



New Reactors Division

**Step 4 Assessment of Management for Safety and Quality Assurance for the UK
Advanced Boiling Water Reactor**

Assessment Report: ONR-NR-AR-17-024
Revision 0
December 2017

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Published 12/17

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EXECUTIVE SUMMARY

Hitachi-GE Nuclear Energy Ltd is the designer and GDA Requesting Party for the United Kingdom Advanced Boiling Water Reactor (UK ABWR). Hitachi-GE commenced Generic Design Assessment (GDA) in 2013 and completed Step 4 in 2017.

This assessment report is my Step 4 assessment of the management for safety and quality assurance arrangements for the production of the Hitachi-GE UK ABWR Pre-Construction Safety Report (PCSR) and supporting documentation.

The scope of the Step 4 assessment was to review the management for safety and quality assurance arrangements and to carry out inspections to confirm their implementation and continuing suitability and effectiveness. In addition, I have provided a judgement on the adequacy of the Management for Safety and Quality Assurance (MSQA) information contained within the PCSR.

My assessment conclusion is:

- Hitachi-GE developed, implemented and continually improved adequate management arrangements for the development, approval and verification of the GDA UK ABWR PCSR and supporting documents which ensured the safety case was produced to a consistent standard and the expectations in the guidance to requesting parties [Ref. 10] were fulfilled.
- Hitachi-GE has met all the MSQA related requirements for documentation and processes which are specified in the guidance to requesting parties [Ref. 10]
- The Generic PCSR Chapter 4 (Safety Management Throughout the Plant Lifecycle) provides suitable and sufficient information on safety and quality management to demonstrate the power plant will be constructed in accordance with the design and safety case requirements and it provides a good basis for moving forward into the site specific and licencing stages.

My judgement is based upon the following factors:

- MSQA meetings, workshops and inspections have confirmed that Hitachi-GE has made and implemented adequate MSQA arrangements which have controlled development, production, verification and approval of the generic Pre-Construction Safety Report (PCSR) and its supporting information. (Noting the quality of each section of the PCSR was assessed by ONRs specialists and is recorded in their assessment reports.)
- MSQA assessment in all the GDA steps has seen Hitachi-GE continually improve its quality management arrangements for the design and safety case production. Corrective action has been taken to resolve quality deficiencies identified by Hitachi-GE's internal audits, regulators inspections and regulatory assessment of the safety submissions.
- The assessment reports for GDA steps 2 [ref.2] and 3 [ref.3] concluded that the management for safety and quality assurance arrangements were adequate for each step. The majority of the quality system was put in place during steps 2 and 3 so their conclusion remains valid.
- Two inspections [ref. 4 & 5] were carried out at the Hitachi Works in Japan and no major shortfalls in the GDA quality arrangements were found. The findings were described in two regulatory queries (RQs) and Hitachi-GE put in place resolution plans and carried out the corrective actions within the agreed timescales.
- During step 2, ONR identified and Hitachi-GE acknowledged that while their engineers and safety case authors were competent and experienced nuclear engineers they did not have sufficient knowledge or experience in producing UK style safety cases. In discussion with ONR, Hitachi-GE took corrective action by recruiting UK safety case experts and used them to write pertinent guidance in the form of a safety case manual.

The UK experts also provided specialist support, advice and training to Hitachi-GE's safety case team throughout step 4. The improvement action was timely and provided the necessary expertise needed to deliver the safety case.

- As required by the guidance to requesting parties Hitachi-GE has identified the process which will be used to move the safety case into the operating regime. This has included developing a system to capture safety case assumptions and requirements so they can be tracked into construction, commissioning and operation. I judged the process was defined in sufficient detail for the end of GDA and fulfils the requirement.
- As required by the guidance to requesting parties [ref.10] Hitachi-GE has regularly updated the Master Document Submission list and the Design Reference throughout step 4. Four batches of design changes were agreed before the design reference point and all subsequent changes have been subject to a design change process whereby ONR agreed to including any safety significant changes in GDA. I judged this fulfils the requirement.

Overall, based on the samples undertaken:

I am broadly satisfied that the management arrangements which controlled the development and production of the PCSR during the GDA process were adequate and consistent with relevant good practice. For this reasoning the UK ABWR should be awarded a DAC provided the individual specialist assessments confirm the adequacy and quality of the safety submissions.

