromise one another, of SSR 2/1 (ref. [67])

84. However, it is positive to note that the RP identifies that further work is needed to meet this IAEA requirement with respect to security (FA items PSR18-164 and PSR18-166) and Safeguards (FA items PSR18-166 and PSR18-177 (ref. [22]).A future BWRX-300 case would need to demonstrate that HFI has been adequately incorporated into any Safeguards considerations.

85. With the addition of the forward actions that address the HFI scope shortfalls, I consider that the RP has established a suitable and sufficient HFI scope. A future safety case will need to demonstrate that the shortfalls in relation to Security and Safeguards have been addressed and evidence that HF is proportionally applied across the whole of the SSSE case.

86. Reference [22] also establishes the minimum interfacing stakeholders, and the transactional activities between each discipline and HF. These comprise the following:

- Mechanical and Electrical Engineering
- Instrumentation and Control Engineering
- Civil Engineering
- Plant Integration Engineering
- Risk and Reliability Engineering
- Simulation Assisted Engineering
- Product Management Training (which covers operational aspects such as the devement of operator training)

87. I consider these interfaces to be acceptable, when judged in concert with the declared scope, which would require additional discipline interactions (for example, security, environment, waste management, severe accident response).

88. It is positive that the RP's process requires each of the above disciplines to nominate a representative who then receives HFE fundamentals training. This provides a common understanding between disciplines and helping to mitigate any customer / supplier knowledge gaps, and has been proven to be highly effective on previous GDAs. (ref. [86])

89. The RP has adopted the US graded (essentially risk informed targeting in UK terms) approach to targeting HF on those areas that are most risk important. Sections 3 and 9 of the RP's Human Factors Engineering Program plan (ref. [81]) describe the scope of application, the grading

scheme, and what this means with respect to the application of HF methods and standards.

90. The grading scheme adopts three levels High, Medium and Low. High is assigned when an associated human action is credited in the Deterministic Safety Analysis (DSA) or is risk important within the PSA, or if there is a risk of death or serious personal injury. It also considers asset protection and availability criteria. Low is assigned where there is no credit in the DSA or PSA, or for low level hazards to personnel safety. A minor shortfall in this approach is that the RP does not define the specific criteria, which would need to be set out and justified in a future safety case.

91. I noted that with the grading scheme approach there is scope to elevate the initial rating to a higher level based on a review by the HFE technical leads with support from operations and maintenance specialists. This is in cases where, for example, the tasks under review are novel, complex, or are time sensitive. I welcome this, which aligns with regulatory expectations, and recognises the importance of task design and complexity. For nuclear safety, I am content that the proposed approach to scoping HFI provides the flexibility to ensure that the areas of higher human risk are the main focus, and generally aligns with previous practices adopted by other RPs.

92. However, I note that, similarly to the wider HF scope, it doesn't currently consider Security, Safeguards, and Environment. A future safety case would need to demonstrate the proportionate application of HF across these functions, and evidence that the application of this approach is effective.

4.3.1.3. Managing Issues and Assumptions

93. The RP manages HFE issues and discrepancies via its HFE Issue Tracking System (HFEITS) (ref. [81]). The HFEITS functionality is integrated within the project issue and action tracking system, in accordance with the design process and action tracking process included in BWRX-300 Design Plan (ref. [87]). This is positive as it ensures that consideration of HF issues is appropriately integrated into the wider project and limits the potential for siloed working

94. The RP defines each as:

- Discrepancy: A departure of the design from HFE design guidance and/or human performance criteria as identified during the execution of HFE V&V activities; and
- Issue: A problem or finding that is known to the industry or is identified throughout the life cycle of the HFE aspects of design, development, and evaluation. Issues are items that need to be addressed later and are tracked to ensure they are not overlooked.

95. Discrepancies and issues are prioritised based on the safety consequence: Priority 1 = direct or indirect safety consequence to Priority 3, which is viewed as an enhancement with no safety consequences.

96. The process also has scope to consider the cumulative effects of lower priority issues to determine whether, collectively, they may present a significant risk. This can elevate the priority of the discrepancy or issue. I welcome this good practice as it addresses the risk of multiple similar HFE issues around a related theme combining to be highly detrimental to future human reliability.

97. The HFEITS is used to support the following functions:

- Evaluation of HEDs to determine significance and whether the HED warrants correction when evaluated in the context of the integrated plant design;
- Identification of appropriate solutions to address issues/HEDs, including, as appropriate, changes to Human System Interface (HSI also known as Human Machine Inteface HMI) design, procedures, staffing/qualifications, or training;
- Verification that the solutions implemented to address the issue/HED resolves the problem without generating additional issues/HEDs; and
- Documented traceability of the issue/HED resolution process, including documenting residual risks associated with any unresolved HFE issues/HEDs.

98. Implemented changes to address issues or discrepancies are then subject to normal HF V&V activities to substantiate adequate resolution.

99. I consider that, in principle, this process is suitable for its intended purpose as it aligns with RGP in that it should actively capture, sentence, resolve, and V&V any shortfalls. However, the RP did not submit any of the HFEITS content or resolved examples for assessment, so I cannot assess the application of this tool. I have no reason to doubt that it is informing the design, so do not consider this to be a significant risk, but a future safety case would need to demonstrate that the output of the HFEITS is being appropriately sentenced and reflected in the design.

100. Additionally, it is not clear from BWRX-300 Human Factors Engineering Program Plan (ref. [81]) or the BWRX-300 Design Plan (ref. [87]) how HF related assumptions are being captured and managed for future validation (or whether these are captured as ‘issues’ within the HFEITS). This would need to be substantiated by a future safety case.

101. I am content that the RP has a process for managing issues and discrepancies that aligns with RGP (Ref. TAG HFI). However, a future safety

case will need to demonstrate the application of the HFEITs approach and provide evidence of its effectiveness in managing HF issues and discrepancies to resolution.

4.3.1.4. Operational Experience

102. The summary of the RP's approach to operating experience reviews is described within the Human Factors Engineering Program Plan (ref. [81]). It also provided material (ref. [85]) on the BWRX-300 operating experience review process and results for information only to evidence the application of this process.

103. The RP claims to have ~ 10,000 data points in its live database of Operating Experience. These data comprise information from current and past BWR plant designs, INPO and WANO databases, and general nuclear industry sources.

104. This review has resulted in (currently) 194 datapoints that are HF specific and relevant to this design and design guidance shared for information only (ref. [85]) shows how this learning has been translated into design guidance or requirements.

105. From a purely nuclear perspective, this review appears to be extremely comprehensive and looks to have been instrumental in informing the HFE guidance and requirements. However, for OPEX and LFE (Learning From Experience), the GB expectation (SAP MS.4) is to consider lessons from both within and outside the nuclear industry. I found no evidence of the consideration of extra-nuclear learning. This shortfall against expectations is minor and could be addressed under normal business. A future safety case will need to provide evidence that relevant extra-nuclear learning has been considered in the BWRX-300 design.

4.3.1.5. Standards, Codes, Methods, and Guidance

106. ONR's guidance on ALARP (ref. [60]) notes that "in many commonly-encountered situations it is understood what measures are needed to reduce a risk to ALARP and it is unnecessary to revert to a detailed, first-principles analysis".

107. On this basis, in the interests of proportionality, I have adopted a graded approach to my assessment and have focussed on those standards, codes, methods, and guidance that ONR is unfamiliar with, or are proprietary to this design.

