Office for Nuclear Regulation

ONR Assessment Report

Generic Design Assessment of the BWRX-300 – Step 2 assessment of Management for Safety and Quality Assurance

ONR Assessment Report

Project Name: Generic Design Assessment of the GE--Hitachi BWRX-300 – Step 2

Report Title: Step 2 Assessment of Management for Safety and Quality Assurance

Authored by: Quality Specialist Inspector, ONR

Assessment report reference: AR-01602

Project report reference: PR-01880

Report issue: 1

Published: December 2025

Document ID: ONRW-2126615823-7060

Executive summary

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

This report presents the outcomes of my Management for Safety and Quality Assurance (MSQA) 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 2 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 case, 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 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 SSSE cases:

- Targeted Area 1. Organisational Capability and Capacity
- Targeted Area 2. Control of Documented Information
- Targeted Area 3. Design Control
- Targeted Area 4. Management of Safety Case Outputs
- Targeted Area 5. Quality Management Performance
- Targeted Area 6. Regulatory Processes

Based upon my assessment, I have concluded the following:

- Organisational capability and capacity, where sampled, was found to be adequately controlled and effectively maintained through the RP and the designers (GVHA) quality management system arrangements.
- Documented information, where sampled, was found to be adequately controlled and effectively maintained through implementation of the RP and the designers (GVHA) quality management system arrangements.
- The RP's quality management system arrangements, where sampled, were demonstrated as being adequately made and implemented to provide confidence in the processes for management of the design.
- The designers (GVHA) management system arrangements where sampled, were demonstrated as being adequately made and implemented to provide confidence in the processes for management of the design.
- The RP's quality management system arrangements, where sampled, were demonstrated as being adequately made and implemented to provide confidence in the management of processes for determining SSSE case outputs.
- The designers (GVHA) quality management system arrangements, where sampled, were demonstrated as being adequately made and implemented to provide confidence in the management of processes for determining SSSE case outputs.
- The RP and the designers (GVHA) management system arrangements, where sampled, provided confidence in the processes made and implemented for systematic quality governance and oversight of the GDA project.
- Regulatory processes, where sampled, were found to be adequately controlled and effectively maintained through the RP's quality management system arrangements.
- Chapter 17 provides an adequate and accurate description of applicable GDA management system arrangements.

Overall, based on my assessment to date 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; 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
BAT	Best Available Technique
BWR	Boiling Water Reactor
CNSC	Canadian Nuclear Safety Commission
DAC	Design Acceptance Confirmation
DEC	Design Extension Conditions
DRP	Design Reference Point
DRR	Design Reference Report
ESBWR	Economic Simplified Boiling Water Reactor
FAP	Forward Action Plan
GARP	Gap Analysis Review Panel
GB	Great Britain
GDA	Generic Design Assessment
GVHA	GE-Hitachi Nuclear Energy Americas LLC
GNF2	Global Nuclear Fuel 2
GSR	Generic Security Report
IAEA	International Atomic Energy Agency
INPO	Institute of Nuclear Power Operations
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
PA	Protected Area
PCSR	Pre-construction Safety Report
PER	Preliminary Environment Report
PIP	Project Implementation Plan
PSAR	Preliminary Safety Analysis Report
PSR	Preliminary Safety Report
RGP	Relevant Good Practice
RITE	Risk Informed, Targeted Engagements
RP	Requesting Party
RI	Regulatory Issue
RO	Regulatory Observation
RQ	Regulatory Query
SBWR	Simplified Boiling Water Reactor
SSSE	Safety, Security, Safeguards and Environment Cases
SAP	Safety Assessment Principle(s)
SQEP	Suitably Qualified and Experienced Person
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 Management for Safety and Quality Assurance (MSQA) assessment of the GE-Hitachi 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 GE-Hitachi's Safety, security, safeguards and environment cases (SSSE) head document [1], specifically chapter 17 [2], the associated revision of the Design Reference Report (DRR) [3] and supporting documentation.

2. Assessment was undertaken in accordance with the requirements of the ONR's Management System and follows ONR's guidance on the mechanics of assessment, NS-TAST-GD-096 [4] and ONR's Risk Informed, Targeted Engagements (RITE) guidance [5]. The ONR Safety Assessment Principles (SAPs) [6] together with supporting Technical Assessment Guides (TAGs) [7], 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-PER-GD-015) [8].

1.1. Background

4. The ONR GDA process [9] calls for an assessment of the RP's 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 Verona Hitachi Nuclear Energy International LLC United Kingdom (UK) Branch is the RP. GE Verona 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 MSQA [10]. 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 [11]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 [1] [12].

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 [13]. This is further supported by its DRR [3] and the Master Document Submission List (MDSL) [14]. 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 New Power Plant (NPP) design that is proposed for consideration in the GDA. The DRR provides a list of the systems, structures and components (SSC) 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 [4] and ONR's guidance on Risk Informed, Targeted Engagements (RITE) [5].

19. As appropriate for Step 2 of the GDA, detailed 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:

- Detailed quality management procedural arrangements for developing the safety case into a site-specific Pre-Construction Safety Report (PCSR).

20. My assessment has considered the following aspects:

- **Organisational Capability and Capacity** – The adequacy of the project organisation to demonstrate key quality roles have been and continue to be fulfilled by Suitably Qualified and Experienced Persons (SQEP), responsibilities between the RP and their technical support contractor (Amentum) are adequately defined and are being effectively maintained, and evidence that nuclear safety culture continues to be embedded with consideration of Operational Experience (OPEX) being used where relevant.

