GE Hitachi Nuclear Energy

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UK Protective Marking: Not Protectively Marked

BWRX-300 UK Generic Design Assessment (GDA) Chapter 17- Management for Safety and Quality Assurance

US Protective Marking: Non-Proprietary Information
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NEDO-34189 Revision A

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EXECUTIVE SUMMARY

The BWRX-300 Generic Design Assessment (GDA) Preliminary Safety Report Chapter 17 presents a high-level description of how BWRX-300 management of safety and quality assurance is achieved within the GDA process.

The Nuclear Management System is an Integrated Management System (IMS) that ensures adequate programs and processes are implemented to enable GEH to meet its objectives. GEH has experience and a proven management system framework approved by the United States Nuclear Regulatory Commission (USNRC).

The GEH Quality Program is based on the US 10 CFR Part 50 App B (NQA-1) GEH Quality Program and approved by USNRC. The GEH Project Management and Quality Arrangements for conduct of GDA are in accordance with the GEH IMS. Chapter 17 provides a description of the general characteristics of the safety management and quality assurance, including how key indicators are measured and assessed. A discussion is included on how continuous improvement is captured in the program along with how safety culture is at the core of the GEH organisation.

There are no chapters which support Chapter 17 - “Management for Safety and Quality Assurance” (MSQA), however the majority of chapters refer to the MSQA in support.

Claims and arguments relevant to GDA Step 2 objectives and scope are summarized in Appendix A, along with an As Low As Reasonably Practicable (ALARP) position. Appendix B provides a Forward Action Plan.

ACRONYMS AND ABBREVIATIONS

Acronym	Explanation
ALARP	As Low As Reasonably Practicable
BL0	Baseline 0
BL1	Baseline 1
BL2	Baseline 2
BL3	Baseline 3
CAE	Claims, Arguments and Evidence
CAQ	Conditions Adverse to Quality
CFR	Code of Federal Regulations
CFSI	Counterfeit, Fraudulent & Suspect Items
CRA-V	Check, Review, Approve and Verification
FNEF	Future Nuclear Enabling Fund
FSF	Fundamental Safety Functions
GDA	Generic Design Assessment
GEH	GE-Hitachi Nuclear Energy Americas, LLC
GSR	General Safety Requirements
IAEA	International Atomic Energy Agency
IMS	Integrated Management System
ISO	International Organization for Standardization
JPO	Joint Programme Office
MSQA	Management for Safety and Quality Assurance
OPEX	Operational Experience
PIP	Project Implementation Plan
PLM	Product Lifecycle Management
PRD	Product Requirements Document
PSR	Preliminary Safety Report
QA	Quality Assurance
QAPD	Quality Assurance Program Description
RGP	Relevant Good Practice
RI	Regulatory Issue
RIO	Regulatory Interface Office
RMP	Requirements Management Plan
RO	Regulatory Observation
RP	Requesting Party
RQ	Regulatory Queries
SAPs	Safety Assessment Principals

Acronym	Explanation
SQEP	Suitably Qualified and Experienced Person
SSC	Structures, Systems, and Components
SSSE	Safety, Safeguards, Security, and Environment
TSC	Technical Support Contractor
UK	United Kingdom
USNRC	United States Nuclear Regulatory Commission
WENRA	Western European Nuclear Regulators Association

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17 MANAGEMENT FOR SAFETY AND QUALITY ASSURANCE

This chapter presents the BWRX-300 safety management for the Preliminary Safety Report (PSR) and wider BWRX-300 programme. The Nuclear Management System is a GEH Integrated Management System (IMS) that ensures adequate programs and processes are implemented to enable GEH to meet its objectives. GEH has experience and a proven management system framework approved by the USNRC.

There are no chapters which support PSR Ch. 17 - “Management for Safety and Quality Assurance” (MSQA), however the majority of chapters refer to the MSQA in support.

Claims and arguments relevant to GDA step 2 objectives and scope are summarized in Appendix A, along with an ALARP position. Appendix B provides a Forward Action Plan.

17.1 General Characteristics of the Management System

17.1.1 GEH Quality Program

The GEH Quality Program NEDO-11209-A “Nuclear Energy Quality Assurance Program Description,” (QAPD) (Reference 17-1) is based on the US 10 CFR Part 50 App B (NQA-1) and approved by USNRC.