108. In this section I assess the RP's approaches to:

- HFE design guidelines / requirements
- Allocation of Function Method

- target Audience Description
- task Analysis

Design Requirements and Guidance

109. ONR expects that workspaces should be designed to support reliable task performance and that suitable and sufficient user interfaces should be provided at appropriate locations to provide effective monitoring and control of the facility in normal operations, faults and accident conditions. (SAPs EHF.6 and EHF.7). To achieve this, the design should be informed by HF RGP guidance.

110. The RP describes, within the PSR, its suite of key design guidance documents (none of which were submitted for assessment during GDA. The first document was supplied for information only):

- BWRX-300 HFE Design Requirements Document;
- BWRX-300 Human System Interface Style Specification; and
- BWRX-300 Alarm Management Process Specification

111. The above documents are briefly summarised in the RP's Human Factors Engineering Design Support and Evaluation Summary Report (ref. [88]).

112. Whilst I have been unable to formally assess the RP's design requirements document, I am content, based on the material supplied for information only, and the suitability of supporting references to documents that have been submitted, that the RP is appropriately taking account of international RGP.

113. The HSI (HMI) specification covers the following topics and is also supported by a software object library for use in the development of software-based HMIs:

- control rooms
- local control and monitoring stations
- portable equipment, skid-mounted control panels or tablets
- computer-based procedures
- emergency response facilities
- process line (e.g., piping, ductwork) and equipment-mounted instruments
- maintenance, inspection, and test equipment provided by the RP
- simulator

114. The scope of the HSI (HMI) specification covers the areas of plant where the human contribution to risk is greatest, and I have no reason to doubt that the information contained within does not draw from the same HF RGP sources used throughout this project.

115. The Alarm Management Process Specification is based on the following recognised good practice, and when taken into context with the requirement for Integarted System Validation (ISV) trials that will test any alarms system efficacy, I have no reason to doubt that it cannot support the development of a suitable and suffiicent alarm system:

- IEC 62682:2014, Management of Alarms Systems for the Process Industries; and
- IEC 62241:2004, Nuclear Power Plants – Main Control Room – Alarm Functions and Presentation.

116. Further, ONR has also previously assessed many of the supporting references, as part of other GDAs, and during the GDA of the Hitachi-GE UK ABWR (ref. [89]), and found them to be suitable and sufficient.

117. The supporting references include the relevant HF IAEA guidance, NRC's HF NUREGs, and other requirements, defence standards, and various international standards recognised as RGP, all of which can be seen to influence the RP's HF design requirements.

118. I therefore have no reason to doubt that the HF requirements derived from this selection, cannot support a suitable and sufficient design.

119. The application of the RP's HF requirements and guidance are managed via a combination of stand-alone guidance, requirements management database, and coded into development tools, for example, the development software for the plant HMIs (ref. [22]). These apply to both the RP's design scope as well as the supply chain.

120. Requirements are split between process requirements, which relate to how the HFI process is delivered, and product requirements, which relate to the feature of the design necessary to support reliable human operation.

121. This process is not novel and generally aligns with processes used on previous GDAs, similarly aligning with NUREG and IAEA guidance. Any risks from these processes are typically revealed during the detailed application phase and detected via later verification and validation activities. These are activities beyond the scope of Step 2.

122. I am content that for Step 2, the RP has submitted sufficient material to demonstrate that the design will benefit from the application of HF RGP as it progresses.

123. A future safety case will need to formally submit the design requirements and guidance for assessment to demonstrate that it meets RGP and demonstrate that they have influenced the design to underpin the legal requirement that human error is reduced SFAIRP (So Far As Is Reasonably Practicable).

Allocation of Function Method

124. ONR expects (EHF. 2 ref.) that: "When designing systems, dependence on human action to maintain and recover a stable, safe state should be minimised. The allocation of safety actions between humans and engineered structures, systems or components should be substantiated." Allocation of Function (AoF) is also a clear expectation within IAEA guidance (Ref.)

125. AoF is a fundamental process within complex systems design and is done by systematically considering identified capabilities and limitations of humans and technology and their relative failure likelihoods separately or jointly in delivering a function. This is done with the aim of producing an optimal design solution for function delivery and thereby minimising failure risk to ALARP.

126. Traditionally, AoF has applied only to nuclear safety functions, but current RGP, and thus ONR's expectations (ref.), extend AoF to all functions. This is due to their interrelated and sometimes conflicting nature. An additional expectation is that whatever AoF methods are selected, they recognise that automation capability far exceeds what was previously possible on previous generation designs.

127. Thus, I would expect the RP to consider the following functions as a minimum:

- Operational
- Safety
- Safeguards
- Security – both Protective Security and Cyber
- Environmental

128. I would also expect (ref. [66]) that AoF determinations go beyond binary solutions and consider the human implications of too much automation, and the impact of automation failure on operating personnel. Thus, I expect decisions to balance the implications of automation failure as well as the expected benefits.

129. The RP's AoF methodology – not submitted for assessment – but summarised in the PSR (ref. [22]), is based IAEA and NUREG approaches (Refs IAEA-TECDOC-668 and NUREG/CR-2623). Both these methods are

now dated (being ~ 30 and 40 years old) and neither recognise the advances in automation technology that requires a more nuanced approach to human-technology teaming. For highly automated, active, plant designs, where operators are required to respond to the failure of automation, the lack of nuance in these approaches may introduce a design foreclosure risk.

130. However, in the BWRX-3000 design, which has a high degree of passive safety, and a design goal to enable a seven-day coping period without the need for significant operator interventions in the event of automation failure, the risk of design foreclosure is likely to be significantly lower. This, in combination with a robust design process, that aligns with NUREG 0700 and 0711, and culminates in Integrated System Validation trials, where automation failure effects are specifically tested, has the potential to deliver an optimised AoF solution. I am therefore content that for Step 2, the approach adopted is fit for purpose.

131. The RP's method only applies to nuclear safety functions. However, it is positive to note that the RP self-identified this shortfall and proposes two forward actions to address it: Consideration of security and environmental protection functions PSR18-166) and Allocation of local control functions and the design of the HMI for radioactive waste management PSR18-176.

132. For the non-nuclear safety functions, humans may need to take a more active role in ensuring that these are delivered. This may require enhancements to the RP's extant AoF methodology to recognise the non-binary nature of modern human-technology teaming and thus arrive at an optimised solution. A future safety case will need to demonstrate the adequacy of AoF across all the SSSE functions.

<u>Target Audience Description</u>

133. ONR expects (TAG 058 ref. [62]) that, for new-build projects, the physical, mental, cognitive, educational, and cultural characteristics of the intended user population are captured and used to inform the design.

134. The RP has not submitted a specific UK Target Audience Description (TAD), but much of the expected content of a TAD is split between:

- BWRX-300 Human Factors Engineering Concept of Operations (COO) (ref. [82]); and
- BWRX-300 Human Factors Engineering Design Requirements – submitted for information only (ref. [85])

135. As the design intent for the BWRX-300 is that it is standardised with minimal country specific variations, it is positive to note that the RP has developed a comprehensive anthropometric database, informed by the bounding data from country specific, and international, anthropometric studies. (ref. [82]). However, I did note during my assessment that the majority of the

anthropometric data sits within the COO and is not replicated in the working level HFE design requirements document. Dispersing important design information does increase the risk of key requirements being missed. This is a minor shortfall but is raised as it provides an opportunity for the RP to further optimise its HFE design requirements as the project progresses.

136. Additional data that would be expected (ref. [62]) in the TAD is either absent or includes simple commitment type statements rather than data. It is positive to note that the RP self-identifies the lack of TAD as a shortfall to address via its forward action plan (ref. [22] FA item PSR18-169).

