Office for Nuclear Regulation

Civil Nuclear Reactor Build - Generic Design Assessment

Step 2 Assessment of the Management of Safety and Quality Assurance Arrangements for Generic Design Assessment of Hitachi-GE's UK Advanced Boiling Water Reactor (UK ABWR)

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EXECUTIVE SUMMARY

This report presents the results of the joint regulatory assessment of the Management of Safety and Quality Assurance (MSQA) Arrangements for the Generic Design Assessment (GDA) of Hitachi-GE Nuclear Energy Ltd.'s (Hitachi-GE) UK Advanced Boiling Water Reactor (UK ABWR) undertaken as part of Step 2 of the Office for Nuclear Regulation's (ONR) and Environment Agency's (EA) GDA.

The GDA process calls for a step-wise assessment of the Requesting Party's (RP) safety submission with the assessments getting increasingly detailed as the project progresses. Step 2 is an overview of the acceptability, in accordance with the regulatory regime of Great Britain, of the design fundamentals, including review of key nuclear safety, nuclear security and environmental safety claims with the aim of identifying any fundamental safety, security or environmental shortfalls that could prevent the issue of a Design Acceptance Confirmation (DAC) by ONR or a Statement of Design Acceptability (SoDA) by EA. Our work has therefore focused on the assessment of the adequacy and effectiveness of the RP's management system arrangements and judging their ability to fulfil the regulators' expectations when compared to international quality standards and the regulators' GDA guidance documents.

The criteria we have used to judge the adequacy of the RP's management system arrangements for GDA are:

- ONR's Safety Assessment Principles (SAP) on Leadership and Management for Safety;
- ONR's Technical Inspection Guide on Management Systems;
- IAEA Safety Standard on Management System for Facilities and Activities;
- British and International Standards on Quality Management Systems (Requirements and Guidelines for Quality Plans);
- New Nuclear Reactors: Generic Design Assessment Guidance to Requesting Parties (2013);
- Generic Design Assessment Interface Arrangements (between the Regulators and RP)

Our step 2 assessment work has involved regular engagement with the RP in technical exchange workshops and progress meetings. In addition, our understanding of the ABWR technology and of the RP's Management System Arrangements, particularly those for managing and controlling GDA submissions, and, therefore, our assessment, has significantly benefited from visits to Hitachi Works, Rinkai Works and the ABWR units at the Kashiwazaki-Kariwa Nuclear Power Plant.

Our assessment has been based on the management system documentation submitted by the RP and an inspection, at the Hitachi Works, which assessed the implementation of the management system arrangements. The RP's management system documentation consisted of:

- GDA Project Plan
- Quality Management Plan (for UK ABWR GDA Project)
- Compliance Table for Regulatory Expectations
- GDA specific procedures

During our Step 2 assessment we have identified the following areas of strength:

- The RP have a quality management system which is certificated to ISO 9001:2008 and have developed specific management system arrangements for

the GDA project which will control the development, review, independent review and approval of the safety, security and environmental submissions to deliver the regulators expectations for GDA. These arrangements were generally of a good standard.

- Our implementation inspection at the Hitachi Works in Japan concluded that the RP have implemented suitable management system arrangements for the GDA project which, based on the sample taken, should ensure that the Regulators' expectations for GDA are fulfilled, and that the safety, security and environmental documentation produced within GDA will be adequately reviewed and independently verified.
- Our implementation inspection identified ten areas for improvement; these included process improvements and minor documentation changes. The RP have undertaken corrective action and provided evidence which has enabled us to verify that the actions are complete.

In our assessment of the management arrangements for the UK ABWR GDA we have identified the following areas that require follow-up:

- An area for improvement found during our inspection related to the recording of Nuclear Safety and Best Available Techniques (BAT) discussions and considerations during the design review meetings. The RP carried out prompt corrective action by introducing a "Summary of Design Review" and, in response to an RQ, has sent examples of these reviews to demonstrate the effectiveness of this process. In Step 3 ONR will continue dialogue with the RP to ensure the reviews adequately record discussion of Nuclear Safety and BAT.
- The RP have submitted a matrix to show how the Regulators' expectations for GDA Steps 3 and 4 will be met. This will need to be monitored throughout Step 3.

In relation to the interactions with their Subject Matter Experts (SME) in the MSQA area, we have found the RP's personnel to be suitably knowledgeable and experienced quality management professionals. Meetings and interactions with the SMEs were open and transparent. Our comments and the areas for improvement identified during the inspection were dealt with efficiently and quickly.