LIST OF ABBREVIATIONS

ALARP	As Low As Reasonably Practicable
ASME	The American Society of Mechanical Engineers
BSL	Basic Safety Level
BSO	Basic Safety Objective
DRP	Design Reference Point
GDA	Generic Design Assessment
IAEA	The International Atomic Energy Agency
IEC	International Electrotechnical Commission
JSCO	Joint Safety Case Office
MDEP	Multi-national Design Evaluation Programme
MSQA	Management for Safety & Quality Assurance
ONR	Office for Nuclear Regulation
PCSR	Pre-construction Safety Report
PSA	Probabilistic Safety Assessment
PSR	Preliminary Safety Report
RGP	Relevant Good Practice
RP	Requesting Party
RQ	Regulatory Query
SAPs	Safety Assessment Principles
SFAIRP	So Far As Is Reasonably Practicable
SSC	System, Structure (and) Component
SSER	Safety, Security and Environmental Report
TAG	Technical Assessment Guide
TIG	Technical Inspection Guide
TSC	Technical Support Contractor
US NRC	United States (of America) Nuclear Regulatory Commission
UK ABWR	United Kingdom Advanced Boiling Water Reactor
WEC	Westinghouse Electric Company
WENRA	Western European Nuclear Regulators' Association

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1 INTRODUCTION

1.1 Background

1. Information on the GDA process is provided in a series of documents published on our website (<http://www.onr.org.uk/new-reactors.htm>). The expected outcome is a Design Acceptance Confirmation (DAC) for ONR and a Statement of Design Acceptability (SoDA) for the Environment Agency (EA) and Natural Resources Wales (NRW).
2. The GDA Step 3 summary report is published on our website (<http://www.onr.org.uk/new-reactors/uk-abwr/reports/step3/uk-abwr-step-3-summary-report.pdf>). Further information on the GDA process in general is also available on our website (<http://www.onr.org.uk/new-reactors/index.htm>).
3. Hitachi-GE commenced GDA in 2013 and completed Step 4 in 2017. The Step 4 assessment is an in-depth assessment of the safety, security and environmental evidence. Through the review of information provided to ONR, the Step 4 process should confirm that Hitachi-GE:
 - Has properly justified the higher-level claims and arguments.
 - Has progressed the resolution of issues identified during Step 3.
 - Has provided sufficient detailed assessment to allow ONR to come to a judgment of whether a DAC can be issued.
4. During the step 4 assessment ONR has undertaken a detailed assessment and inspection, on a sampling basis of the MSQA arrangements for the production of the safety and security case evidence. The full range of items that might form part of the assessment is provided in ONR's GDA Guidance to Requesting Parties (<http://www.onr.org.uk/new-reactors/ngn03.pdf>). These include:
 - Consideration of issues identified in Step 3.
 - Judging the MSQA arrangements against the Safety Assessment Principles (SAPs) and relevant good practice.
 - Reviewing details of the Hitachi-GE design controls, procurement and quality control arrangements to secure compliance with the design intent.
 - Assessing arrangements for ensuring and assuring that safety claims and assumptions are realised in the final as-built design.
 - Resolution of identified management system issues, or identifying paths for resolution.
5. This is my report from the ONR's Step 4 assessment of the Hitachi-GE UK ABWR GDA management arrangements.
6. All of the regulatory observations (ROs) issued to Hitachi-GE as part of my assessment are also published on our website, together with the corresponding Hitachi-GE resolution plan. No regulatory issues (RIs) were raised.

1.2 Scope

7. The scope of my assessment is detailed in the MSQA Step 4 assessment plan [ref. 11]
8. The scope of my assessment covered the parts of the Hitachi-GE management arrangements which were established for producing, approving and verifying the GDA PCSR and its supporting information. It also sought to confirm that Hitachi-GE had met the regulatory expectations for step 4 as described in the guidance to requesting parties [ref. 10]. The step 2 and 3 assessments considered the adequacy of the Hitachi-GE arrangements for the design process.

1.3 Method

9. My assessment complies with internal guidance on the mechanics of assessment within ONR (ref.14)

2 ASSESSMENT STRATEGY

2.1 Standards and criteria

10. The standards and criteria adopted within this assessment are principally the Safety Assessment Principles (SAPs) MS 1-4 [ref 12], internal TIGs (ref. 13), relevant national and international standards and relevant good practice informed from existing practices adopted on UK nuclear licensed sites. (see Annex 1-3)

2.1.1 Safety Assessment Principles

11. The key SAPs applied within the assessment are included within annex 1

2.1.2 Technical Inspection Guides

12. The TIGs that have been used as part of this assessment are set out in annex 2

2.1.3 National and international standards and guidance

13. The international standards and guidance that have been used as part of this assessment are set out in annex 3

2.2 Use of Technical Support Contractors (TSCs)

14. Technical support contractors were not used for the MSQA assessment.

2.3 Integration with other assessment topics

15. GDA requires the submission of an adequate, coherent and holistic generic safety case. Regulatory assessment cannot therefore be carried out in isolation as there are often safety issues of a multi-topic or cross-cutting nature. The MSQA assessment focussed on the management arrangements which produced and verified the safety case and it was therefore necessary to listen to the concerns of both the individual specialist assessors and the programme management team to ensure the arrangements were suitable and sufficient and that deficiencies were promptly addressed. In addition to discussing concerns with individuals all the assessment areas were subject to health checks where assessors judged the RP's performance in their area. Concerns were taken forward and resolved during MSQA meetings or escalated through the delivery leads. The key areas which were improved were:

- UK safety case competence.
- Review and verification of documentation
- Identification of requirements and assumptions within the documentation.