The GEH Project Management and Quality Arrangements for conduct of GDA are in accordance with the GEH IMS.

The hierarchy of NEDO-11209-A (Reference 17-1) and the Project Work Plan at the top, flowing down to GEH management documents, then GEH detailed working documents and GDA deliverables at the bottom.

The GEH IMS is divided into 18 sections that support the business model as illustrated in Table 17-1.

The GEH IMS provides a project specific QAPD. Table 17-2 shows the general structure of the QAPD.

17.1.2 Organisational Structure

As Requesting Party (RP), GEH maintains a core capability of staff to ensure effective control and management of Safety, Safeguards, Security, and Environment (SSSE) for the BWRX-300 standard design and site-specific design projects, including for GDA. GEH retains overall responsibility for, and control and oversight of, the nuclear and radiological safety and security of its business, including managing tasks performed by the Technical Support Contractor (TSC). The Project Implementation Plan (PIP), NEDC-34150P, “BWRX-300 UK GDA Project Implementation Plan,” (Reference 17-2) describes the organisational structure.

17.1.3 Project Implementation Plan

NEDC-34150P (Reference 17-2) describes the overall arrangements for the successful conduct and completion of GDA using the established GEH IMS. The PIP conforms to both the National and International Standards and Guides as detailed in Section 17.1.4.

The PIP overall contains project management and quality arrangements for GDA. The PIP describes the arrangements between GEH and the TSCs, contracted and managed by GEH, to support GDA activities. The PIP directly supports this chapter.

The following Management Arrangements are all underpinned in NEDC-34150P (Reference 17-2):

- Suitably Qualified and Experienced Person (SQEP) within the GDA project
- Document Control Interfaces summary
- Regulatory interface office arrangements, submissions, meetings, actions, and correspondence
- Master document submission List/Document list arrangements
- Project Quality and Project Management Oversight
- Lessons Learned/Operating Experience
- Head Document and SSSE Reports Development Control and Management Arrangements

The PIP is maintained using the GEH Product Lifecycle Management (PLM) system. As part of the GEH IMS, controls the necessary reviews, approvals, and document control and records management functions required for maintaining the PIP. The PIP will be updated as necessary

to incorporate any project changes, Relevant Good Practice (RGP), and Lessons Learned Operating Experience during GDA.

17.1.4 Industry Standards

The following National and International Standards and Guides form the basis for the GEH IMS:

- Western European Nuclear Regulators Association (WENRA) “Safety Reference Levels for Existing Reactors 22.020,” February 2021 (Reference 17-3):
  - Issue B: Operating Organization
  - Issue C: Leadership and Management for Safety
- International Atomic Energy Agency (IAEA) Standards and Guidance, and International Organization for Standardization (ISO) Standards:
  - IAEA General Safety Requirements (GSR) Part 2, “Leadership and Management for Safety,” 2016, (Reference 17-4)
  - EN ISO 9001:2015, “Quality Management System” (Reference 17-5)
- The main ONR guidance references applicable to this project include:
  - ONR-GDA-GD-006, “New Nuclear Power Plants: “Generic Design Assessment Guidance to Requesting Parties,” Rev. 0 (Reference 17-6)
  - ONR-GDA-GD-007, “New Nuclear Power Plants: Generic Design Assessment Technical Guidance,” Rev. 0 (Reference 17-7)
  - ONR “Safety Assessment Principles (SAPs), including Leadership and Management for Safety,” (Reference 17-8)
  - NS-INSP-GD-17 “Management Systems,” (Reference 17-9)
  - NS-TAST-GD-004, “Fundamental Principles,” (Reference 17-10)
  - NS-TAST-GD-049, “Licensee Core and Intelligent Customer Capabilities,” (Reference 17-11)
  - ONR “Security Assessment Principles - Leadership and Management for Security,” (Reference 17-12)
- The main EA guidance references applicable to this project include:
  - “New Nuclear Power Plants: Generic Design Assessment Guidance for Requesting Parties,” October 2023 (Reference 17-13)
  - “Radioactive Substances Regulation: Management Arrangements at Nuclear Sites,” April 2010 (update in progress) (Reference 17-14)
  - “Management and leadership for the environment: generic developed principles,” Updated 2 May 2024 (Reference 17-15)

17.2 Specific Elements of the Management System

The Management System is designed to support multiple project disciplines, by adopting the general procedure structure (See Section 6 - Instructions, Procedures, and Drawings of Table 17-1). This provides a consistent framework to any project and the development of the respective QAPD.