- **Control of Documented Information** – The adequacy of the approach taken to control documented information including clarity of records defining the design reference point, validity of the MDSL and adequacy of the implementation of the RP's process for checking, reviewing and approving GDA project documentation.

- **Design Control** – The adequacy of design control arrangements applicable to GDA including requirements management, design management (review, verification and validation) and design change management associated with the Design Reference Point (DRP).

- **Management of Safety Case Outputs** – The adequacy of the approach taken for reaching safety case outputs, including verification of inputs and validation of outputs and including the arrangements in place for capturing associated assumptions, requirements and commitements in the Safety Case.

- **Quality Management Performance** – The adequacy of the approach taken to making and implementing adequate arrangements for project quality performance evaluation including key performance indicators, internal audit

programmes, management of non-compliance and evaluation of the project management system overall effectiveness.

- **Regulatory Processes** – The adequacy of the approach taken to making and implementing adequate arrangements for regulatory processes including management of Regulatory Issues (RI), Regulatory Queries(RQ) and Regulatory Observations (RO).

2. Assessment standards and interfaces

21. 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 cases for the reactor technology being assessed.

22. 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

23. The ONR SAPs [6] 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.

24. The International Atomic Energy Agency (IAEA) safety standards [15] and nuclear security series [16] 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.

25. Furthermore, ONR is a member of the Western European Nuclear Regulators Association (WENRA). WENRA has developed Reference Levels [17], which represent good practices for existing nuclear power plants, and Safety Objectives for new reactors [18].

26. The relevant SAPs, IAEA standards and WENRA reference levels are embodied and expanded on in the TAGs [7]. The TAGs provide the principal means for assessing the Management for Safety and Quality Assurance aspects in practice.

27. The key guidance is identified below and referenced where appropriate within Section 4 of this report. Relevant Good Practice (RGP), where applicable, has also been cited within the body of this report.

2.1.1. Safety Assessment Principles (SAPs)

28. The key SAPs applied within my assessment are:

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

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

2.1.2. Technical Assessment Guides (TAGs)

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

- NS-TAST-GD-096 - Guidance on Mechanics of Assessment [4]
- ONR-GDA-GD-007 - New Nuclear Power Plants: Generic Design Assessment Technical Guidance [9]
- NS-TAST-GD-051 – The purpose, scope and content of safety cases [19]
- NS-INSP-GD-017 – Licence Condition 17 – Management Systems [20]
- NS-TAST-GD-049 – Licensee Core Safety and Intelligent Customer Capabilities [21]

2.1.3. National and international standards and guidance

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

- IAEA SSR-2/1 – Safety of Nuclear Power Plants: Design [22]
- WENRA Safety of New Power Plant designs [23]
- GSR Part 2 – IAEA Safety Standard GSR Part 2 – Leadership and Management for Safety [24]
- ISO 9001:2015 – Quality management systems – Requirements [25]
- IAEA Specific Safety Guide No. SSG-61 – Format and Content of Safety Analysis Report for Nuclear Power Plants [26]

2.2. Integration with other assessment topics

32. To deliver the assessment scope described above I worked closely with a number of other topics including the Environment Agency 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.

33. The key interactions with other topic areas were:

- Engineering – As a cross-cutting topic MSQA assesses the extent to which quality management system procedures have been adequately made and effectively implemented for facilitating design management, thus supporting the assessment of engineering design management outcomes.
- Fault Studies – As a cross-cutting topic MSQA assesses the extent to which quality management system procedures have been adequately made and effectively implemented for facilitating safety case management, thus supporting the assessment of safety case outcomes.
- Environment Agency - As a cross-cutting topic MSQA assesses the extent to which quality management system procedures have been adequately made and effectively implemented for defining design requirements, including environmental aspects, thus supporting the assessment conducted by the Environment Agency.

2.3. Use of technical support contractors

34. During Step 2 I have not engaged Technical Support Contractors (TSCs) to support my assessment of the topic aspects of the BWRX-300 GDA.

3. Requesting Party's submission

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

36. 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.

37. This section presents a summary of the RP's safety case for MSQA. 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

38. 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.

39. 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.

40. The BWRX-300 reactor core houses 240 fuel assemblies and 57 control rods inside a steel Reactor Pressure Vessel (RPV). It uses fuel assemblies Global Nuclear Fuel 2 (GNF2) that are already currently widely used globally.

41. 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.

42. As a cross-cutting topic, this MSQA assessment specifically focuses upon the adequacy of quality management system arrangements as defined in the RP's Project Implementation Plan (PIP) [27] and the extent to which they have

been demonstrated through evaluation as being adequately made and effectively implemented (including assessment of the designers (GVHA) arrangements where appropriate) in order to have confidence in design management outcomes and safety case outputs associated with this GDA.

43. This MSQA assessment is further informed through evidence supporting claims defined in Chapter 17 of the RP's SSSE [2], including adequacy of organisational capability and capacity, control of documented information and quality governance and oversight performance.

3.2. BWRX-300 Case Approach and Structure

44. The RP has submitted information on its strategy and intentions regarding the development of the SSSE [1] [28] [29] [30] [31] This was submitted to ONR during Step 1.

45. 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, and a Preliminary Environment Report (PER), and their supporting documents.