2.4 Sampling strategy

16. It is seldom possible, or necessary, to assess a management system in its entirety, therefore sampling is used to limit the areas scrutinised, and to improve the overall efficiency of the assessment process. Sampling is done in a focused, targeted and structured manner with a view to revealing any weaknesses or non-conformities in the management system.
17. The assessment strategy for this activity was as follows:
 - The majority of the management system was developed during GDA steps 2 and 3 so this assessment takes cognisance of the MSQA assessments carried out during these steps.

- To carry out on-site inspections at the Hitachi Works in Japan to confirm the implementation of the management arrangements and seek corrective action where appropriate.
- Hold regular face to face and video conference MSQA workshops with the Hitachi-GE MSQA subject matter expert to provide advice on regulatory requirements and monitor the delivery of the MSQA processes defined in the guidance to requesting parties.
- Ensure deficiencies in the management system processes identified during GDA were resolved in a timely manner.

2.5 Out of scope items

18. The parts of the Hitachi-GE management systems concerned with manufacturing and supply were not in the scope of this assessment. This will be covered during the site specific phase.

3 REQUESTING PARTY'S MANAGEMENT SYSTEM FOR GENERIC DESIGN ASSESSMENT.

19. Hitachi-GE has a management system which covers all its design and manufacturing activities. This system meets the requirements of international quality management system standards (ISO 9001 - quality management systems requirements). For controlling design activities Hitachi-GE used this system as appropriate and for GDA it was supplemented with GDA specific arrangements for the development of the safety case and other GDA activities. This was described in a quality plan showing how the GDA quality requirements were met.
20. The management system provides control and direction for producing the safety case in the following areas
- A quality plan showing how the requirements for GDA will be fulfilled and identifying the additional processes beyond the existing management system needed to achieve this.
 - A definition of Hitachi-GE's organisational structure and lines of communication.
 - The Generic Design and Development controls covering the development and verification of safety case and documenting the six step process used for agreeing design changes for inclusion in GDA after the design reference point (see 12 in Table 1).
 - Purchasing controls to ensure contractors engaged in the production of the safety case were suitably competent and able to deliver good quality outputs.
 - Document control.
 - Training and competence for GDA personnel.
 - Management system assessment, non-conformance control and corrective action.
 - A safety case development plan.
 - A safety case manual providing guidance on the content and methodology of the safety case.
21. A process has been implemented to capture safety case limits and conditions and the process for transferring the safety case into the operating regime has been identified ready for the site specific stage. (see 10 & 11 in Table 1)
22. The Hitachi-GE Management System for the production and verification of the safety case for the UK ABWR is documented in the following UK ABWR specific procedures for GDA.

Table 1

No.	Title	Doc. ID	Doc. No.
1	QUALITY MANAGEMENT PLAN (For UK ABWR GDA Project)	GA70-1501-0007-00001	GNQA13-0066
2	Communication, Reporting Lines and Distribution of Information in the GDA Organization	GA70-1501-0001-00001	GNQA13-0199
3	Generic Design Development Control	GA70-1501-0002-00001	GNQA13-0201
4	Design Change Control and Documentation	GA70-1501-0003-00001	GNQA13-0202

5	Purchasing Control	GA70-1501-0004-00001	GNQA13-0203
6	Control of general documents and records	GA70-1501-0005-00001	GNQA13-0215
7	SQEP Requirements for HITACHI-GE and Supplier Personnel	GA70-1501-0010-00001	GNQA13-0255
8	Control of Non-conformance, Corrective Action, and Preventive Action	GA70-1501-0008-00001	GNQA13-0256
9	Assessment of GDA Arrangements (Internal Audits, Self-Assessment)	GA70-1501-0009-00001	GNQA13-0257
10	Standard Control Procedure for Identification and Registration of Assumptions, Limits and Conditions for Operation	GA91-0512-0010-00001	XD-GD-0042
11	Technology Transfer to Licensee and Operating Regime	GA70-1502-0001-00001	QGG-GD-0001
12	Instruction to Six Step Process	GA70-1501-0016-00001	QGG-GD-0002
13	Modification Notice Implementing Procedure	GA70-1501-0017-00001	QGG-GD-0003
14	UK ABWR Nuclear Safety and Environmental Design Principles (NSEDPs)	GA10-0511-0011-00001	XD-GD-0046
15	Safety Case Development Plan	GA10-0511-0002-00001	XD-GD-0018
16	Safety Case Development Manual	GA10-0511-0006-00001	XD-GD-0036

4 ONR STEP 4 ASSESSMENT

23. This assessment has been carried out in accordance with ONR internal guidance on the “Purpose and Scope of Permissioning” (ref. 15).

4.1 Scope of Assessment Undertaken

24. The scope of my assessment covered the parts of the Hitachi-GE arrangements which were established for producing, approving and verifying the GDA PCSR and its supporting information. The step 2 and 3 assessments also considered the adequacy of the Hitachi-GE design process.