The GEH IMS follows the conventional document structure hierarchy that provides a robust framework to any project type. Figure 17-1 provides a graphical representation of the document hierarchy:

NEDO-11209-A (Reference 17-1) contains further information and description of the Management System Manual, relevant policies, Procedures. Processes, templates, work instructions, forms, and guidance. The following sub-sections refer to elements of the management system directly relevant to the production of this PSR and the management of the BWRX-300 design.

17.2.1 Competency Management

All personnel working on the GDA in a position of responsibility or authority are trained and qualified as SQEP, with records maintained documenting the GEH RP competence assessment.

17.2.2 Contractor Management

TSCs are assisting, in a consulting capacity, GEH to ensure adequate personnel are available to move forward in the GDA process.

17.2.3 Document Management Interfaces and Systems

Common Procedure CP-25-300, “New Power Plants Licensing Basis Document Development & Control Process,” (Reference 17-16), describes the processes for the development, issuance, updating, and document control of New Power Plants and Products Licensing Basis Documents (i.e., Nuclear Engineering Documentation), and for the receipt, development, and issuance of responses to Requests for Information which include Regulatory Queries (RQs), Regulatory Observations (ROs) and Regulatory Issues (RIs) from the Regulators including any affected Final Licensing Basis Document content markups.

17.2.3.1 Document Interface Management

The TSCs are required by GEH to use their own project-specific Document Management procedures in conjunction with their established corporate procedures for document production and control, including records management.

17.2.3.2 Check, Review and Approve Process

GEH requested deliverable documents produced by the TSCs, and submitted to GEH, are required to undergo a project-specific GEH review and acceptance process. Note that this is required for all formal documentation/deliverables. GEH review and acceptance, including commenting, comment resolution by the TSC, and approval by the UK Licensing Manager, is documented using GEH Supporting Document WI-25-300-01-F06 “NED Report Licensing Review and Comment forms,” (Reference 17-17).

The TSC have adopted the Check, Review, Approve and Verification (CRA-V) process to manage the methodology for planning, managing, and monitoring the checking, reviewing, and approving of deliverables, and publishing the product/service. This process supports the TSC’s submission of all technical documents to the RP.

17.2.3.3 Document Management System

GEH utilises Documentum, Smartsheet, and Confluence tools as part of the collaboration process regarding reviews of Specifications and Reviews as well as control of regulatory

submissions. These tools are identified in 008N3538, “BWRX-300 Future Nuclear Enabling Fund (FNEF) Project Work Plan,” (Reference 17-18), and 008N3539, “BWRX-300 FNEF Project Execution Plan,” (Reference 17-19). Additionally, the TSCs utilise GEH Smartsheet and Documentum tools to transmit draft Specifications and draft Reports to GEH.

Lifecycle Management Tool is the approved document management tool by GEH,

During GDA the TSC (Amentum) is utilising ProjectWise as its document management system as part of the Document Interface management stated in NEDC-34150P (Reference 17-2).

17.2.4 Processes

17.2.4.1 Design Reference Management

In controlling the Design process, the goal is to ensure that a Design, along with its associated design documentation, meets all applicable technical, regulatory, and contractual requirements as stated in NEDC-34154P, “Design Reference Report,” (Reference 17-20). The expectation of meeting regulatory requirements within design control reinforces the concept of enhancing modifications in an environmental context.

As part of the Procedure Requirements in the Design Reference Report, the CAP is used if conditions adverse to quality or safety are identified. This also applies to when a condition has the potential to impact a regulatory requirement. The roles and responsibilities of staff involved in design control are shown in Table 17-3.

Specific details on the actions these roles take in planning, performing, reviewing/approving, releasing, changing, and documenting the design are described in the PIP (Reference 17-2).

17.2.4.2 Design Decisions

006N4173, “BWRX-300 Composite Design Document,” (Reference 17-21) specifies high-level design decisions for the BWRX-300 standard plant which form the overall design basis of the plant.