46. The format and structure of the PSR aligns with the IAEA guidance for safety cases, SSG-61 [26], 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 SA 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 Management of Safety and Quality Assurance

47. The aspects covered by the BWRX-300 safety case in the area of MSQA can be broadly grouped under headings which are summarised as follows:

3.3.1. Organisational Capability and Capacity

48. To provide confidence that adequate management system arrangements have been made and effectively implemented to facilitate design and safety case outcomes the RP demonstrated that key quality SQEP roles have been and continue to be fulfilled, responsibilities and accountabilities between the RP and their technical contractor (Amentum) are adequately defined and are

being effectively implemented and that nuclear safety culture continues to be embedded driven by OPEX where relevant. I noted that the RP did not specifically address ongoing capability and capacity post Step 2, although this was adequately demonstrated by the designer (GVHA) where sampled and considered during this MSQA evaluation.

49. The RP claims that its management system arrangements for the successful completion of GDA are defined within the PIP [27] with specific reference to section 2 and section 3, where arrangements for maintaining organisational capability and capacity are referenced.

50. The RP claims within Chapter 17, section 17.1.2 of the SSSE [2] that a core capability of staff is maintained to effectively control the BWRX-300 standard design.

51. Specifically, the RP claims that all personnel who are in a position of responsibility or authority are trained and suitably qualified, because they are accountable for any technical and licensing decisions made in support of GDA activities. Records are maintained documenting their competence assessment in accordance with the RP's arrangements to meet specific roles and responsibilities, including acting as an intelligent customer.

3.3.2. Control of Documented Information

52. To provide confidence that adequate management system arrangements have been made and effectively implemented to facilitate design and safety case outcomes the RP demonstrated that documented information is effectively managed to provide clarity of records defining the design reference point, adequacy and continued validity of the Master Document Submission List and evidence of the adequate implementation of the RP's process for checking, reviewing and approving GDA project documentation.

53. The RP claims that its management system arrangements for the successful completion of GDA are defined within the PIP [27] with specific reference to section 9, where arrangements for controlling documented information are referenced.

54. The RP claims within Chapter 17, section 17.2.3.2 of the SSSE [2] that it has utilised adequate document management interfaces and systems to ensure that deliverables are checked, reviewed and approved to effectively control the BWRX-300 standard design.

55. Specifically, the RP claims within section 5 of the PIP [27] that its common procedure CP-25-300 (New Power Plants Licensing Basis Document Development and Control Process) is adequately defined to facilitate the processes necessary for the development, issuance, updating and document control of licensing basis documents.

3.3.3. Design Control

56. To provide confidence that adequate management system arrangements have been made and effectively implemented to facilitate design control the RP demonstrated that design requirements are adequately defined, the design is adequately reviewed, design inputs are verified, design outputs are validated and design changes are effectively controlled.

57. The RP claims that its management system arrangements for the successful completion of GDA are defined within the PIP [27] with specific reference to section 11, where arrangements for design control are referenced.

58. The RP claims within Chapter 17, section 17.2.6 of the SSSE [2] that it has utilised adequate design processes to provide assurance that the final design is correct and in compliance with requirements and thus effectively control the BWRX-300 standard design.

59. Specifically, the RP claims that it controls the design processes along with associated design documentation to meet all applicable technical, regulatory and contractual requirements, and it incorporates the concept of defence in depth layers to achieve plant safety and protection of the public.

3.3.4. Management of Safety Case Outputs

60. To provide confidence that adequate management system arrangements have been made and effectively implemented to facilitate control of safety case outputs the RP demonstrated the approach taken for verifying and validating safety case outcomes and the arrangements for capturing assumptions, requirements and commitments in the safety case.

61. The RP claims that its management system arrangements for the successful completion of GDA are defined within the PIP [27] with specific reference to section 8, where arrangements for controlling safety case outcomes are referenced.

62. The RP claims within Chapter 17, section 17.2.8 of the SSSE [2] that it has utilised robust steps to provide assurance that the safety case outputs are adequately controlled in accordance with relevant good practice and thus are suitable and sufficient in support of the BWRX-300 standard design.

63. Specifically, the RP claims that is has documented processes and procedures for the production, verification, oversight, governance and control of SSSE reports, including robust steps for the checking, review and approval to ensure completeness and adequacy for the intended purpose.

3.3.5. Quality Management Performance

64. To provide confidence that adequate management system arrangements have been made and effectively implemented to facilitate control of design

and safety case outputs the RP demonstrated the approach taken for measuring and monitoring project quality performance including key performance indicators, an internal audit programme, management of non-compliance and management system effectiveness reviews.

65. The RP claims that its management system arrangements for the successful completion of GDA are defined within the PIP [27] with specific reference to section 13, where arrangements for project quality management including associated governance arrangements are referenced.

66. The RP claims within Chapter 17, section 17.2.10 of the SSSE [2] that the services of this project shall be provided in accordance with its quality assurance programme description [32] in support of the BWRX-300 standard design.

67. Specifically, the RP claims that its project quality performance arrangements, which include layers of quality oversight (including independent audits and surveillance, measuring key performance indicators and monitoring corrective action reports) are aligned to the designers (GVHA) Nuclear Energy Quality Assurance Programme Description and approved by US NRC.

3.3.6. Regulatory Processes

68. To provide confidence that adequate management system arrangements have been made and effectively implemented to facilitate control of design and safety case outputs the RP demonstrated the approach taken for effectively maintaining regulatory processes including adequate management of regulatory issues (RI, RO and RI).

69. The RP claims that its management system arrangements for the successful completion of GDA are defined within the PIP [27] with specific reference to section 6, where arrangements for regulatory interfaces are referenced.

70. The RP claims within Chapter 17, section 17.2.9 of the SSSE [2] that regulatory interactions are managed efficiently via the Regulatory Interface Office (RIO) and that a GDA delivery dashboard is maintained to ensure the health of each topic in support of the BWRX-300 standard design.