137. At this stage of design maturity, the key anthropometric requirements are identified, which is the most important consideration when establishing the design of SSCs, layout and access / egress requirements. I consider the RP has established a suitable set of data, that recognises the international target market.

138. However, as the design matures, and detailed HMIs are developed, a future safety case will need to fully characterise the demographics of the user population expected to operate the design and demonstrate that these characteristics have been recognised within the design. Considerations should include.

- educational levels
- cognitive limitations and recognition of neurodiversity
- social stereotypes and secular cultural trends (for example, the changing relationship with technology types
- potential for secular growth trends noting the 60-year design life

4.3.1.6. HFI Conclusions

139. I consider that the RP has demonstrated that it has:

- A clear understanding of the enabling factors necessary to deliver a modern standards HFI programme;
- Established a proportional scope of HFI that meets regulatory expectations with respect to the applicable areas of the plant, the full scope of the SSE functions, the operational states, and the plant lifecycle; and
- Established a suite of HF guidance and methods, that are based on established and accepted RGP.

140. A future safety case will need to demonstrate that these methods, and the guidance, has demonstrably influenced the BWRX-300 design such that human error has been demonstrated to be reduced ALARP.

4.3.2. Concept of Operations

141. This section describes my assessment of the RP's work to date to establish a suitable concept of operations.

142. In line with my assessment plan, I consider whether the RP has:

- Established a concept of operations for the BWRX-300 design that reduces the risks from human error ALARP.

143. ONR expects (ref. [62]) that a Concept of Operations (COO) be submitted that describes:

- The operational purpose of the system, and the operational requirements under all conditions (normal operations, faults and accident conditions);
- The functions to be performed by the system and how the system is operating to achieve those functions;
- A consideration of the command-and-control philosophy – how is the system intended to be operated during normal operations, faults and accident conditions; and
- The outline staffing concept for the system and an indication of their required roles and responsibilities.

144. The BWRX-300 design implements the concepts of 'defence lines', of which there are 5.

145. Defence Line 1 (DL1) and Defence Line 5 (DL5) do not include performance of automatic plant control or automatic event mitigation functions. DL1 minimises potential for PIEs to occur in the first place and minimises potential for failures to occur in subsequent DLs. DL5 involves emergency preparedness measures to protect the public in case a substantial radioactive release does occur. Defence Line 2 (DL2), Defence Line 3 (DL3), Defence Line 4a (DL4a) and Defence Line 4b (DL4b) comprise plant functions that act to prevent PIEs from leading to significant radioactive releases.

146. The BWRX-300 design basis includes two top-level claims (ref. [77]) in section 3.1.6, which are key design drivers for the design, and highly relevant to my HF assessment:

- For any PIE (Postulated Initiating Event) or event sequence in the Anticipated Operational Occurrences or Design Basis Analysis event categories, fundamental safety functions can be performed and maintained for 72 hours without operator action. This claim is substantiated using conservative analysis techniques; and

- For any PIE or event sequence within the scope of the Coping Capability Sequence Selection process, the fundamental safety functions can be performed and maintained for 7 days without operator action. This claim is substantiated using best estimate or realistic analysis technique.

147. The RP is clear that additional human actions are not precluded, so accommodating this benefit into the design, just not necessary in the event of DB faults. The RP notes that early interventions may be beneficial to lessen the consequences of a fault and there may also be operational process benefits to manual operation.

148. This aligns with IAEA requirement 32 in SSR 2/1 Safety of Nuclear Power Plants: Design (ref. [67]) to limit the likelihood and the effects of operating errors on safety.

149. I would expect the operator role to be explored in detail across the COO and AoF documents.

150. The RP's COO is described in the BWRX-300 Human Factors Engineering Concept of Operations (ref [82]). The submission presents very high-level summary evidence around the following topics:

- operational and automation philosophy
- user group descriptions
- design concepts

151. Whilst it is positive to note that the COO specifically ties some of the philosophies and design features back to specific operational experience, demonstrating that the RP is taking account of design features or tasks that have proved problematic in the past, there are some shortfalls in expectations as set out in TAG 058 (ref. [62]).

152. It does not define a preliminary staffing concept for the design, although it does provide some high-level summaries for key roles.

153. I explored this topic further, and none of the submissions I assessed, for example Chapter 18 Human Factors (ref. [22]), Chapter 13 Conduct of Operations (ref. [9]), and responses to RQs 01745 Concept of Operations (ref. [90]and 01762 Human Contribution to Risk (ref. [91] provided any further staffing concept detail.

154. Whilst the staffing detail is often only provided during licensing, for SMR designs, if an RP is proposing novel staffing solutions – of which it is unclear at Step 2 – it is beneficial to de-risk the concept during GDA.

155. Given the role the operator plays in fault response (discussed below), the design basis affords a degree of flexibility here, so I do not consider this significant for Step 2, as the RP recognises this gap and has identified

forward action: PSR18-174, to validate staffing requirements and qualifications. A future safety case will need to substantiate the staffing model in relation to normal and fault states.

156. I would expect the COO and/or Chapter 15.4 Human Actions (refs. [82] [14]) to summarise, and characterise, the role of the operator beyond the high-level claims around human intervention not being required. However, I found this to be a shortfall in these documents, as they mostly focus on methods, rather than summarising evidence on what the operator does during normal and fault operations.

157. I explored this during my assessment of the suite of formal and 'information only' submissions, along with the use of RQ process, and was able to confirm that the shortfall within the PSR and COO is mostly presentational.

158. The RP's response (ref. [90]) to RQ-01745 'Concept of Operations' provides further detail on the role of the operator for normal operations, and explains that for most evolutions, the BWRX-300 Plant Automation System (PAS) does most of the plant control based on set-point inputs from the operators in control.

159. Further, the RQ-01745 response provides some examples of beneficial (but not credited actions) including manual rod control / scram or manual shutdown.

160. The RP explains (ref. [90]) the difference between credited and non-credited human actions as:

- Operator actions are not currently credited to mitigate fault sequences for events that comprise the Conservative DSA (for the first 72hrs);
- Operator actions may be credited (see paragraphs 157 and 158 for criteria) in complex scenarios involving multiple failures or in exceptional circumstances where automatic mitigation is not practical. This is work in progress and will be reported in a future version of the safety case;
- Operator actions may be credited in SAA scenarios. This is work in progress and will be reported in a future version of the safety case; and
- Operator actions may be reflected in the safety analysis to achieve Defence Line 1[2] measures, or to mitigate design basis hazard scenarios.

[2] Defence Line 1 includes the quality measures taken to minimise potential for failures and initiating events to occur in the first place and to minimise potential for failures to occur in subsequent lines of defence. These quality measures cover the design, construction, operation, and maintenance

- A description of non-credited actions will be provided in the Off-Normal Operational Concept Description (ref. [82]).

161. The RP notes that the HFE team are consolidating operator actions that are reflected in the safety analyses, primarily the Baseline DSA. These outputs are under development and were not available during the GDA assessment period.

162. The SSSE sets out the conditions under which human actions can be credited within the CCA comprise:

- Simple monitoring of key parameters without decision-making or further actions required in response can be claimed; and
- Simple "automatic" rule-based actions that are not part of mitigating the sequence can be claimed. These rule-based actions include:
    - Assessing the radiation environment in and around the plant in line with routine radiation protection assessment processes;
    - Response to personnel hazard alarms, including relocation to a protected, habitable area if personnel are located in an area subject to conditions that cause it to become uninhabitable; and
    - Communicating plant conditions routinely with required parties, including plant public address announcements and interfacing with security and external parties as required.