A BWRX-300 plant safety strategy incorporating the concept of Defence Lines (DLs) is developed using IAEA based guidance for safety assessments and safety design. A systematic approach is used to identify items within each DL that are necessary to fulfil the Fundamental Safety Functions (FSFs) and to identify inherent features that affect or contribute to the FSFs for all plant states.

A DL represents one of a series of independent “layers” in a defence-in-depth strategy to achieve plant safety and protection of the public. This statement underpins not only the safety of the operators on site, but also the protection of the broader public and the environment.

17.2.4.3 Key Systems Decisions

Decisions or issues that have significant cost, schedule, or regulatory risk are managed using a systems decision process that provides a means for traceability and ensures that no knowledge or investment is lost throughout the project lifecycle, as stated in 006N3139, “BWRX-300 Design Plan,” (Reference 17-22). The process also provides a means for managing systems decisions to aid in monitoring and controlling the scope of a complex systems design project.

17.2.4.4 Phased Design Process in the Standard Design Development

The BWRX-300 design uses a standard design approach to minimise the variation from project-to-project. Maintaining a standard design reduces engineering costs for follow-on projects. The first-of-a-kind design of BWRX-300 will be performed in a phased design process, with the following design phases:

- Baseline 0 (BL0) design phase

- Baseline 1 (BL1) design phase
- Baseline 2 (BL2) design phase
- Baseline 3 (BL3) design phase

The generation and flow down of requirements is described in 005N9036, “BWRX-300 Requirements Management Plan,” (RMP) (Reference 17-23). Regarding the integration of requirements, the BL0 design phase includes the gathering (elicitation) of top-level requirement sources (product, regulations, owner) and decomposition and establishment of relationships to lower-level requirements (plant, system, component).

17.2.5 Design Principles

17.2.5.1 Product Requirements

The GEH document 005N1084, “Product Requirements Document,” (PRD) (Reference 17-25), defines the high-level requirements the standard design must satisfy. The PRD also defines the potential markets for the standard design, which will drive the regulatory requirements that must be satisfied. The PRD is the source for the key stakeholder requirements and is managed by the Product Management team and provided as an input to the engineering design process.

17.2.5.2 Requirements Management Plan Process

Requirements describe the necessary functions and features of the BWRX-300 design to be conceived, designed, implemented, and ultimately operated. The “BWRX-300 Requirements Management Plan” (Reference 17-23) covers the full scope of the Requirements Management process, from elicitation of Source Requirements through verification that requirements have been met and describes how requirements are handled by internal tools.

17.2.6 Design Review

During the Review/Approval stage in Design Control, GEH is capable of having its Responsible Engineer(s) provide assurance that the final design is correct and in compliance with requirements by reviewing Design Inputs, compliance to requirements, assumptions, Design methods and computer program.

17.2.7 Management of Changes

Where technical revisions to design documents are made during Baseline 3 of the design phase, or where application data sheets are issued, CP-03-113, “Engineering Change Control,” (Reference 17-24) can be applied to determine whether any of the changes are appropriate for incorporation into the Standard Design configuration within the PLM System, the same system used to maintain NEDC-34150P (Reference 17-2).

Where a change in design is needed within the design control process, the Responsible Engineer evaluates identified issues to determine the need for a change to the design. If minor changes to a document such as editorial or administrative changes are made (not considered a change to the design) then only approval from the Responsible Manager is required.

If a change to the design itself is required, then portions of the plan phase that are affected are then re-performed and the effects of these changes on the overall design are evaluated. Design control measures commensurate with those applied to the original design are applied. The groups/organisations that reviewed and approved the original design documents in the approval of the design changes are included.

17.2.8 Safety, Safeguards, Security and Environmental Reports

The SSSE reports reflect international standards and policies, and relevant good practices from UK industry. Alignment between the SSSE reports ensure it is visible, documented, monitored, and controlled.

There are documented processes and procedures for the production, verification, oversight, governance, and control of SSSE reports. Robust steps are in place for the checking, review, and approval of SSSE reports for completeness and adequacy for the intended purpose. CP-25-300 (Reference 17-16) requires the Engineering Point of Contact responsible for technical review of all licensing basis documents and responses to regulatory requests for information.

17.2.9 Regulatory Management

GEH leads all regulatory interactions with support from TSCs. All formal communication between the RP and the Regulators is via the Regulatory Interface Office (RIO) and Regulator's Joint Programme Office (JPO). The Regulatory Interface Arrangements are used to govern the interface between the RP and the Regulators. WI-25-300-01, "Regulatory Interface Office," (Reference 17-26) lists all the roles and responsibilities of the RIO.