71. Specifically, the RP claims that its interface arrangements ensure that all interactions, communications and information exchanges between the regulators and the RP are properly defined and managed, including management of meeting agendas, export controls and meeting documentation and correspondence requirements.

3.4. Basis of assessment: RP’s documentation

72. The principal documents that have formed the basis of my MSQA assessment of the SSSE are:

- GE-Hitachi BWRX-300 UK GDA Project Implementation Plan [27]
- GE-Hitachi BWRX-300 UK Generic Design Assessment (GDA), Chapter 17 – Management for Safety and Quality Assurance [2]
- GE-Hitachi, NEDO-11209-A – Nuclear Energy Quality Assurance Program Description [32]

3.5. Design Maturity

73. My assessment is based on revision 2 of the DRR [3]. The DRR presents the baseline design for GDA Step 2, outlining the physical system descriptions and requirements that form the design at that point in time.

74. The reactor building and the turbine building, along with the majority of the SSC are housed with the ‘power block’. The power block also includes the radwaste building, the control building and a plant services building. For security, this also includes the PA boundary and the PA access building.

75. The GDA Scope Report [13] 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).

76. In the March 2024 design reference, SSC 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.

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

78. As a cross-cutting topic MSQA has been demonstrated as being mature through demonstration of an adequate PIP [27] primarily adopting the designers (GVHA) quality management system arrangements, which are certified by its external ISO accreditation to ISO 9001:2015. The RP has also adopted the designers (GVHA) Quality Assurance Program Description [32] which has been endorsed by US NRC.

4. ONR assessment

4.1. Assessment strategy

79. 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 MSQA 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 [33].

80. GVHA is currently engaging with regulators internationally, including the 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.

81. Whilst there is no operating BWR plant in the UK, ONR has previously performed a four-step GDA on the Hitachi-GE UK ABWR [34]. 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.

82. My MSQA assessment strategy [10] was to conduct monthly level 4 meetings with the RP in order to gather objective evidence of the extent to which project quality management system arrangements were effectively maintained in order to demonstrate control through suitable methodologies and thus the fundamental adequacy of the design and safety cases for the BWRX-300 standard design.

83. My MSQA assessment strategy included an evaluation based upon a sampling approach in order to gather objective evidence of the extent to which project quality management system arrangements were effectively implemented in order to demonstrate control through suitable methodologies and thus the fundamental adequacy of the design and safety cases for the BWRX-300 standard design.

4.2. Assessment Scope

84. 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.

85. 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.

86. 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 MSQA. 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.

87. My assessment scope included a sample of the designers (GVHA) arrangements where appropriate to ensure that the design process was adequate and to ensure that any learning from this GDA would be embedded into the appropriate procedural arrangements for this design.

88. In order to fulfil the aims for the Step 2 assessment of the BWRX-300, I have assessed the following items, which I consider important:

- Organisational Capability and Capacity – I assessed the extent to which the project organisation and the designer (GVHA) demonstrated that key quality SQEP roles have been and continue to be fulfilled, the evidence that responsibilities and accountabilities between the RP and their technical support contractor (Amentum) are adequately defined and effectively implemented and that nuclear safety culture continues to be embedded with consideration of relevant OPEX where relevant. This topic was jointly assessed with the Environment Agency who focused upon key environmental SQEP roles.

- Control of Documented Information – I assessed the extent to which the project organisation demonstrated clarity of records in defining the design reference point, adequacy and continued validity of the MDSL and evidence of the adequate implementation of the RP's process for checking, reviewing and approving GDA project documentation. This topic was jointly assessed with the Environment Agency who focused upon control of documented information supporting environmental claims.

- Design Control – I assessed the extent to which the project organisation and the designer (GVHA) demonstrated control of the design including design requirements, design verification and design change management. This topic was jointly assessed with the Environment Agency who focused upon control of design elements which support significant environmental aspects.

- Management of Safety Case Outputs – I assessed the extent to which the project organisation demonstrated control of safety case outcomes including the methods for verifying inputs and validating safety case outputs and the RP's arrangements for capturing assumptions, requirements and commitments in the safety case during and beyond Step 2. This topic was jointly assessed with the Environment Agency who focused upon control of the safety case elements which demonstrate Best Available Technique (BAT) and subsequently support the environmental safety case.

- Quality Management Performance – I assessed the extent to which the project organisation including the designer (GVHA) where applicable demonstrated adequate management system arrangements had been made and implemented

for quality performance evaluation, including evidence of measuring and monitoring key quality performance indicators, maintaining an internal audit programme, managing non-conformance and conducting project management system effectiveness reviews. This topic was jointly assessed with the Environment Agency who specifically focused on elements supporting evidence of the environmental management system performance.

- Regulatory Processes – I assessed the extent to which the project organisation demonstrated adequate quality management system arrangements were made and effectively implemented for managing regulatory issues (RI, RO and RI). This topic was jointly assessed with the Environment Agency who specifically focused upon the control of regulatory interactions relating to environmental topic matters.

4.3. Assessment

4.3.1. Organisational Capability and Capacity

89. I sampled organisational capability and capacity to determine the extent to which quality management system arrangements have been adequately made and effectively implemented.

90. I assessed the evidence presented by the RP with consideration of Safety Assessment Principle MS.2 (Capable organisation) [6] and IAEA Safety Standards GSR Part 2 [15], Requirement 9 (Provision of resources).

91. I noted from the outcome of my MSQA engagements during Step 1 [35] and subsequent routine engagements during Step 2 (including Level 4 MSQA Meeting 12) [36] that the maturity of the RP's management system procedures for maintaining organisational capability and capacity as defined within the PIP [27] Section 2 and 3 remained adequate and aligned with relevant good practice.