4.2 Assessment

25. The elements of my assessment are set out below:

4.2.1 MSQA Inspection at Hitachi Works in April 2016

26. An inspection was carried out at the Hitachi Works in April 2016. Details are given in the contact report [ref. 4].

27. The objective was to examine the implementation and effectiveness of the arrangements that Hitachi-GE have put in place to deliver a Safety Case for the UK ABWR that meets UK expectations. The following three areas were included;

- Safety Case Quality Improvements
 - Effectiveness of Joint Safety Case Office
 - Implementation of Safety Case Development Manual
 - Implementation of Commitments Capture process
 - Effectiveness of GDA specific training
- Technology Transfer – moving Safety Case into Operating Regime
 - Development of Requirements & Assumptions List for both safety and environmental impacts
 - Development of Generic Technical Specification
- Design Review & Change
 - Inclusion of changes into GDA (6 step process)
 - Effectiveness of review to identify Safety Case & Environmental impacts

28. Five observations and recommendations were made:

- Review the target date specified for PCSR Chapter leads to review impact of commitments made for the closure of RQ0661 to ensure sufficient time is allowed for implementing changes into their Chapters post this review.
- Define the word OPERABLE, as used in the statement of Requirements & Assumptions.
- Amend procedure “Instruction for Six Step Process” (QGG-GD-0002) to include a justification for selection of change categorisation.
- Submit change UKABWR-NDCP-0032 and at least two subsequent category C or D changes to the ONR for technical assessment of the justification of categorisation.

- Provide a list of the ⁴four Batches of changes to the Design Reference Point that were agreed between Hitachi-GE and ONR prior to introduction of the Six Step process. List to include; change title, description of change, whether change is completed or expected completion date, when/ how communicated to the ONR.
29. The observations and recommendations were included in a Regulatory Query (RQ) [ref. 6] and Hitachi-GE provided a suitable response document [ref. 8] which was discussed and actions verified by ONR during the regular MSQA workshops. This closed out the inspection findings.
30. The MSQA arrangements are therefore considered adequate based on the sample taken during the inspection.

4.2.2 MSQA Inspection at Hitachi Works in October 2016

31. A second inspection was carried out at the Hitachi Works in October 2016. Details are given in the contact report [ref. 5].
32. The objective was for the ONR and EA to gain confidence in the ability of Hitachi-GE and JSCO to meet the overall GDA programme and submit fit-for-purpose and right-first-time documentation to the ONR GDA team. The following four areas were assessed;
- Programme management
 - Secure Design Office
 - Management and resourcing of the PCSR Revision C production and review programme
 - Change Management Arrangements
 - Management of Safety Case interdependencies
 - Programme risk management
 - Internal Challenge
33. Seven queries were identified during the inspection, listed below:
- Hitachi-GE to review key managerial or control documents (including the Step-4 plan) to determine whether sufficient information is contained in the Revision History to allow the reader to understand the full impact of the changes.
 - Hitachi-GE to review; (1) the Design Reference Point change management arrangements to ensure they cover all contingencies and (2) the entries in Annexes 1 and 2 of the up-to-date Design Reference for UK ABWR to ensure consistency with these arrangements.
 - Hitachi-GE determine to whether the discrepancy between the Safety Functional Claim table specified in XD-GD-0042 and that contained in PCSR Chapter 12 is significant and correct if necessary.
 - Hitachi-GE to provide information on the extent to which procedure XD-GD-0042 has been implemented within Basis for Safety Cases and what alternative arrangements are in place to identify safety case interdependencies for areas where implementation is not yet complete.

⁴ Hitachi-GE and ONR agreed that 4 batches of design changes would be carried out using the Hitachi-GE in-house design change procedures before the Design Reference Point (DRP) was finalised. After the DRP was 'frozen', Hitachi-GE would then use the specific GDA design change '6 Step' process which allowed ONR to formally agree to include new design changes, made after the design reference point. See paragraph 43.

- Hitachi-GE should consider whether document production could be improved based on learning from: (1) periodic analysis of the comments received during Hitachi-GE review/ verification of documents and (2) analysis of the relationship between the level of Hitachi-GE internal review/ verification and feedback from UK Regulators.
 - Hitachi-GE should determine: (1) why there is no evidence that the expected review of Design Inputs was undertaken during the production of Topic Report WPE-GD-0206 (2) whether there are other examples where Design Inputs have not been adequately reviewed.
 - Hitachi-GE should review the verification process to determine whether improvement can be gained by adoption of any of the following opportunities, making changes to the process or supporting information as needed.
 - enhancing consideration of the strategic needs of the overall UK ABWR GDA project
 - broadening the scope of verification beyond the immediate functional requirements of the specific deliverable
 - improving the independence of the verifier from the production process
 - encouraging greater use of alternative techniques and independently derived conclusions
 - clearly including operational experience and learning
 - recording greater detail of the verification approach and methodology adopted on the Verification Report
 - better recording and retention of key feedback between Verifier and Preparer throughout the document production process
34. The seven queries above were included in a RQ [ref. 7] and Hitachi-GE provided a suitable response document [ref. 9]. Closure of the actions were discussed and verified by ONR during the regular MSQA workshops. This satisfactorily closed out the inspection findings.
35. The inspection conclusions were:
- Hitachi-GE was open and transparent, providing the information and assistance required to successfully complete the inspection.
 - Processes are well developed and are being followed with only minor deviations even under time pressure. There are no widespread process deficiencies.
 - Hitachi-GE demonstrated confidence in their arrangements.
 - There are however some additional questions and areas for improvement that have been identified, these have been recorded in the seven queries (above).
36. The MSQA arrangements were therefore then considered adequate based on the sample taken.