A GDA delivery dashboard is utilised to track the health of each topic area. Each month, a traffic light score is assigned as an efficient means of viewing the relative health of each topic area. The dashboards enable comparisons of relative health of topic areas each month.

17.2.10 Quality Management

The services of this project shall be provided in accordance with NEDO-11209-A, (Reference 17-1), and its implementing procedures. Any amendments or additions to those procedures are detailed in this document or reference provided to another project specific document for details.

17.2.11 Quality Management System Review

GEH management reviews the GEH Quality Management System to ensure its continuing suitability and effectiveness. The review is performed to integrate and communicate quality-related matters, problems, corrective actions, status, and effectiveness of assigned projects for continuous improvement, and annual reports on the status and adequacy of the quality management system to the top-level management. These reviews identify opportunities for improvement and needed changes. Records are maintained of the management review meetings.

During management reviews, typical input includes the following:

- Results of audits and assessments
- Customer feedback
- Customer and regulatory requirements
- Process performance and product conformity
- Status of corrective and preventive actions
- Follow-up actions from previous management reviews
- Planned changes that could affect the Quality Management System
- Recommendations for improvement

Output from the management review shall include decisions and actions related to the following:

- Improvement of the effectiveness of the Quality Management System and its processes
- Improvement of product related to customer requirements
- Resource needs to ensure proper implementation of the Quality Management
- System, and assignment of responsibilities for completing actions

17.2.12 Measurement, Assessment, and Improvement of the Management System

Quality personnel monitor activities affecting quality against acceptance criteria to ensure satisfactory performance. These criteria are outlined in implementing procedures.

17.2.13 Assurance, Oversight and Surveillance

GEH management conducts oversight and surveillance reviews, throughout the life cycle of the project as stated in the NEDO-11209-A (Reference 17-1) to ensure the GEH IMS meets the projects expectations.

17.2.14 Project Surveillance

The GDA Project includes surveillance to confirm that activities conform to established quality requirements during implementation of the GDA Project and up to and including GDA Step 2 completion.

The Project will include independent audits and surveillances to confirm that activities conform during implementation of this Plan and up to and including Step 2 completion. Surveillances will follow implementing procedures, CP-18-102, “Surveillance Process,” (internally) (Reference 17-27) and CP-07-04, “Supplier Surveillance,” (externally) (Reference 17-28). Surveillance frequency is determined based on perceived issues within the project, e.g., trends in condition report issuance and other observations.

17.2.15 Quality Management and Continuous Improvement

The services of this project are provided in accordance with NEDO-11209-A (Reference 17-1). The programme meets American Standards Mechanical Engineers’ Nuclear Quality Assurance (NQA-1) and ISO 9001:2015.

GEH continuous improvement program includes the use of Corrective Action Program in accordance with NQA-1-2015 Criteria 16.

17.3 Fostering a Culture for Safety

Safety Culture is at the core of the GEH organisation and is an integral element of the management system being implemented through the highest tier defining document “Nuclear Safety & Security Culture Policy” and as safety culture and safety conscious work environment in Section 6 of Part III of the NEDO-11209-A (Reference 17-1).

A key nuclear safety and security culture trait is a safety conscious work environment, which is a work environment where individuals feel free to raise nuclear safety concerns without fear of retaliation, intimidation, harassment, or discrimination. It is GEH’s policy to foster such an environment by encouraging employees to raise nuclear safety and security concerns; providing alternate reporting mechanisms through which those concerns may be raised (e.g., supervision, Corrective Action Program, ombuds program); and, commensurate with their potential nuclear safety and security significance, promptly reviewing, prioritising, and resolving the concerns with timely feedback to the originator.

Values are premised on the principle that everyone, regardless of position, is responsible for nuclear safety and security and that their behaviours must reflect a strong questioning attitude, conservative decision making, and safety-over-output prioritisation.

GEH management performs the following actions to establish the appropriate safety conscious work environment:

- Ensures common understanding of the key aspects of safety culture within the organization. Provides the means by which the organisation supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organisation.
- Reinforces a learning and questioning attitude at all levels of the organisation.
- Provides the means by which the organisation continually seeks to develop and improve its safety culture.
- Provides the means by which the organisation assesses the performance of its safety culture.