92. Specifically, I considered from my MSQA evaluation [37] that:

- The RP and the designer (GVHA) demonstrated that their latest organisational chart aligns to the current PIP, roles identified were filled and a structure was utilised, which supports intelligent customer capability.

- The RP and the designer (GVHA) demonstrated adequate control of processes for authorisation of GDA deliverables (including deliverables facilitated via their Technical Support Contractor) through the use of rules embedded within their document management system, which assigns SQEP persons to facilitate checks, reviews and approvals.

- The RP demonstrated via sampling how the use of role profiles and associated SQEP records are recorded, reviewed and systematically updated (such as to reflect a role change) to demonstrate capability.

- The designer (GVHA) demonstrated, where sampled, that country specific training requirements are identified and evidenced within individuals' SQEP records.
- The RP demonstrated, where sampled, that newly onboarded employees have clearly defined Line Management, a formal mentor/buddy system and follow a full face-to-face induction programme at the RP's headquarters (Wilmington, US).
- The RP demonstrated, where sampled, that formal mentoring is facilitated through the mentor/buddy designation system.
- The RP and the designer (GVHA) demonstrated, where sampled, that individuals' training requirements, including evidence of completion status are systematically monitored and adequately maintained.
- The designer (GVHA) demonstrated a strong nuclear safety culture, examples including adoption of the five Institute of Nuclear Power (INPO) technical conscience principles.
- The RP demonstrated that their subcontractors maintain processes for a positive nuclear safety culture which are reflective of and in accordance with the RP's nuclear safety culture.
- The RP and the designer (GVHA) demonstrated that lessons learned are adequately facilitated through their corrective action management procedure.
- The RP and the designer (GVHA) demonstrated that lessons learned are communicated efficiently and effectively (including with their Technical Support Contractor) via their management system arrangements.

93. I concluded that the information that has been submitted is consistent with my expectations, as set out in the Safety Assessment Principles MS.2 [6] and relevant good practice, namely IAEA Safety Standards GSR Part 2 [15] (Requirement 9). I am content that there are no fundamental shortfalls in MSQA, which would prevent the RP or the designer (GVHA) from further developing the generic BWRX-300 design and associated SSSE evidence to support any future permissioning activities for the construction of a power station based on the design.

4.3.2. Control of Documented Information

94. I sampled control of documented information to determine the extent to which quality management system arrangements have been adequately made and effectively implemented.

95. I assessed the evidence presented by the RP with consideration of IAEA Safety Standards GSR Part 2 [15], Requirement 8 (Documentation of the management system) and relevant good practice including BS EN ISO 9001:2015 [25] Section 7.5 (Documented information).

96. I noted from the outcome of my MSQA engagements during Step 1 [35] and subsequent routine MSQA engagements during Step 2 (including MSQA Workshop 9) [38] that the maturity of the RP's management system procedures for maintaining documentation as defined within the PIP [27] Section 9 remained adequate and in alignment with relevant good practice.

97. In addition, I noted that minor shortfalls (deviations from the prescribed procedural requirements for facilitating the DL and MDSL encountered through Step 2 of this GDA when detected were corrected systematically by the RP.

98. Specifically, I considered from my MSQA evaluation [37] that:

- The RP and the designer (GVHA) demonstrated, where sampled, that their document control arrangements continue to be adequately controlled and implemented.
- The RP demonstrated, where sampled, that the document process associated with managing the regulatory meeting tracker is adequately controlled and implemented.
- The RP demonstrated, where sampled, that the document process for managing the RQ tracker is adequately controlled and maintained, including valid version control of associated referenced documents.
- The RP and the designer (GVHA) demonstrated, where sampled, that the process for check, review and approval of documented information is being adequately controlled and implemented prior to communication of information via RIO/JPO.
- The designer (GVHA) demonstrated, where sampled, that validated records are available to support the DRP, which are traceable and readily retrievable in accordance with management system arrangements.
- The designer (GVHA) demonstrated, where sampled, that quality management system arrangements for configuration control of the design are adequately maintained through the use of reference tags embedded in drawings supporting the DRP, which trigger an update to the design reference if the drawing is updated to a newer version.
- The RP and the designer (GVHA) demonstrated, where sampled, that drawings supporting the DRP are revision controlled, referenced and authorised in accordance with quality management system arrangements.
- The designer (GVHA) demonstrated where sampled that its records are traceable and retrievable to support the DRP, configuration control of the design is adequately managed and drawings supporting the DRP are adequately maintained in accordance with its management system arrangements including CP-03-100 (Design Control) as referred within the PIP [27]

99. Following my recommendation the RP updated the Forward Action Plan (FAP) procedure (and referenced this update in the final Project Implementation Plan) to detail their systematic methodology for capturing and refining future commitments (such as commitments made in RQs) and ensuring that they are traceable and readily retrievable in the future.

100. I recommended the addition of a regulatory review stage within the updated procedure. This could mitigate the need for the regulators to raise ROs for FAP items in the future, where the regulator considers there is insufficient definition in the forward action. (This was not embedded as part of the final submission, instead the RP completed a review with a targeted group of assessors, where the changes to the FAP were considered significant). Consequently, the RP decided to proceed at risk, which I have considered during my MSQA assessment.

101. I concluded that the information that has been submitted is consistent with my expectations, as set out in IAEA Safety Standards GSR Part 2 [15] (Requirement 8) and relevant good practice including BS EN ISO 9001:2015 [25]. I am content that there are no fundamental shortfalls in MSQA which would prevent the RP or the designer (GVHA) from further developing the generic BWRX-300 design and associated SSSE evidence to support any future permissioning activities for the construction of a power station based on the design.