4.2.3 Defining the Process for Moving the Safety Case to an Operating Regime.

37. In Step 4 the RP is required to submit arrangements for moving the safety case to an operating regime. This was regularly discussed at the MSQA workshops during Steps 3 and 4 to ensure the regulatory requirements were understood. It was clear that for previous ABWR's Hitachi-GE had prepared construction criteria, technical specifications, operating instructions, maintenance manual etc. to ensure safety requirements were included in the operating regime. Similar documentation is proposed for the UK ABWR. However, Hitachi-GE has recognised that a process must be in place to identify requirements and assumptions in the safety case and ensure

they are included in construction, commissioning, operational or decommissioning documentation. In Step 3 RO-ABWR-0057 was issued relating to developing arrangements to move the safety case into the operating regime. Hitachi-GE developed and have implemented the resolution plan [ref. 23] and a letter closing the issue [ref. 24] was issued.

38. Hitachi-GE has put arrangements in place to identify requirements and assumptions in the safety case [ref. 16] and to log them in an IT system (AIRIS Plus). This process was discussed at the MSQA workshops and is judged to be satisfactory based on the information sampled but it will be for individual specialist assessors to determine if the requirements, limits and conditions identified in their parts of the PCSR are adequate. Importantly in Step 4 the requirements and assumptions in the PCSR are being captured ready for transfer to the operating regime as the site specific PCSR is developed and construction, commissioning and operational documentation is developed.
39. A documented process is available [ref.17] which describes how the assumptions, limits and conditions captured during the production of the PCSR will be transferred to the operating regime (i.e. the licensee). This will be through construction criteria, technical specification, manuals etc. The process has been discussed at the MSQA workshops and the description of moving the safety requirements into the operating regime is sufficient for the end of GDA and ensures that a clear process has been defined for moving into the site specific stages.
40. I therefore judged the requirement in the guidance to requesting parties [ref.10] to define the arrangements for moving the safety case to an operating regime has been fulfilled.

4.2.4 GDA Documentation required by Guidance to Requesting Parties.

4.2.4.1 Design Reference

41. The RP is required to submit a Design Reference which lists all the documents that describe the design of the reactor and associated plant that the GDA submissions refer to. ONR will expect this to be 'frozen' at a specific date known as the Design Reference Point.
42. In 2014 the RP submitted the Definition of Design Reference Point [ref. 27] and it was agreed Design Reference would list system level drawings and descriptions which describe the UK design submitted for GDA.
43. ONR and Hitachi-GE agreed 4 batches of design changes would be carried out before GDA design change control was implemented and have used the 6 Step design change process (see 4.2.5) to agree further changes. Changes made using the 6 step process are listed in the annexes of the design reference document.
44. Hitachi-GE has regularly updated the design reference as the 4 batches were progressed and other changes made. The final document will be issued at the end of step 4 to accompany the PCSR. I therefore judge that the design reference accurately describes the UK design submitted with the PCSR for GDA and the document is satisfactory.

4.2.4.2 Master Document Submission List

45. RP was required to put in place management arrangements to keep track of the documents submitted, of subsequent changes to these documents, and of documents withdrawn, etc. Key to these arrangements is a Master Document Submission List,

which is a 'live' document that allows ONR to understand and reference precisely what constitutes the latest versions of the GDA submissions.

46. The original first issue of the Master Document Submission List was in September 2014 for the start of step 3. The list has subsequently been updated at approximately three monthly intervals and a final version will be available at the end of GDA to describe the safety case and its supporting documents.

47. I therefore consider the requirement for a master submission list has been fulfilled.

4.2.5 Process for ONR to Accept Design Changes after the Design Reference Point (DRP)

48. The guidance for requesting parties [ref.10] recognises the RP may wish to make changes to the generic design after the Design Reference Point has been agreed or changes to the design may also be necessary to respond to Regulatory Observations or Regulatory Issues. It requires a process to be put in place to allow ONR to agree to include design changes in GDA after the DRP. Before the application of this process ONR agreed that four batches of changes could be completed.

49. Hitachi-GE developed and implemented a process to control design changes after the Design Reference Point [ref. 18]. It is colloquially referred to as the 'six step process' The process is robust and the categorisation system employed to determine if ONR needs to agree to include the change is based on safety significance and is consistent with the categorisation criteria in the LC 22 technical inspection guide [ref. 20]. The changes are considered by committee within Hitachi-GE and significant changes submitted to ONR for agreement.