163. Exclusions include:

- Actions to provide back-up to failed automatic Defence Line functions;
- Actions to reconfigure a process system (start/stop pumps or fans, open/close valves or dampers); and
- Actions to reconfigure electrical systems (load shedding, reconfiguring of I&C equipment.

164. A future safety case will need to provide a more coherent picture of the actual role of the operator (both formally credited and beneficial) to more effectively demonstrate that the BWRX-300 has been designed to support reliable human performance of the credited and non-credited actions. It is

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of the plant. DL1 also includes the use of appropriate conservatism in design and analyses. Accident monitoring instrumentation supports functions in more than one DL and receives DL1 treatment by application of applicable industry standards for accident monitoring indication – GE-Hitachi, NEDO-34169- BWRX-300 UK GDA Chapter 7 – Instrumentation and Control, Revision B, July 2025, ONRW-2019369590-22414.

positive to note that the RP indicates that it recognises that further work is needed around non credited claims for 'off-normal' operations.

165. The lack of human intervention required for the first 72hrs of a DBA, (noting only one train of ICS may be left in service following a DBA), I view positively, as it provides significant contingency to plan for any human actions that may then be necessary post 72hrs. It also eliminates immediate post fault human actions that are typically less reliable due to time and stress factors.

4.3.2.1. Concept of Operations Conclusion

166. Overall, for Step 2, I am content that the RP has provided sufficient information characterising the Concept of Operations and the safety importance of the operator role on the BWRX-300 design for Step 2. Noting that the work is ongoing, the analysis to date (see also ONR's Fault Studies and PSA assessments (refs. [92] [93]) demonstrates a design that likely reduces the human contribution to risk further than existing operational designs. The commitment to further work in this area around the identification and substantiation of human actions (refs [14] [22]), the development of a staffing model, and the comprehensive HFE programme support this conclusion.

4.3.3. Allocation of Function and Substantiating the Role of the Operator (HRA)

167. This section describes my assessment of the RP's work to date to allocate functions appropriately across the sociotechnical system and substantiate the role of the operator.

168. In line with my assessment plan, I have considered whether the RP has/is:

- Appropriately allocating functional requirements across the socio-technical system;
- Identifying HBSCs effectively; and
- Effectively modelling the human contribution to risk[3].

169. ONR's assessment of the HRA is therefore, for this Step, mostly contained within the PSA assessment report (ref. [93]). For judgement on the representation of HEPs within the PSA, the reader is referred to ONR's PSA assessment report.

170. With respect to the safety role of the operator on a nuclear power plant, ONR expects that:

[3] 1. Due to the design and safety analysis maturity, I have not been able to sample individual HRAs or their supporting task analyses as they were not submitted for assessment.

- When designing systems, dependence on human action to maintain and recover a stable, safe state should be minimised. The allocation of safety actions between humans and engineered structures, systems or components should be substantiated (EHF.2);

- A systematic approach should be taken to identify human actions that can impact safety for all permitted operating modes and all fault and accident conditions identified in the safety case, including severe accidents (SAP EHF.3 ref. [28]). IAEA impose similar requirements, i.e., Requirement 32: Design for Optimal Human Performance (ref.) and Requirement 11: Assessment of human factors (ref. [67]);

- Proportionate analysis should be carried out of all tasks important to safety and used to justify the effective delivery of the safety functions to which they contribute;

- Human reliability analysis should identify and analyse all human actions and administrative controls that are necessary for safety (EHF.10); and

- *for all fast-acting faults (typically less than 30 minutes) safety systems should be initiated automatically and no human intervention should then be necessary to deliver the safety function(s)*; *Where human intervention is needed to support a safety system following the start of a requirement for protective action, then the timescales over which the safety system will need to operate unaided, before intervention, should be demonstrated to be sufficient* (SAP ESS.9); The dependence on human action to maintain a safe state should be minimised, *where reliable and rapid protective action is required, automatically initiated, engineered safety measures should be provided.* (ERL.3).

4.3.3.1. Allocation of Function

171. This section links to Section 4.3.1.5, which assessed the adequacy of the RP's AoF methodology. This section discusses the outputs from that process which have been shared to date.

172. The PSR does not present any summary substantiation evidence of the AoF process (noting that Chapter 18 does reference a non-submitted document (Functional Requirements Analysis, Allocation of Function and Task Grading Results Report for BWRX-300)

173. Therefore, it is not possible to make conclusive judgements during Step 2 regarding the RP's claim that "all functions have been derived and substantiated taking into account RGP and OPEX, and processes are in place to maintain these through-life" (ref [22]) is valid.

174. The suitability and sufficiency around AoF was explored via RQ-01745 Concept of Operations.

175. The RP's response (ref. [90]) (Appendix A) shows a high degree of operator-initiated automation on the BWRX-300 design for normal operations. For example, evolutions such as start-up (taking the plant critical / pressurisation and heat-up), synchronisation, turbine trip, cooldown and other normal operations are all either fully automated or are performed automatically from an operator commanded set-point.

176. As already discussed, No human intervention is required for the first 72hrs of a DBA, noting only one train of ICS may be left in service following a DBA. In less onerous faults where all 3 ICS trains may be put into service then up to 7 days may be available.

177. Although the RP has not submitted its rationale for the discrete task-level AoF decisions, ONR has previously assessed Hitachi-GE's approach to AoF for the Advanced Boiling Water Reactor (ABWR) during that GDA and found that the process provides "an appropriate allocation of function between personnel for the execution of safety actions" (ref. [89]). The approach used here for the BWRX-300 is based on the same methodologies, so I am confident that the AoF process can in due course deliver a suitable allocation that reduces human error risk ALARP.

178. Having looked at the allocation summary within the RP's response to RQ-01745 (ref. [90]), the preliminary allocations have face validity, as they are not dissimilar to other designs previously assessed during GDAs. Given that the human-system allocations will be tested during future ISV trials, I am content with the level information presented at Step 2.

179. I would also expect that any future AoF work explores the risks of too high a degree of automation on the situational awareness associated with plant states.

180. For step 2, I consider the degree of evidence sufficient to judge that the design is actively attempting to allocate functional requirements appropriately and minimise the risk of operator error. However, a future safety case will need to demonstrate, via the planned ISV trials (or via alternative means), the suitability of the BWRX-300 AoF decisions, and that they reduce the risk from human error ALARP.

4.3.3.2. Evidence of Identification and Substantiation of HBSCs (HRA)

181. This section describes my assessment of the RP's approach to the identification and representation of HBSCs within the safety analysis. The reader is advised to read this section in concert with ONR's PSA and Fault Studies assessment (refs. [93] [92]), as these assessments are complimentary in that they provide the wider context of fault tolerance for the BWRX-300 design.

182. Of key relevance is that ONR's PSA assessment assesses the adequacy of the human action modelling within the PSA, and whether the selected

Human Error Probabilities (HEPs) are appropriately best estimate, given the uncertainties created by the maturity of the design and supporting analysis.

183. The PSA assessment, on the adequacy of the RP's HRA and representation of human error within the PSA, concludes that there are shortfalls around the representation of Type A and B errors within the PSA and that there is a general lack of qualitative evidence at this stage supporting the HEP numbers. However, on the basis that the RP recognises this, and proposes a forward action to explicitly capture and model these error types, is content that the RP has done enough for Step 2.

184. Noting how few HBSCs are currently modelled, and the lack of submitted HEP substantiation, I have therefore focussed my assessment on the adequacy of the RP's process, and whether it has the potential to deliver the suitable and sufficient identification and substantiation of HBSCs as the project progresses, if implemented appropriately.