4.3.3. Design Control

102. I sampled design control to determine the extent to which quality management system arrangements have been adequately made and effectively implemented.

103. I assessed the evidence presented by the RP with consideration of IAEA Safety Standards SSR-2/1 – Safety of Nuclear Power Plants: Design [22], Requirement 2 (Management system for plant design) and IAEA Safety Standards GSR Part 2 [15], Requirement 10 (Management of process and activities) to determine the extent to which the RP's processes have been effectively managed and implemented without compromising safety.

104. I noted from the outcome of my MSQA engagements during Step 1 [35] and subsequent routine MSQA engagements during Step 2 (including MSQA Workshop 10) [39] that the maturity of the RP's management system procedures for maintaining control of the design as defined within the PIP [27] Section 11 remained broadly adequate and in alignment with relevant good practice.

105. During my MSQA evaluation [37] I assessed the designers (GVHA) process arrangements where appropriate, including management of design requirements, review, verification, validation, records and design change management.

106. I considered where sampled that the designers (GVHA) procedural arrangements ensure that records of design requirements are readily retrievable, the decision basis for review, verification and validation of design outputs are adequately controlled, and design changes are fully traceable and transparent in accordance with its management system arrangements including CP-03-100 (Design Control) as referred within the PIP [27].

107. Specifically, I considered from my MSQA evaluation [37] that:

- The designers (GVHA) management system arrangements to break down the design into individual segments, (at plant, system and component level) whilst assigning design requirements was demonstrated as being adequately controlled and effectively implemented, where sampled.

- The designers (GVHA) management system processes for defining UK specific requirements were demonstrated, where sampled, as being adequately recorded and referenced back to individual approved lines within their requirements management tool.

- The designers (GVHA) check, review and approval of design requirements were found to be adequately recorded, where sampled, within their document management system, including details of comments raised and closed out prior to final approval.

- The designer (GVHA) was able to demonstrate examples, where sampled, of US, Canadian and IAEA requirements, which aligned with UK specific requirements (including demonstrating that they have been defined, reviewed, approved and embedded as a record at the appropriate level) in accordance with their management arrangements for design control. Although the regulators understood that UK specific requirements would only be formally added should the UK project proceed and a specific baseline 3 UK design were to be developed.

- The designer (GVHA) demonstrated a graded approach for defining specific design verification methodology in accordance with their management system arrangements, where sampled, including individual, team, alternate calculation and qualification.

- The designer (GVHA) demonstrated traceability, where sampled, between design verification outcomes and the associated authorised requirement, in order to systematically inform and repeat design verification work if future design requirements change (such as to align with project or country specific requirements).

- The designer (GVHA) demonstrated that changes to the design specification, where sampled, are traceable and controlled and that the basis for verification and approval of design changes is captured adequately within the Design Basis Record (DBR) within their document management system. Although the justification for changes, where sampled, did not always explicitly discuss safety

and security benefits, appropriate SQEP persons were involved in the decision and follow on actions with recognition of the potential impact.

- The designers (GVHA) procedural requirements for identification screening (of potential design changes) and subsequent decision making were found to be adequately controlled through the change control board, with consideration of safety risk and cost, where sampled.
- The designers (GVHA) procedural steps for design decision making, where sampled, were found to include controlled steps for developing, reviewing, approving and implementing a solution, including assigning appropriate decision makers with consideration of risk and complexity.
- Design decision engagement and process flow, where sampled, (including records of relevant stakeholders) were found to be adequately captured within the RP's collaboration management tool (Confluence), where sampled, for design change.
- The designers (GVHA) formal classification of design change and associated authorisations were found to be adequately recorded, where sampled, within the Engineering Change Authorisation records in accordance with management system arrangements.
- The designer (GVHA) demonstrated, where sampled, how changes to the standard BWRX-300 design can be categorised through the use of common design elements, project/country specific elements and subsequent component specifications.
- The designer (GVHA) demonstrated, where sampled, that design requirements differing from the standard design are adequately captured at the appropriate (system, sub-system, component) level in their document management tool (PLM) as application datasheets.
- The designer (GVHA) demonstrated, where sampled, that management system arrangements for issues tracking are adequate to ensure that ongoing/open (future) design change actions are visible and transparent as document management (PLM) records, and can be made traceable to Forward Action Plans (FAP).
- The designer (GVHA) demonstrated, where sampled, that records associated with design requirements, review, verification, validation and design changes are adequately maintained and readily retrievable through their document management system.

108. I concluded that the information that has been submitted is consistent with my expectations, as set out in IAEA Safety Standards SSR-2/1 – Safety of Nuclear Power Plants: Design [22], Requirement 2 (Management system for plant design) and IAEA Safety Standards GSR Part 2 [15] (Requirement 10). I am content that there are no fundamental shortfalls in MSQA which would prevent the designer (GVHA) from further developing the generic BWRX-300

design and associated SSSE evidence to support any future permissioning activities for the construction of a power station based on the design.

4.3.4. Management of Safety Case Outputs

109. I sampled management of Safety Case Outputs to determine the extent to which quality management system arrangements have been adequately made and effectively implemented.

110. I assessed the evidence presented by the RP with consideration of IAEA Safety Standards SSR-2/1 – Safety of Nuclear Power Plants: Design [22], Requirement 3 (Safety of the plant design), IAEA Safety Standards GSR Part 2 [15], Requirement 10 (Management of process and activities) and IAEA Specific Safety Guide No. SSG-61 [26], Chapter 17 (Management for safety) to determine the extent to which the RP's processes have been effectively managed and implemented without compromising safety.