50. At the MSQA workshop in July 2017 I sampled a number of lower safety category changes to confirm the categorisation was correct and they should not have been submitted to ONR for approval [ref.19]. I concluded that based on the sample taken I was satisfied that Hitachi-GE have categorised changes correctly.

51. I am satisfied that the requirement for a design change process has been fulfilled and it is implemented and working as planned.

4.2.6 Review of Generic Pre-Construction Safety Report (PCSR) Chapter 4 (Safety Management Throughout the Plant Lifecycle)

52. During the MSQA GDA assessment a number of iterations of Chapter 4 were reviewed by ONR's Management Systems Specialist. ONR provided comments and Hitachi-GE addressed them in subsequent drafts [ref. 21 & 22]. Formal assessment of chapter 4 was not carried out as it predominantly describes intentions for future management activities rather than claims, arguments and evidence which justify the safety of the UK ABWR design.

53. The PCSR provides an adequate overview of safety management throughout the plant lifecycle and describes in sufficient detail what safety management arrangements will need to be considered and implemented during the site specific and licensing stages. I consider the following topics have been suitably addressed

- An overview of Hitachi-GE's safety and quality philosophy and a commitment to developing a nuclear safety culture provides an expectation for the site specific and licensing stages. There is also an overview of Hitachi-GE Management System recognising its certification to ISO standards and ASME codes.

- There is recognition of Hitachi-GE's construction experience and safety performance on six other reactor build projects.
- The safety management framework identifies that ultimate responsibility for safety will be with the licensees but it also acknowledges that Hitachi-GE as the vendor and potentially in the role of responsible designer will need to have systems in place to support the licensee's design authority. It also addresses the transfer of technology to the licensee/operator including safety case requirements and assumptions.
- It describes Hitachi-GE's role as a tier one supplier during construction and recognises appropriate arrangements will need to be developed which give the licensee the necessary oversight of the process.
- There is an adequate description of the design processes used to control the reactor design which confirms the design management systems will be compliant with ISO 9001, ASME and IEC international codes and standards.
- The section on the construction phase recognises the importance of quality in construction so that design requirements are fulfilled. Hitachi-GE management systems are ISO 9001 certificated and chapter 4 states that contractors for the construction phase will be ISO 9001 certificated or will be evaluated by Hitachi-GE for suitability. The quality management and conventional safety management systems for construction will be developed during the site specific and licensing stages. A Quality Assurance Plan for Construction will be prepared and verification activities will be defined in Quality Plans. A graded approach will be adopted for verification activities.
- Provides an overview of the controls required for modular construction
- Hitachi-GE already has an ISO 9001 certificated management system which covers commissioning and chapter 4 recognises they will be used alongside the licensee's arrangements which will be required for LC 21 compliance. These arrangements will be developed in the licensing phase.
- It recognises Hitachi-GE's role in supporting the licensee in the operating phase and transferring technology and knowledge in the form of technical specifications, operating manuals, maintenance manual etc.
- It contains an overview of how the operating envelope of the plant will be described in technical specifications, operating manuals, maintenance manual etc.
- It describes how Hitachi-GE will provide maintenance requirements for the plant.
- It contains an adequate overview of the management arrangements for decommissioning.
- It describes how assumptions and limiting conditions from the safety case will be transferred into the operating regime.

4.2.7 Management of Minor Shortfalls Identified in ONR's Assessment Reports

54. ONR's GDA assessment reports have identified minor shortfalls which may be of significant value to the future licensee in developing the generic safety case into a robust site specific safety case. ONR expects that the licensee will consider the minor shortfalls and take account of them where appropriate.
55. While these shortfalls are not sufficiently significant to merit regulatory oversight the licensee shall put in place proportionate and effective arrangements to ensure that minor shortfalls are considered, actioned as appropriate, and that records are maintained of such consideration and action. Thereby transposing the experience and learning from the GDA process into licensing and the site specific safety case.

56. To ensure this action is taken by the future licensee ONR has made the Assessment Finding below.
'Because the addressing of minor shortfalls does not merit significant regulatory oversight and a process for their management is not explicit in the GDA process, the licensee shall put in place proportionate arrangements to ensure that they are considered, actioned as appropriate, and that records are maintained of such consideration and action.'

4.2.8 Learning from Experience

57. The UK ABWR safety case is the first UK style safety case which Hitachi-GE has produced. Throughout the GDA process Hitachi-GE has been implementing continual improvements to enhance safety case authors' knowledge and experience of UK safety cases and where necessary have employed UK experts. The management system has also been improved throughout GDA in response to internal audits, regulatory inspections and non-conformities in the safety submissions. This was consistent with the regulators expectations.
58. The end of GDA step 4 provides an excellent opportunity to review what has been learned writing the Generic PCSR and to use this information to improve the safety case management arrangements and organisation for the site specific stage. Because a review was not carried out during step 4, the future licensee should review the safety case management arrangements and implement any improvements necessary before starting the site specific stage. This has been identified as a residual matter and listed as a minor shortfall in Annex 6 to ensure it is considered by the future licensee.