185. The status of the wider HRA was explored via RQs:

- RQ-01762 Human Contribution to Risk
- RQ-01964 Modelling of Human Reliability Analysis in the PSA

186. These supplemented the assessment of the relevant PSR chapters, for example Chapter 15.4 Safety Analysis – Human Actions (ref. [14]).

187. It is RGP (IAEA-SSG3, Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants Reference [94]) to categorise human errors as either of the following, which the RP does:

- Type A – Pre-initiator (human errors made during EIMT / commissioning activities;
- Type B – Initiator (human errors that lead to the initiating event for a plant fault); and
- Type C – Post fault (human errors made following the failure of an engineered system).

188. This includes the consideration of both errors or omission and commission within scope, and ONR also expects (ref. [65]) the proportionate consideration of violation induced faults based on qualitative analysis.

189. I can confirm that error Types A to C are included within the scope of analysis for errors of omission. The RP self-identifies (ref. [14]) that errors of commission are not currently considered and proposes the following forward action to address this shortfall.

- PSR15.4-187 Methodologies for analysing human actions to be revised to include consideration of errors of commission. [errors of commission are currently not modelled within PSA].

190. The RP also notes (ref. [14]) the current lack of treatment of dependency between error types so proposes the following forward action.

- PSR15.4-184 Methodologies to be revised to address human error dependency between Type B and Type C human actions.

191. A further omission (again self-identified (ref. [14]) is the lack of consideration of design induced violations. It proposes the following forward action to address this shortfall

- PSR15.4-189 The task analysis methodology and approach to HFE V&V should be revised to give consideration to the potential for design induced violations, for instance, whether task design is inefficient, such that operators could be motivated to seek more efficient ways of completing tasks.

192. The RP summarises the extant analysis of HBSCs within Chapter 15.4 of PSR (ref. [14]). I commend the addition of a discrete Chapter on this topic, beyond the IAEA expectations (ref. [69]), as it enhances the utility of the safety case and should it be expanded in the future to summarise the human contribution to risk, could provide a useful view of how important the role of the operator is on this design and where.

193. The RP is identifying HBSCs via, for example, the following:

- PSA
- DSA
- SAA
- allocation of Function analysis
- operational experience reviews
- task analytical methods (Hierarchical Task Analysis, Link Analysis, Timeline Analysis, Cognitive Workload Analysis)
- HFE which provides the vehicle to identify and address negative performance shaping factors
- verification and validation trials.

194. It is positive to note that these approaches are being deployed across all phases of the design life (ref. [14]) from construction through to decommissioning. This gives some confidence that a comprehensive suite of HBSCs should in due course be identified.

195. Determining the degree of analysis detail of HBSCs considers, for example, the following (ref. [14]):

- complexity of the action
- anticipated complexity and constraints of the Human-Machine Interface (HMI)
- complexity of the system
- frequency of the task
- physical environment
- cognitive environment
- novelty of the action, system, or HMI technology
- time sensitivity of the action

196. I consider this an appropriate approach for determining the relative importance and subsequent targeting of resource.

197. Where these approaches identify HBSCs, these are managed via the Human Safety and Reliability Claims Database (ref. [14]), which was not submitted for assessment during GDA. This made it difficult to confirm the extent of HBSC capture to date during Step 2 or the adequacy of the underpinning qualitative analysis.

198. However, I do not consider this prejudicial at Step 2 for several reasons:

- The RP has listed (albeit not submitted) 61 HFE workbooks, which include task analysis and cover many of the BWRX-300's safety systems. One workbook (ref. [85]) was provided for information, which I can confirm does contain detailed task analysis. It is therefore likely that the database includes the same information in relation to operator claims;
- The RP provided an example for information only of one of its task analyses which captures, inter alia, the expected: who, what, where, when, how, details;
- Safety of this design during fault conditions is not reliant on expedited human actions, it is reliant on passive safety features; and
- The SSCs supporting the successful deployment of the passive safety features are included within the HFE scope and are not finalised. A degree of SSC maturity is also required to generate HEPs as the detail on how EIMT is performed is required.

199. A future safety case would need to adequately demonstrate that the role of the operator has been considered. However, for the purposes of Step 2, I consider the RP has provided sufficient information, based on work being undertaken for the Darlington New Nuclear Project, that it has adequate consideration of this within its methodologies.

200. Within the database, I found that each HBSCs is graded as either:

- Category 1 - Human performance claims for human action credited in the DSA for event mitigation (e.g., task performance time) and associated assumptions;
- Category 2 – Human Error Probability (HEP) quantifications for human failure events modelled in the PSA and associated assumptions; and
- Category 3 – All other claims (e.g., assumptions regarding particular procedures or alarms, generally made to support qualitative human performance claims).

201. It is positive to note a graded approach to focus HF resources appropriately.

202. Where the analytical methods identify deficiencies in the engineering or task design, they are captured for sentencing via the RP's Human Factors Engineering Issues Tracking System (HFEITS) (ref. [22]).

203. The probabilistic modelling of human errors within the PSA follows the EPRI HRA calculator approach (ref. [14]). ONR has not assessed the validity of this method at Step 2, due to the disproportionate costs associated with acquiring it, and the maturity of the RP's HRA which does not justify this. ONR has also not previously carried out a detailed assessment of this method, so there is uncertainty about its validity, as I note that international studies (ref. [95]), for example, NUREG-2127 have found weaknesses around:

- The treatment of diagnosis;
- Time-related performance shaping factors – the method uses time-reliability curves, which are not considered valid as having longer to respond may not equal better reliability if the cues required to correct an error are lacking in cogency and coherency; and
- A reduced set of performance shaping factors, which may not be adequate to identify important driving factors that influence crew performance.

204. Additionally, where ONR has assessed prescriptive and formulaic style HRA tools in the past (of which the EPRI HRA calculator is one example of this approach), it has found that they can confine, and sometimes undermine, the underpinning qualitative analysis, such that it is neither suitable or sufficient when it comes to being able to effectively influence the design.

205. The holistic application of this tool, and how it is supported qualitatively, would need be demonstrated in the future BWRX-300 case. However, for Step 2, and given the limited inclusion of HRA within the PSA, I am content with its use to rapidly populate the PSA for screening purposes at this stage. There are benefits to having an early conservative HRA in the development of a new reactor as it supports the risk-informed targeting of HF resource.

206. A future safety case will need to demonstrate that all HEPs are underpinned by suitably detailed qualitative analysis, and that this analysis is informing the design.

207. I note positively, the self-assessment carried out by the RP of its HRA, which notes the following, and commits to addressing these shortfalls during the PCSR / site-specific stage:

- PSR15.4-183 Methodologies to be revised to address [shortfalls in the extant treatment of] human error dependency between Type B and Type C human actions;
- PSR15.4-185 The approach to determining the risk significance of Category 2 Human Safety and Reliability Claims [HBSCs] should include measures of risk significance that are not influenced by the HEP [the current approach only uses Fussell-Vesely without consideration of other risk-importance factors];
- PSR15.4-187 Methodologies for analysing human actions to be revised to include consideration of errors of commission. [errors of commission are currently not modelled within PSA]; and
- PSR15.4-188 Methodologies for analysing human actions to be revised to explain and justify the use of the cognitive models within the EPRI HRA Calculator in relation to screening and task analysis. [This addresses the gap in RGP in the EPRI HRA calculator regarding the use of time reliability curves].