Table 17-1: GEH Quality Assurance Program Description (QAPD)

No	Area	Purpose
1	Organisation	• Establish and execute a quality management system. • Define authority and duties of persons and organizations performing activities affecting the functions of Structures, Systems, and Components (SSC) including functions to attain quality objectives and provide Quality Assurance (QA) • Quality has sufficient authority and autonomy to initiate/recommend or provide solutions & verify implementation of solutions. • Quality reports to a management level that ensures sufficient effectiveness and independent from cost and schedule
2	Programme	• Quality program is established & effectively executed. • Verify activities by checking, auditing, and inspection. • Document by policies, procedures & instructions • Provide control of activities affecting quality • Identify need for verification by inspection and test. • Establish training requirements
3	Design	• Assure that applicable regulatory requirements and design bases are correctly translated into specifications, drawings, procedures, and instructions. • Includes reactor physics, stress, thermal, hydraulic, and accident analyses, compatibility of materials, accessibility for in-service inspection, maintenance and repair, and acceptance criteria for inspections and tests. • Specify quality standards in design documents. • Control deviations from standards. • Control selection and review of materials, parts, equipment, and processes that are essential to the safety functions of the SSC. • Provide design interface guidance, ensure design adequacy, and control design changes. • Includes development of software and use of engineering computer programs
4	Procurement Document Control	• Applicable design basis, technical & regulatory requirements. • Applicable quality assurance program requirements. • Right of access. • Documentation requirements. • Non-conformance reporting requirements. • Procurement document change controls. • Requirement for a supplier quality assurance program.

No	Area	Purpose
5	Control of Purchased Material, Equipment, and Services	• Assure that purchased material, equipment, and services conform to procurement documents. • Perform source evaluation and selection at the contractor or subcontractor source. • Provide objective evidence of quality furnished by subcontractor, and inspection and examination of products upon delivery. • Periodically assess the effectiveness of the contractors and subcontractors' quality control consistent with the importance, complexity, and quantity of the product or services.
6	Instructions, Procedures, and Drawings	Activities affecting quality are prescribed by: • Documented instructions. • Procedures or Drawings. • Instructions, procedures, and drawings shall include acceptance criteria for determining that activities have been satisfactorily accomplished.
7	Document Control	• Control the issuance and changes of documents, including procedures and drawings. • Assure that documents are reviewed, approved by authorized personnel, distributed, and used. • Assure Changes to documents are reviewed and approved by the same organizations that performed the original review and approval unless otherwise designated. • Maintain configuration control when passing documents between GEH and Suppliers.
8	Identification and Control of Materials, Parts, and Components*	• Identify and control materials, parts, and components, including partially fabricated assemblies by heat number, part number, serial number, or other appropriate means. • Identification may be either on the item or on records traceable to the item. • ID must be maintained throughout fabrication, installation, and use of the item. • Prevent the use of incorrect or defective material, parts, and components. * Includes inspection for Counterfeit, Fraudulent & Suspect Items (CFSI) – includes CFSI paperwork “US NRC Generic Letter 89-02, Actions to Improve the detection of Counterfeit & Fraudulently Marked Products,” (Reference 17-30).
9	Control of Special Processes	Special processes, including welding, heat treating, and non-destructive testing, are: • Accomplished by qualified personnel. • Using qualified procedures. • In accordance with applicable codes, standards, specifications, and criteria.