4.2.9 Regulatory Issues

59. No Regulatory Issues were raised by the MSQA assessment.
(Regulatory Issues (RIs) are matters that ONR judge to represent a 'significant safety shortfall' in the safety case or design and are the most serious regulatory concerns. RIs are required to be addressed before a DAC can be issued.)

4.3 Regulatory Observations

60. No Regulatory Observations were raised during the Step 4 MSQA Assessment.
(Regulatory Observations (ROs) is raised when ONR identifies a potential regulatory shortfall which requires action and new work by the RP for it to be resolved. Each RO can have several associated actions.)
61. Two ROs from Step 3 were closed out:
62. RO-ABWR-0057 relating to developing arrangements to move the safety case into the operating regime. See resolution plan [ref. 23] and closure letter [ref. 24]. Hitachi-GE developed appropriate arrangements see section 4.2.3.
63. RO-ABWR-0058 relating to closure of actions from the Step 3 MSQA inspection. See resolution plan [ref. 25] and closure letter [ref. 26]. This concluded the corrective actions required by the inspection.

4.4 Comparison with standards, guidance and relevant good practice

64. International quality management system standards [see Annex 3] have been used in the MSQA assessment to evaluate Hitachi-GE's management system processes and to determine the scope and criteria for the inspections which confirmed their implementation and adequacy.
65. Hitachi-GE management system processes and procedures were discussed during the MSQA workshops. ONR saw the draft documents before issue and Hitachi-GE

addressed ONR's comments before formally issuing the documents. Hitachi-GE GDA management system and procedures are therefore considered to be consistent with the relevant standards, guidance and good practice.

4.5 GDA Issues

66. During my assessment no residual matters were identified as GDA Issues.

4.6 Assessment findings

67. During my assessment one residual matter was identified as an assessment finding for a future licensee to take forward in their site-specific safety submissions. Details of this are contained in annex 5

4.7 Minor shortfalls

68. During my assessment one residual matter was identified as a minor shortfall, but is not considered serious enough to require specific action to be taken by the future licensee. Details of this are contained in Annex 6.

5 CONCLUSIONS

69. This report presents the findings of my Step 4 MSQA assessment of the Hitachi-GE UK ABWR GDA Management System.
70. To conclude, I am broadly satisfied with the management system which has been used to control the development, verification and approval of the UK ABWR PCSR and supporting documentation. I consider the management system has provided sufficient quality management controls in the production of the UK ABWR PCSR to ensure it is produced to a consistent standard. Provided the specialist assessments confirm the content of the PCSR is acceptable I consider that from an MSQA view point, the Hitachi-GE UK ABWR design is suitable for construction in the UK and should be awarded a DAC, subject to future permissions and permits being secured.

5.1 Key Findings from the Step 4 Assessment

71. I consider that from a MSQA view point, the UK ABWR design is suitable for construction in the UK, at this present time subject to completion of GDA Issues, future permissions and permits being secured.

6 REFERENCES

Ref	
1	http://www.onr.org.uk/new-reactors.htm
2	Generic Design Assessment of HGNE's Advanced Boiling Water Reactor (ABWR) - Step 3 Assessment of the Management for Safety and Quality Assurance of Hitachi GE's UK Advanced Boiling Water Reactor (UK ABWR). TRIM Ref 2015/205183
3	Generic Design Assessment of HGNE's Advanced Boiling Water Reactor (ABWR) - Step 2 Assessment Report for MSQA, ONR-GDA-AR-014 Revision 0. ONR August 2014. TRIM Ref 2014/326177
4	MSQA Inspection 18 – 20 April 2016 ONR-NR-CR-16-114 Revision 1 TRIM Ref 2016/0207110
5	MSQA Inspection 17 – 19 October 2016 ONR-NR-CR-16-812 Revision 0 TRIM Ref 2016/425696
6	RQ-ABWR-0936, Actions arising from MSQA Inspection April 2016. TRIM 2016/278335
7	RQ-ABWR-1233, Response to October 2016 MSQA Inspection of UK ABWR. TRIM ref 2017/98191
8	Actions arising from MSQA Inspection April 2016 (Response to RQ-ABWR-0936), GA91-9201-0003-01383, QGE-GD-0073. TRIM 2016/278338
9	Actions arising from MSQA Inspection Oct. 2016 (Response to RQ-ABWR-1233), GA91-9201-0003-01902, QGE-GD-0089. TRIM 2017/98202
10	New nuclear reactors: Generic Design Assessment Guidance to Requesting Parties, ONR-GDA-GD-001 Revision 3, September 2016. TRIM 2016/401569
11	Generic Design Assessment of Hitachi-GE's UK Advanced Boiling Water Reactor (UK ABWR), Step 4 Assessment Plan for Management for Safety and Quality Assurance, ONR-GDA-AP-15-009 Revision 0. TRIM ref 2015/359671
12	Safety Assessment Principles for Nuclear Facilities 2014 Edition Revision 0 http://www.onr.org.uk/saps/index.htm
13	Nuclear Safety Technical Inspection Guide - LC 17- Management Systems - NS-INSP-GD-017 Revision 4. http://www.onr.org.uk/operational/index.htm
14	Office for Nuclear Regulation, Guidance on Mechanics of Assessment TRIM:2013/204124
15	Office for Nuclear Regulation, Guidance on Purpose and Scope of Permissioning, NS-PER-GD-014
16	Standard Control Procedure for Identification and Registration of Assumptions, Limits and Conditions for Operation, XD-GD-0042, GA91-0512-0010-00001. Hitachi-GE
17	Technology Transfer to Licensee and Operating Regime, QGG-GD-0001, GA70-1502-0001-00001 TRIM 2016/316689 Hitachi-GE
18	Instruction to Six Step Process, QGG-GD-0002, GA70-1501-0016-00001, rev 0 TRIM ref 2016/61375
19	Contact Record, ONR-NR-CR-17-215 Revision 0, NS-INSP-GD-022 Revision 3, LC 22.: TRIM ref 2017/258158
20	Nuclear Safety Technical Inspection Guide – LC 22, Modification or Experiment on Existing Plant, NS-INSP-GD-022 Revision 3. http://www.onr.org.uk/operational/index.htm