4.3.3.3. Representation of HBSC’s Within the Fault Schedule

208. The RP claims (ref. [91]) that there are currently no HBSCs credited within the fault evaluation to deliver the defence line functions which bring the reactor to a controlled state. De-emphasising the role of the operator during this critical phase significantly reduces the risk of human error (noting that not crediting does not preclude human interventions).

209. It is positive that the RP recognises that the safety analysis is ongoing and may identify the need to credit HBSCs to achieve a safe stable state (sub critical with a long-term cooling function established) (Forward Action PSR15.5-38 (ref. [15]).

210. I have not assessed the RP's approach to Severe Accident Analysis (SAA) modelling as it is too early to do so at Step 2 (noting the SAA methodology was not available within Step 2 timescales). However, I note positively that the SAA will include (ref. [15]): a summary of insights into important human actions for consideration during development of accident management procedures and that severe accidents are included within the scope of the HFE programme (ref. [22]).

211. At this stage it is not possible to confirm whether the current lack of DSA / SAA HBSCs will remain the case as the safety analysis matures, therefore a future safety case will need to demonstrate any role that the human plays in prevention or mitigation within DSA and SAA.

4.3.3.4. AoF and Substantiation Conclusions

212. Overall, I am content that the RP has demonstrated it:

- Is developing a design where the HFE design process is actively seeking to limit the risk from human error;
- Understands the importance of optimised functional allocation, and is integrating this into the design process;
- Has a process for the identification and substantiation of human actions, and has shown evidence of progress in this area in support of the HFE process; and
- Has been reflective on its HRA work to date, and what is required in the future to fully meet RGP. It has proactively proposed a number of forward actions to address where the HRA, and scope of HBSC substation, does not currently meet RGP.

213. Any shortfalls against RGP identified above are indicative of the design and safety analysis maturity and could be addressed under normal business by a future safety case.

4.3.4. Human Factors Engineering

214. This section describes my assessment of the RP's application of HFE across the BWRX-300 design. I have focussed my assessment on confirming that HFE is being applied appropriately across the design, and on areas where the design is novel in comparison to previously assessed reactor designs.

215. ONR expects that, for the design of workspaces and HMIs:

- Workspaces in which operations (including maintenance activities) are conducted should be designed to support reliable task performance. The design should take account of the physical and psychological characteristics of the intended users and the impact of environmental factors (SAP EHF.6.); and
- Suitable and sufficient user interfaces should be provided at appropriate locations to provide effective monitoring and control of the facility in normal operations, faults and accident conditions (SAP EHF.7.).

216. IAEA imposes similar requirements via Requirement 32 Design for Optimal Human Performance (ref. [67]) and provides specific guidance on HFE design in reference [73] (which ONR's HFE related TAGs take account of).

217. The BWRX-300 has several control locations:

- Main Control Room (MCR)
- Secondary Control Room (SCR)
- Emergency Response and Support Facilities
- Radwaste Building Control Room or Control Stations
- Local Control Station interfaces
- Equipment- and process line-mounted interfaces (e.g., control actuators and gauges)
- HMIs related to auxiliary and support facilities external to the main reactor and powerhouse buildings (e.g., hydrogen tanks or fuel oil supplies)

218. It is positive to note that these are all included (ref. [22]) within the declared HFE program scope and as such, they align with ONR expectations.

219. The key HMI and workplace focus for my assessment was the MCR and the SCR as they are the two most developed parts of the wider design, they are also, arguably, the most complex HMIs and therefore a useful measure of the RP's HFE capability.

220. The primary locus of control and monitoring is the main control room (MCR) situated within the Control Building.

221. If the MCR becomes uninhabitable, or control and monitoring becomes untenable due to MCR HMI failures, a Secondary Control Room (SCR) is provided within the Reactor Building.

222. The HMI detail in both these locations (at the time of assessment) was sparse, which is not unusual at Step 2, is indicative of the early stages of design, and has not impacted my regulatory judgements around fundamental viability.

223. To provide confidence that it is following good practice in the area of HMI design, the RP submitted BWRX-300 Human Factors Engineering Baseline 1 Testing and Evaluation Report (ref. [96]). This submission describes an example of the RP's iterative (A / B comparison) approach to the design, testing and evaluation of HMIs.

224. This submission described a comprehensive, and data-rich, test and evaluation programme, that meets sufficient regulatory expectations for Step 2 (use of target audience participants, tests an appropriate range of HMI features, use of real operational and fault scenarios, and use of design-phase appropriate data collection tools (e.g. a focus on obtaining usability feedback)).

225. It also demonstrated that the test programme was identifying HF issues for future resolution, as the development programme continues.

226. Included within the submission were some example HMI screens, which I consider align with good practice HMI design principles: e.g. simple and clear object designs and layout, without excessive clutter, sparing use of colour, no 3D shading or animation to cause distractions. Should HMI designs continue to evolve along the lines presented in this submission, I see no major challenges to developing a safe and operable HMI design.

227. The concept for both the BWRX-300 control locations is broadly similar (with respect to HMI provisions, staffing, and layout) to those designs previously assessed by ONR during other GDAs. This is because the BWRX-300 control locations are informed by similar US and International standards and guidance (e.g. IAEA, NUREGs and EPRI). These standards and guidance have previously been assessed, and judged to be broadly acceptable, to deliver fit for purpose control room designs.

228. The BWRX-300 Safety Strategy (ref. [77]) claims the design will reduce the reliance on human actions following a PIE. The BWRX-300 is designed such that the fundamental safety functions are delivered for any PIE or event sequence in the AOO or DBA event categories for 72 hours with no operator action. Further, those PIEs within the coping capability sequence selection process are supported for 7 days with no operator actions.

229. Given the design maturity of the control locations, and the acceptability of the standards and guidance driving these design aspects, and the confidence offered by the early HMI testing submission, I have therefore focussed the rest of my assessment on where there are areas of novelty for the UK.

230. These areas of MCR / SCR design include:

- The lack of class 1 instrumentation within either location;
- The MCR location having lower seismic protection than the SCR due to the choice of location; and
- The use of SC3 class HVS for the MCR to ensure habitability.

4.3.4.1. Safety Classification of HMI

231. The primary means of interacting with the plant from either MCR / SCR location is via an SC3 class, screen-based HMI. In the event of the SC3 class HMI failure, additional control functionality is provided via the co-located diverse SC1 PPS, which provides hard-wired controls for the manual initiation of the following critical safety functions:

- Hydraulic Scram Function
- Isolation Condenser System Function
- Reactor and Containment Isolation Functions
- Isolation Condenser Isolation Function

232. This concept sufficiently aligns with the philosophy of previously assessed (and judged to be acceptable) designs (including the previous ABWR design), so I consider this an appropriate approach. However, there is divergence around confirmation that a safety system has initiated. Whilst the controls are SC1, there is no commensurately classified indication, which may fail to meet the expectation of SAP ESS.13 (confirmation to operating personnel). The HMI maturity does not support a conclusive judgement at Step 2.

233. The absence of a high integrity display, or indication, is novel in the UK. High integrity indications of key plant parameters are usually claimed to support the operator to maintain situational awareness of the state of the plant in an event and to positively confirm that the safety systems have initiated and achieved their safety functions, aligned with SAP ESS.13 (confirmation to operating personnel) and EHF.7 (user interfaces). Such indications also support the operator to maintain the safety systems by applying operational bypasses for testing and calibration.

234. While the objective to reduce reliance on human actions is aligned with the engineering hierarchy of controls set out in SAP EKP.5 (safety measures), GVHA and any future GB developer will need to justify the classification of displays once all human actions are identified in response to events and to maintain the safety systems. Cyber security assessments should also consider how compromise of the SC3 displays could result in the operator either falsely initiating safety functions when not required or failing to take actions when required (spoofing).