No	Area	Purpose
10	Inspection	• Provide inspection and/or process monitoring to assure product quality. • Verify conformance with the documented procedures, and drawings. • Performed by independent individuals. • Define hold points as needed.
11	Test Control	• Include proof tests prior to installation, preoperational tests, and operational tests. • Incorporate the design requirements and acceptance limits. • Assure prerequisites have been met, that instrumentation is adequate, and environmental conditions are suitable. • Results are documented and evaluated.
12	Control of Measuring and Test Equipment	• Control of tools, gages, instruments, and other measuring and testing devices, periodically calibrated, and adjusted.
13	Handling, Storage and Shipping	• Control the handling, storage, shipping, cleaning and preservation of material and equipment to prevent damage or deterioration. • Provide special protective environments, such as: - Specific moisture content levels - Temperature levels, when appropriate
14	Inspection, Test and Operating Status	• Identify status of inspections and tests using markings such as stamps, tags, labels, routing cards, or other suitable means. • Identify items that have passed inspections and tests to preclude inadvertent bypassing of inspections and tests.
15	Nonconforming Materials, Parts, or Components	• Control materials, parts, or components that do not conform to requirements to prevent inadvertent use or installation. • Identify, document, segregate, and dispose of nonconforming items and notify affected organizations. • Disposition may include Rework, Repair, Use-as-is, or reject.
16	Corrective Action	• Assure that Conditions Adverse to Quality (CAQ) are promptly identified and corrected. • Linked to “US 10 CFR Part 21 – Reporting of Defects and Non-compliance,” (Reference 17-31) reporting requirements. • For significant CAQ, assure that the cause is determined, and corrective action taken to preclude repetition
17	Quality Assurance Records	• Maintain records to furnish evidence of activities affecting quality. • Records shall be identifiable and retrievable. • Records include inspections, tests, and audits. • Monitoring of work, performance, and materials analysis. • Personnel qualifications, procedures, and equipment. • Identification of inspector, type of observation, results, and acceptability. • Retention requirements.

No	Area	Purpose
18	Audits	• Plan and execute periodic audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the QA program. • Perform audits with detailed check lists. • Perform audits by independent trained personnel.

Table 17-2: QAPD General Structure

Management System & Business Planning	Support Management	Monitoring	Operations
• Business strategy • Quality objectives • Business alignment and integration needs	• Resources • Communications • Management reviews	• Continuous improvement • Customer feedback • Data analysis	• Planning and control • Requirements flow-down • graded approach to quality • Product traceability

Table 17-3: Roles and Responsibilities in the Design Control Process

Role Name	Description
Responsible Manager	The project(s), product, program, or engineering manager(s) responsible for performing the work. This authority may be delegated.
Responsible Engineer	The person(s) responsible for performing the work
Reviewers / Approvers	Individuals identified to review and approve the Design with a specified scope (Design verification, materials/process application, code compliance, system compatibility, etc.)

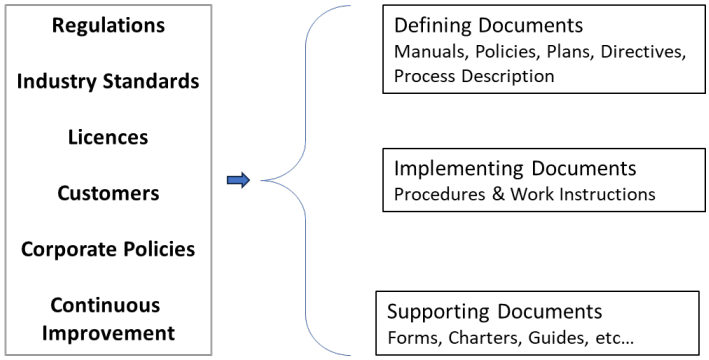

Figure 17-1: Management System Documentation

17.4 References

17-1 NEDO-11209-A, “Nuclear Energy Quality Assurance Program Description,” GE-Hitachi Nuclear Energy, Americas, LLC.

17-2 NEDC-34150P, “BWRX-300 UK Generic Design Assessment Project Implementation Plan,” GE-Hitachi Nuclear Energy, Americas, LLC.

17-3 “Safety Reference Levels for Existing Reactors 22.020,” WENRA, February 2021.

17-4 IAEA No. GSR Part 2, “Leadership and Management for Safety,” IAEA, 2016.

17-5 EN ISO 9001:2015, “Quality Management System,” IAEA, 2015.

17-6 ONR GDA-GD-006, “New Nuclear Power Plants: Generic Design Assessment Guidance to Requesting Parties,” Rev. 0.

17-7 ONR GDA-GD-007, “New Nuclear Power Plants: Generic Design Assessment Technical Guidance,” Rev. 0.

17-8 “Safety Assessment Principles for Nuclear Facilities,” ONR, 2014.

17-9 NS-INSP-GD-17, “LC17 - Management Systems,” ONR, March 2023.