21	ONR Comment on DR4 Generic PCSR Chapter 4 : Safety Management throughout Plant Lifecycle - D Morgan - 14 July 2015 TRIM ref 2015/261552 and 2015/261564
22	PCSR Strategy and Chapter Specifications - FEEDBACK FORM - Topic – MSQA. TRIM ref 2016/19535
23	UK ABWR -GA91-9201-0004-00056 - QGE-GD-0040 - Rev 0 - Resolution Plan for RO-ABWR-0057 Hitachi-GE's development of arrangements for the safety case to be met in practice - 3 July 2015. TRIM 2015/248626
24	RO-ABWR-0057 - Closure of Regulatory Observation: RO-ABWR-0057: Hitachi-GE's Development of Arrangements for the Safety Case to be met in Practice - 25 November 2016 - PUBLISHED CLOSURE LETTER. TRIM ref 2016/460363
25	UK ABWR - GA91-9201-0004-00055 - QGE-GD-0044 - Rev 0 - Resolution Plan for RO-ABWR-0058 Step-3 MSQA Improvement Actions - 03 July 2015. TRIM ref 2015/248502
26	RO-ABWR-0058 - Step 3 MSQA Improvement Actions - 27 May 2016 - PUBLISHED CLOSURE LETTER. TRIM ref 2016/217891
27	Definition of Design Reference Point, GA91-9901-0017-00001, XE-GD-0109, March 2014. TRIM ref 2014/110064.
28	ONR-NR-AR-17-024-UKABWR Peer Review Pro-forma TRIM 2017/382684
29	ONR-NR-AR-17-024-UKABWR Professional Lead Acceptance Check Sheet TRIM 2017/387638

Annex 1

Safety Assessment Principles

SAP No	SAP Title	Description
MS 1-	Leadership and management for safety - Leadership	Directors, managers and leaders at all levels should focus the organisation on achieving and sustaining high standards of safety and on delivering the characteristics of a high reliability organisation.
MS-2	Leadership and management for safety - Capable organisation	The organisation should have the capability to secure and maintain the safety of its undertakings.
MS-3	Leadership and management for safety - Decision making	Decisions made at all levels in the organisation affecting safety should be informed, rational, objective, transparent and prudent.
MS-4	Leadership and management for safety - Learning	Lessons should be learned from internal and external sources to continually improve leadership, organisational capability, the management system, safety decision making and safety performance.

Annex 2
Technical Inspection Guide

TIG Ref	TIG Title
NS-INSP-GD-017 Revision 4	LC 17- Management Systems

Annex 3

National and International Standards and Guidance

National and International Standards and Guidance

IAEA Safety Standards, Leadership and Management for Safety, General Safety Requirements No. GSR Part 2 IAEA. Vienna. 2016. www.iaea.org

BSI Standards Publication, BS EN ISO 9001:2015, Quality management systems Requirements.

Annex 4

Regulatory Issues / Observations

RI / RO Ref	RI / RO Title	Description	Date Closed	Report Section Reference
None				

Annex 5

Assessment Finding

Assessment Finding Number	Assessment Finding	Report Section Reference
AF-ABWR-MSQA-01	Because the addressing of minor shortfalls does not merit significant regulatory oversight and a process for their management is not explicit in the GDA process, the licensee shall put in place proportionate arrangements to ensure that they are considered, actioned as appropriate, and that records are maintained of such consideration and action.	4.2.7

Annex 6
Minor Shortfalls

Minor Shortfall Number	Minor Shortfall Finding	Report Section Reference
MS-ABWR-MSQA-01	<p>The end of GDA step 4 provides an excellent opportunity to review what has been learned writing the Generic PCSR and to use this information to improve the safety case management arrangements and organisation for the site specific stage.</p> <p>Because a review was not carried out during step 4, the future licensee should review the safety case management arrangements and implement any improvements necessary before starting the site specific stage.</p>	4.2.8