235. To conclude, given the design maturity of the MCR / SCR HMIs and their underpinning safety case, and the fact that the work on identification of human actions is ongoing, it is not possible to give a definitive judgement on the acceptability of the lack of Class 1 indication of safety system initiation at Step 2. However, I do not consider that, should the continuing analysis identify the need for SC1 indication, this poses an irresolvable engineering challenge, so I am content at this stage.

4.3.4.2. MCR / SCR Location

236. The BWRX-300 spatially segregates the MCR and SCR between the Control Building (Seismic Category 2) and the Reactor Building (Seismic Category 1A) respectively. Whilst this may offer benefits by separating the MCR from internal reactor building hazards, it is situated within a location that features a lower level of seismic withstand than the Reactor Building. It is typical in modern NPP designs that both the MCR, SCR, and linking route share the same degree of hazard protection, to maximise the survivability of the MCR operators, and enable the evacuation from one to the other. This lower level of seismic withstand may be inconsistent with the expectations of Requirement 65 in IAEA SSR-2/1 (ref. [67]), which requires the control room to be operable in all operational states and from which measures can be taken to maintain the plant in a safe state, or to bring it back into a safe state after anticipated operational occurrences and accident conditions. Given the reduced reliance on the operator for DB faults, and thus the MCR, such an inconsistency with IAEA requirements may be justified. A future safety case would need to make this demonstration.

237. The underpinning justification behind this novel approach was explored via RQ-01883 MCR-SCR location (ref [97]).

238. The RP argued that this was acceptable based on:

- Optioneering: During the early design optioneering (DEC-000007 Main and Alternate Control Room Locations) “no compelling case could be made which would disqualify the planned [e.g. MCR within the CB] configuration” (ref [97]). However, this optioneering analysis was not supplied by the RP for assessment so I am unable to comment on whether the optioneering adequately considered Requirement 65;

- Safety strategy and analytical basis: BWRX-300 Safety Strategy (ref. [77]) requires that "for any human actions claimed within the various safety analyses, and for required monitoring of plant parameters, the design ensures that a habitable location is available and accessible during the associated event conditions. This applies across all Anticipated Operational Occurrences (AOOs), Design Basis Accidents (DBAs), and Design Extension Conditions (DEC) category event sequences." Demonstration of meeting this strategy will be provided by Habitability and Operability Analysis (CRHOA), which has yet to be performed; and

- Design: The RP recognises that an important outcome of the CP-03-100-G330 Technical Review (ref [97]) was the identification of the requirement "to protect the on-shift operating crew from incapacitating injury, even in events which functionally disable the MCR, such that the crew can then transfer to the SCR to conduct accident response."

239. In this response, I do not consider that the RP has yet provided a suitable and sufficient demonstration that the MCR location, and the evacuation route to the SCR, are suitably protected against DB seismic or air crash events, and thus habitable.

240. However, I note that future analysis – The discussed CRHOA study – has yet to be performed, and the RP states that: "In the event that this analysis cannot demonstrate availability of a habitable and operable control room for one or more design basis scenarios, additional analysis, redesign and/or regulatory exception would need to be pursued, as appropriate." It is positive to note that the RP recognises the possibility of a shortfall and does not foreclose the design.

241. To conclude, I have not identified any fundamental shortfalls in the MCR/SCR concept. However, the RP has not fully demonstrated the suitability of the MCR/SCR locations and their habitability at Step 2, so this will need to be substantiated in a future safety case.

4.3.4.3. MCR / SCR Heating and Ventilation System

242. ONR expects that workspaces support reliable task performance (SAP EHF.6.).

243. The RP has designated the MCR / SCR HVS as SC3 and SC2 respectively, which is relatively novel, as the importance of MCR / SCR habitability, post fault, has often required the supporting HVAC systems to be designated as Class 1. This is usually because of the requirement for long-term occupation for control and monitoring purposes. The BWRX-300 reduces the reliance on the operator post fault so the extant HVS design may be appropriate.

244. However, the safety analysis maturity in relation HRA, and categorisation and classification work, does not currently support a definitive judgement on the acceptability of the HVS at Step 2. I have discussed the topic of HVS

classification with ONR's mechanical engineering inspector, and they have provided confidence that because the HVS features no novel components and there is sufficient scope for scaling, that even if further safety analysis or CRHOA study identifies the need for change to safety classification, there is scope to do so. The RP even notes that CRHOA study results have the agency to influence the design if judged necessary.

245. I am therefore content that the novelty in the HVS design – with respect to habitability – does not pose an unacceptable design foreclosure risk at this time.

4.3.4.4. HFE In Equipment Design

246. ONR expects (ref. [61]) that a safety case "demonstrate that the facility conforms to relevant good engineering practice and sound safety principles".

247. Whilst it cannot be expected that a PSR fully meets this requirement, ONR does expect that the PSR provide a - project maturity appropriate - degree of detail that demonstrates that the design is meeting RGP.

248. Whilst the RP claims that the scope of the BWRX-300 Human Factors Engineering Program Plan (ref. [81]) is whole plant, which I consider aligns with RGP, The RP's PSR (ref. [22]) falls short of evidencing this claim as Section 18.5 Design Implementation, excludes it from the scope of Step 2: "The content of this PSR chapter reflects the level of maturity of the HFE Program, plant design, and safety analyses at the time of submission and the scope of a GDA Step 2 PSR. This technical element, which describes the implementation of the HFE design requirements in the final realised design is outside the scope of the GDA Step 2 safety case." This shortfall was explored via RQ-01747 (ref. [98]), and my wider assessment of submissions, to understand whether this is a reporting gap or a significant shortfall against expectations of a GDA.

249. In the response to the RQ (ref. [98]), the RP explained that it is a formal requirement of the project design process that for each Main Plant List (MPL) item (MPLs essentially provide a scope boundary for the major plant systems) to have an associated HFE workbook if the SSC has operating or maintenance considerations. The RP confirmed that 61 workbooks have been developed to date, which include a range of nuclear and non-nuclear systems. These are typically at preliminary or development status, which is appropriate for a maturing design.

250. The RP elected not to submit these for assessment[4], so has not taken the opportunity afforded by the GDA to de-risk its ongoing working level HFE design activities.

[4] An example workbook on fuel pool cooling and clean-up was provided for information only, which does provide evidence of a significant amount of HF work being undertaken.

251. Instead, the RP submitted a summary report: Human Factors Engineering Design Support and Evaluation Summary (ref. [88]). This describes HFI in the following areas:

- HF issues identified to date – 50 resolved and 155 open;
- Control and Instrumentation supporting the development of AoF and automation strategy along with HFE lead activities on the design of the MCR / SCR and HSI (HMI) testing platforms to support future V&V activities;
- Plant integration and Layout, during which it is positive to note that HF support identified 54 points of feedback around: adequate spacing for the performance of tasks; missing/unlabelled areas; layout non-compliances; environmental non-compliances; challenges to ingress and egress; safety issues;
- Means of Ingress and Egress; and
- Safety Concerns.

252. General plant layout considerations accommodating HF requirements are not subject to the MPL – HFE workbook process as they span multiple systems and areas. Instead, the requirement to manage adequate space allocation around SSCs, access / egress, though-life replacement of equipment, and efficacy of evacuation routes, is managed via CAD assessment.