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APPENDIX A CLAIMS, ARGUMENTS AND EVIDENCE

A.1 Claims, Argument and Evidence

The Claims, Argument and Evidence (CAE) approach can be explained as follows:

1. Claims (assertions) are statements that indicate why a facility is safe
2. Arguments (reasoning) explain the approaches to satisfying the claims
3. Evidence (facts) supports and forms the basis (justification) of the arguments

The GDA CAE structure is defined within NEDC-34140P, “BWRX-300 UK GDA Safety Case Development Strategy,” (Reference 17-29) and is a logical breakdown of an overall claim that:

> *“The BWRX-300 is capable of being constructed, operated and decommissioned in accordance with the standards of environmental, safety, security and safeguard protection required in the UK.”*

This overall claim is broken down into Level 1 claims relating to environment, safety, security, and safeguards, which are then broken down again into Level 2 area related sub-claims and then finally into Level 3 (chapter level) sub-claims.

The Level 3 sub-claims that this chapter demonstrates compliance against are identified within NEDC-34140P (Reference 17-29) and are as follows:

2.2.1 Appropriate MSQA procedures controlling documentation production are in place.

2.2.2 Suitable organizational arrangements are in place to control and manage the design and substantiation of the BWRX-300.

2.2.3 Appropriate governance and assurance arrangements are in place to manage the design and substantiation of the BWRX-300.

In order to facilitate compliance, demonstration against the above Level 3 sub-claims, this PSR chapter has derived a suite of arguments that comprehensively explain how their applicable Level 3 sub-claims are met (see Table A-1).

It is not the intention to generate a comprehensive suite of evidence to support the derived arguments, as this is beyond the scope of GDA Step 2. However, where evidence sources are available, examples are provided.

A.2 Risk Reduction As Low As Reasonably Practicable

It is important to note that nuclear safety risks cannot be demonstrated to have been reduced ALARP within the scope of a 2-Step GDA. It is considered that the most that can be realistically achieved is to provide a reasoned justification that the BWRX-300 SMR design aspects will effectively contribute to the development of a future ALARP statement. In this respect, this chapter contributes to the overall future ALARP case by demonstrating that:

- The chapter-specific arguments derived may be supported by existing and future planned evidence sources covering the following topics:
  - Relevant Good Practice (RGP) has demonstrably been followed,
  - Operational Experience (OPEX) has been taken into account within the design process,
  - All reasonably practicable options to reduce risk have been incorporated within the design.
- It supports its applicable level 3 sub-claims, defined within NEDC-34140P (Reference 17-29)
- Probabilistic safety aspects of the ALARP argument are addressed within PSR Ch. 15.

Table A-1: Management for Safety and Quality Arrangements Claims and Arguments

Level 17 Chapter Claim	Chapter 17 Argument	Sub-sections and/or Reports that Evidence the Arguments
2.2 The BWRX-300 has been developed in accordance with approved procedures, with appropriate governance and assurance arrangements by a competent and clearly defined organization.		
2.2.1 Appropriate MSQA procedures controlling documentation production are in place.	Procedures controlling the creating, receiving, classifying, controlling, storing, retrieving, updating, revising, and deleting documents, records, and reports relevant to the operation of the facility can be developed.	17.2.10 Quality Management
2.2.2 Suitable organizational arrangements are in place to control and manage the design and substantiation of the BWRX-300.	The organizational structure is defined with defied roles and responsibilities. There are arrangements in place which control and manage design decisions supplemented by design principles.	17.1.2 Organisational Structure
2.2.3 Appropriate governance and assurance arrangements are in place to manage the design and substantiation of the BWRX-300.	Oversight and governance of the BWRX-300 Design and substantiation are managed by the assurance, oversight and surveillance procedures embedded in the GEH Nuclear Energy Quality Assurance Program Description.	17.2.11 Quality Management System Review

APPENDIX B FORWARD ACTION PLAN

The Forward Action Plan (FAP) is not required to capture the 'normal business of Safety, Security, Safeguards, and Environmental case development as the design progresses from concept to design for construction and commissioning. FAP items can arise from several sources:

- Assumptions and commitments made in the GDA submissions that will require future verification/implementation, for example, by the future constructor and/or plant operator
- A gap in the underpinning of the GDA submissions currently under development
- A potential gap in a future phase of submissions if additional work is not performed
- A gap identified by the regulators and communicated to the Requesting Party through a Regulatory Query or Regulatory Observation

There are no FAP items associated with PSR Ch. 17.