111. I noted from the outcome of my MSQA engagements during Step 1 [35] and subsequent routine MSQA engagements during Step 2 (including MSQA Workshop 11) [40] that the maturity of the RP's management system procedures for management of safety case outputs as defined within the PIP [27] Section 8 remained adequate and in alignment with relevant good practice.

112. Specifically, I considered from my MSQA evaluation [37] in regard to defined arrangements for developing safety case into a site-specific PCSR that:

- The RP provided an example upon which to base confidence from ongoing interactions associated with meeting Canadian Nuclear Safety Commission (CNCS) expectations, which included a commitments list utilised for capturing CNCS commitments. This was specifically demonstrated through an example associated with the Break Exclusion Zone, including its current process for logging forward actions and use of the Gap Analysis Review Panel (GARP) in order to determine the potential significance of a gap. This basis for confidence was found to be aligned with CNSC during a subsequent MSQA workshop [41].

- The RP demonstrated (although not for the Canadian example) how a regulatory action request is generated once a deliverable is agreed, which included the action owner, status, associated regulatory action and commitment reference.

- The RP confirmed that the commitments process is aligned and linked to the project plan and associated hold points and project milestones via a project schedule management tool in order to provide confidence in the management of future commitments in the pre-construction phase.

- The RP adequately demonstrated their management systems procedure for logging forward actions, including use of the Gap Analysis Review Panel (GARP) in order to determine the potential significance of a gap, where sampled.

113. Specifically, I considered from my MSQA evaluation [37] in regard to arrangements for maintaining the commitments and actions register that:

- The RP adequately demonstrated traceability between the RQ and the FAP item lines in both directions
- The designer (GVHA) provided confidence that records associated with FAP commitments, where sampled, are approved, traceable and retrievable through their document management system (during and beyond Step 2). An example was specifically sampled associated with diesel storage tanks (via RQ-1827), which demonstrated traceability between the RQ and the FAP item line in both directions including retrievability via the designers (GVHA) records management system.
- The RP demonstrated where sampled that the designers (GVHA) management system processes adequately maintain traceability between safety case outputs, which underpin design requirements, ensuring that alignment is maintained as the design develops and matures.

114. I recommended that the RP updates the FAP management systems procedure to robustly demonstrate alignment with the detailed controls demonstrated, including a regulatory interface to reduce the potential need for raising ROs to address commitments made within regulatory responses at a later date. The RP subsequently updated the FAP management systems procedure but to date have not added a regulatory interface, thus choosing to proceed at risk (which I considered during my MSQA evaluation).

115. I concluded that the information that has been submitted is consistent with my expectations, as set out in the IAEA Safety Standards SSR-2/1 – Safety of Nuclear Power Plants: Design [22], (Requirement 3) and IAEA Safety Standards GSR Part 2 [15] (Requirement 10). I am content that there are no fundamental shortfalls in MSQA which would prevent the designer (GVHA) from further developing the generic BWRX-300 design and associated SSSE evidence to support any future permissioning activities for the construction of a power station based on the design.

4.3.5. Quality Management Performance

116. I sampled Quality Management Performance to determine the extent to which quality management system arrangements have been adequately made and effectively implemented.

117. I assessed the evidence presented by the RP with consideration of Safety Assessment Principle MS.4 (Learning) [6] and IAEA Safety Standards GSR Part 2 [15], Requirement 13 (Measurement, assessment and improvement of the management system) to determine the extent to which the RP's processes have been effectively managed and implemented.

118. I noted from the outcome of my MSQA engagements during Step 1 [35] and subsequent routine MSQA engagements during Step 2 (including MSQA Workshop's 14 and 15) [42] [43] that the maturity of the RP's management system procedures for measuring quality performance as defined within the PIP [27] Section 13 remained adequate and in alignment with relevant good practice.

119. I took cognisance of the endorsement from the US NRC of the designers (GVHA) quality management programme description [32].

120. Specifically, I considered from my MSQA evaluation [37] that:

- The RP and the designer (GVHA) demonstrated that project quality management system procedures and processes continue to be adequately implemented and systematically measured and monitored in accordance with their procedural requirements and following a risk graded approach.
- The RP and the designer (GVHA) demonstrated, where sampled, that a defence in depth approach is adequately maintained for systematic measurement and monitoring of the quality management system effectiveness (including the processes and procedures utilised for managing the design and reaching safety case outcomes).
- The RP and the designers (GVHA) arrangements for recording, categorising and taken action to deal with corrective action reports were found to be adequate, where sampled.
- The RP's formal quality management system review outputs, where sampled, (including key performance indicators) were demonstrated as being systematically recorded and adequately communicated to relevant stakeholders in order to inform best practice and to drive improvements where appropriate.
- The RP demonstrated, where sampled, that the project internal audit plan continues to be adequately defined and effectively, including demonstration of a risk graded approach (including a forward focus upon design management).
- The RP's project internal audit plan was demonstrated as being conducted in accordance with the designers (GVHA) overarching quality assurance programme and was found to be following the designers CP-18-102 surveillance process internally and its CP-07-04 process for supplier surveillance as defined within the PIP [27].
- The RP demonstrated, where sampled, that surveillance reports are suitably detailed to inform stakeholders and that corrective actions are fully traceable through to completion and effective review.