253. It is positive to note that the RP recognises the importance of adequate space allocation around SSCs, access / egress, though-life replacement of equipment, and efficacy of evacuation routes. The RP evidenced this via a demonstration (ref. [99]) of the way it manages and allocates internal space using a combination 3D CAD model and percentile mannequins to review contested areas. The RP highlighted areas where deficiencies were identified and compromises in layout sought to accommodate HF spatial requirements.

254. It was clear during this demonstration, that the RP has been, and is proactively managing space allocation to ensure that operators and their equipment can effectively navigate and interact with the plant for EIMT and through life replacement activities.

255. The RP also recognises (ref. [87]) the importance of EIMT in a design where reliable technology is fundamental to extended coping capability. As such it has established its RAMI programme (Reliability, Availability, Maintainability, and Inspect-ability), which takes a risk informed approach to those SSCs that are critical in delivering fundamental safety functions and ensures that they are optimised for EIMT (RAMI). It is evident that the HFE programme is integral to this programme, which I consider aligns with RGP.

256. Overall, I consider that RP has provided sufficient evidence (when also taking into account declared forward actions) to demonstrate the credibility of its HFE programme. However, evidence of application submitted was minimal and a future safety case will need to proportionately demonstrate that the BWRX-300 design meets HF RGP across the SSSE functions, plant life cycle and operational states.

4.3.4.5. HFE In Decommissioning

257. ONR expects that facilities should be designed so that they can be safely decommissioned (SAP DC.1). This aligns with IAEA safety requirement 12 - Special consideration shall be given at the design stage of a nuclear power plant to the incorporation of features to facilitate radioactive waste management and the future decommissioning and dismantling of the plant.

258. The RP did not submit any specific HFE in decommissioning examples, but I was able to confirm (via the BWRX-300 HFE engineering design requirements [85]) that the RP's general HFE requirements extend to considering them during design for decommissioning, although there are no specific requirements.

259. Further, I was unable to identify any operational experience or learning related to decommissioning of previous BWR designs. I consider this a shortfall against regulatory expectations (MS.4).

260. At Step 2, whilst the RP has indicated that decommissioning is within the HFI scope, it has failed to provide sufficient evidence that HFE is being systematically integrated into the design to support decommissioning activities. This lack of evidence, combined with RO-BWRX300-003 (ref. [100]) on this topic, means that whilst it is positive that RP does recognise HF has a role to play in decommissioning, I cannot be confident it has developed a suitable and sufficient approach for integrating HF into this area of the BWRX-300 design process as yet.

261. ONR has raised to RO-BWRX300-003 (ref. [100]) to capture the general shortfalls in the RP's design for decommissioning process and requires it to provide assurance that it will address them and provide assurance that the future risks from decommissioning are reduced ALARP. I consider that this RO, should the RP ensure that all stakeholder disciplines are represented in the solution, adequately addresses the HF elements in this shortfall.

4.3.4.6. HFE Conclusions

262. Overall, I am content that the RP has adequately demonstrated that HFE is being considered as part of the wider design process. Enabling factors for HFI are in place (section 4.3.1), the HFE guidance is comprehensive and aligns with RGP, being based on accepted industry standards and approaches (section 4.3.1.5), and that HFE work is being proportionally applied (will be applied) across the entire plant and across the SSSE functions (this section and the forward actions proposed by the RP). Further

work is however required to demonstrate that the HFE programme is informing the design for decommissioning.

263. A future safety case will need to proportionately demonstrate that the BWRX-300 design meets HF RGP across the SSSE functions, plant life-cycle and operational states, and that the HFE work supports the reduction of human error ALARP.

5. Conclusions

264. This report presents the Step 2 HF assessment for the GDA of the BWRX-300 design. The focus of my assessment in this step was towards the fundamental adequacy of the design and safety case. I have assessed the SSSE chapters and relevant supporting documentation provided by the RP to form my judgements. I targeted my assessment, in accordance with my assessment plan (ref. [32]), at the content of most relevance to Human Factors against the expectations of ONR's SAPs, TAGs and other guidance which ONR regards as relevant good practice.

265. Based upon my assessment, I have concluded the following:

- I did not identify any fundamental HF shortfalls that could prevent ONR permissioning the construction of a power station based on the BWRX-300 design, should the design develop in-line with the declared HF requirements and methods;
- I note positively that the design of the BWRX-300 is intended to reduce the significance of human error during normal and fault operations in comparison to older reactor designs. No human intervention is required for the first 72hrs of a DBA, noting only one train of ICS may be left in service following a DBA. In less onerous faults where all 3 ICS trains may be put into service then up to 7 days may be available. For normal plant operations, the design features a high degree of automation. These claims will need to be fully validated as the design and safety case matures;
- I judge that the RP has established an HFE programme that aligns with international good practice, with some minor exceptions. The scope considers all lifecycle phases, all areas of the plant, and all normal and fault operations. It is positive to note that the RP identifies that the current scope does not entirely meet GB regulatory expectations for Environmental, Security and Safeguards functions within its HFE programme and provides forward actions to address these shortfalls;
- I judge that the RP has demonstrated a competent HF capability and an understanding of what is required organisationally to deliver an effective HFE programme. However, a future safety case would need to demonstrate suitable and sufficient resource to deliver the broad scope of HFE on a modern NPP;
- The RP's HFE methods, requirements and guidance align with international good practices and appear to be being applied in a targeted and proportionate manner. There is a high degree of alignment in method type, and guidance sources, to those methods and guidance applied during previous successful GDAs;

- I judge that the RP has conducted a thorough review of nuclear operational experience, and there is evidence of this being translated into design requirements and guidance;

- The representation of HRA within the PSA is currently immature and lacks suitable representation of Type A and B errors, and errors of commission. The RP notes this and has committed to address this shortfall as a forward action; Further, whilst the RP has conducted task analysis, this has not been submitted for assessment so there is no current formal underpinning for the modelled HEPs. A future safety case would need to substantiate that any HEPs used within the PSA are best estimate, either via qualitative task and error analysis or via simulation; and

- The wider HF SSSE case lacks evidence of application of the declared HFE programme to fully support the PSR claims around integration. The HF topic is presented predominantly across two PSR chapters (18 and 15.4), and these chapters contain very little summary evidence of the application of HFE. It was apparent that more evidence exists than was submitted for assessment, in this area. However, I do not judge this to be a fundamental shortfall as it is for the RP to determine what evidence is to be submitted for regulatory assessment. I have been able to assess sufficient evidence for Step 2 from the formal submissions and evidence shared for information only, to conclude that: the RP understands the applicable modern standards and scope of HFE, and HF is influencing the design. A future safety case will need to expand upon the presentation of HFE evidence underpinning the claims of HFI. This is an expectation as part of demonstrating that human error risks are reduced ALARP.

266. Overall, based on my assessment, and subject to the provision and assessment of suitable and sufficient supporting evidence in either a future Step 3 GDA or during site specific activities, I have not identified any fundamental safety shortfalls that could prevent ONR permissioning the construction of a power station based on the generic BWRX-300 design.

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Appendix 1 – Relevant SAPs considered during the assessment

SAP reference	SAP title
MS.2	Capable Organisation
MS.4	Learning
EHF.1	Integration within design, assessment and management
EHF.2	Allocation of safety actions
EHF.3	Identification of actions impacting safety
EHF.5	Task analysis
EHF.6	Workspace design
EHF.7	User interfaces
EHF.10	Human reliability
EHF.11	Staffing levels
ECS.2	Safety classification of structures, systems and components
SC.4	Safety case characteristics
ESS.8	Automatic initiation
ESS.13	Confirmation to Operating Personnel
EKP 5	Safety Measures
DC.1	Design and Operation