121. I concluded that the information that has been submitted is consistent with my expectations, as set out in the Safety Assessment Principles MS.4 [6] and IAEA Safety Standards GSR Part 2 [15] (Requirement 13). I am content that

there are no fundamental shortfalls in MSQA which would prevent the RP or the designer (GVHA) from further developing the generic BWRX-300 design and associated SSSE evidence to support any future permissioning activities for the construction of a power station based on the design.

4.3.6. Regulatory Processes

122. I sampled the management of Regulatory Processes to determine the extent to which quality management system arrangements have been adequately made and effectively implemented.

123. I assessed the evidence presented by the RP with consideration of IAEA Safety Standards GSR Part 2 [15], Requirement 10 (Management of processes and activities) and relevant good practice including BS EN ISO 9001:2015 [25] Section 7.4 (External communication) to determine the extent to which the RP's processes have been effectively managed and implemented.

124. I noted from the outcome of my MSQA engagements during Step 1 [35] and subsequent routine MSQA engagements during Step 2 (including MSQA Workshop 9) [38] that the maturity of the RP's management system procedures for maintaining regulatory processes as defined within the PIP [27] Section 6 remained broadly adequate and in alignment with relevant good practice.

125. I considered from my MSQA evaluation [37] that:

- The RP demonstrated, where sampled, that regulatory processes are adequately controlled and implemented.
- The RP demonstrated, where sampled, that RQs defined within the current regulatory tracker have been reviewed and approved prior to transmission in accordance with the controls defined within their latest procedural requirements.
- The RP demonstrated the use of their management system procedural steps, where sampled, to ensure that changes as a result of an RQ response are captured within the Tranche 5 submissions.
- The RP demonstrated, where sampled, that records associated with RQ responses are catalogued and adequately maintained.

126. I recommended that the RP aligns RQ responses as applicable to affected PSR chapters to ensure effectiveness and efficiency of future work (at the time of this assessment the RP has chosen to proceed at risk, which I have considered during my MSQA evaluation).

127. I recommended that the RP updates the current RIO work instruction to clearly capture the practice demonstrated of transmitting supporting/referenced documents associated with the RQ response (at the

time of this assessment the RP has chosen to proceed at risk, which I have considered during my MSQA evaluation).

128. I concluded that the information that has been submitted is consistent with my expectations, as set out in the IAEA Safety Standards GSR Part 2 [15] (Requirement 10) and relevant good practice including BS EN ISO 9001:2015 [25] Section 7.4 (External communication). I am content that there are no fundamental shortfalls in MSQA which would prevent the RP from further developing the generic BWRX-300 design and associated SSSE evidence to support any future permissioning activities for the construction of a power station based on the design.

5. Conclusions

129. This report presents the Step 2 MSQA 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 [10], at the content of most relevance to MSQA against the expectations of ONR's SAP's, TAGs and other guidance which ONR regards as relevant good practice, such as IAEA standard GSR Part 2.

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

- Organisational capability and capacity, where sampled, was found to be adequately controlled and effectively maintained in accordance with the RP's quality management system arrangements to support the fundemental design and safety case.

- Documented information, where sampled, was found to be adequately controlled and effectively maintained through implementation of the RP's quality management system arrangements to support the fundemental design and safety case.

- The RP and the designers (GVHA) quality management system arrangements, where sampled, were demonstrated as being adequately made and implemented to provide confidence in the processes for management of the design.

- Specifically, the designer (GVHA) was able to demonstrate where sampled that organisational capability is effectively maintained, documented information is being adequately controlled, safety case outputs and design decisions are being made following controlled and repeatable processes with a suitable level of quality governance and oversight aligned to a defence in depth approach.

- The RP's quality management system arrangements, where sampled, were demonstrated as being adequately made and implemented to provide confidence in the management of processes for determining safety case outputs.

- The RP's management system arrangements, where sampled, provided confidence in the processes made and implemented for systematic quality governance and oversight of the GDA project to support the fundemental design and safety case.

- Regulatory processes, where sampled, were found to be adequately controlled and effectively maintained through the RP's quality management system arrangements to support interactions associated with the fundemental design and safety case.

- Chapter 17 provides an adequate and accurate description of applicable GDA management system arrangements.
- The RP followed my recommendation to update the Forward Action Plan (FAP) procedure (and reference this update in the final Project Implementation Plan). Although it did not specifically add detail of their systematic methodology for capturing and refining future commitments (such as commitments made in RQs) and ensuring that they are traceable and readily retrievable in the future (instead choosing to proceed at risk, which I have considered during my MSQA evaluation).
- Furthermore, I recommended that additional work is completed by the RP to add a regulatory review stage within the updated FAP procedure. This may mitigate the need for the regulators to raise ROs for FAP items in the future, where the regulator considers there is insufficient definition in the forward action. The RP did not follow this recommendation but instead put alternative informal arrangements in place, which resulted in a FAP that was acceptable to ONR and therefore the risk was not realised.
- I noted that the additional work completed by the RP relating to the FAP procedure is adequate to mitigate the need for the regulators to raise ROs for FAP items in the future, where the regulator considers there is insufficient definition in the forward action.
- I noted that there have been no formal regulatory actions (RQ, RI, or RO) raised for the MSQA topic during this Step 2 assessment (although some items were discussed during Level 4 meetings and corrected effectively without the need to raise a formal regulatory action).
- I concluded that the overall quality and maturity of the RP's documentation within the scope of this Step 2 GDA for MSQA is adequate, taking into consideration the recommendations I made in this Assessment Report for additional work associated with the maturity of the Forward Action Plan.

131. 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.1	Leadership and management for safety - Leadership
MS.2	Leadership and management for safety – Capable organisation
MS.2	Leadership and management for safety – Decision making
MS.4	Leadership and management for safety - Learning