Overall, the ONR and EA Inspectors see no reason, on MSQA grounds, why the UK ABWR should not proceed to Step 3.

LIST OF ABBREVIATIONS

AFI	Area for Improvement
ABWR	Advanced Boiling Water Reactor
BAT	Best Available Technique
BMS	Business Management System
DAC	Design Acceptance Confirmation
DRP	Design Reference Point
EA	Environment Agency
GDA	Generic Design Assessment
Hitachi-GE	Hitachi-GE Nuclear Energy Ltd.
IAEA	International Atomic Energy Agency
JPO	(Regulators') Joint Programme Office
MDSL	Master Document Submission List
MSQA	Management for Safety and Quality Assurance
NPP	Nuclear Power Plant
ONR	Office for Nuclear Regulation
PCSR	Pre-construction Safety Report
PSR	Preliminary Safety Report
QMP	Quality Management Plan
QMS	Quality Management System
RI	Regulatory Issue
RO	Regulatory Observation
SQEP	Suitably Qualified and Experienced Person
RP	Requesting Party
RQ	Regulatory Query
RWA	Radioactive Waste Advisor
SAP(s)	Safety Assessment Principle(s)
SME	Subject Matter Expert

LIST OF ABBREVIATIONS

SoDA	Statement of Design Acceptability
TAG	Technical Assessment Guide(s)
TIG	Technical Inspection Guide(s)
TSC	Technical Support Contractor
WENRA	Western European Nuclear Regulators' Association

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1 INTRODUCTION

1.1 Background

1. The Office for Nuclear Regulation's (ONR) and Environment Agency's (EA) Generic Design Assessment (GDA) process calls for a step-wise assessment of the Requesting Party's (RP) safety submission with the assessments getting increasingly detailed as the project progresses. Hitachi–GE Nuclear Energy Ltd. (Hitachi-GE) is the RP for the GDA of the UK Advanced Boiling Water Reactor (UK ABWR).

2. During Step 1 of GDA, which is the preparatory part of the design assessment process, the RP established its project management and technical teams and made arrangements for the GDA of its ABWR design. Also, during Step 1 the RP prepared submissions to be evaluated by ONR and the EA during Step 2.

3. Step 2 of GDA is an overview of the acceptability, in accordance with the regulatory regime of Great Britain, of the design fundamentals, including review of key nuclear safety, nuclear security and environmental safety claims with the aim of identifying any fundamental safety or security shortfalls that could prevent the issue of a Design Acceptance Confirmation (DAC) or a Statement of Design Acceptability (SoDA).

4. This report presents the results of our joint (ONR and EA) assessment of the Management of Safety and Quality Assurance (MSQA) Arrangements for the GDA of the UK ABWR as presented in the Quality Management Plan (QMP) for the UK ABWR Project (Ref. 9) and associated management system procedures.

1.2 Methodology

5. Our assessment has been undertaken in accordance with the requirements of ONR's How2 Business Management System (BMS) procedure PI/FWD (Ref. 1). ONR's Safety Assessment Principles (SAP) (Ref. 2), together with supporting Technical Assessment and Inspection Guides (TAG & TIG) (Ref. 3) have been used as the basis for this assessment.

6. Our assessment has followed the GDA Step 2 Assessment Plan for MSQA (Ref 6) prepared in December 2013 and shared with the RP to maximise openness and transparency. The only departure from the plan was the delay of the internal inspection of ONR's compliance with its GDA process and guidance which may now be covered by ONR's Regulatory Assurance Programme.

2 ASSESSMENT STRATEGY

7. This section presents our strategy for the GDA Step 2 assessment of the MSQA of the UK ABWR (Ref 6). It also includes the scope of the assessment and the standards and criteria that we have applied.

2.1 Scope of the Step 2 MSQA Assessment

8. The objective of our GDA Step 2 MSQA assessment for the UK ABWR was to review and judge the adequacy and implementation of the RP's management system arrangements for the production of safety and environmental documentation and for meeting regulatory expectations.

9. The scope of the assessment covered all the GDA activities carried out by the RP as identified in its QMP (Ref. 9). It also examined relevant aspects of the RP's

management system, particularly the processes used to develop the UK ABWR design reference.

10. Finally, during Step 2 we have undertaken the following preparatory work for our Step 3 assessment:

- Discussed with the RP how it plans to meet regulatory expectations during Steps 3 and 4 of GDA. We have received a quality planning matrix from the RP showing how the expectations will be fulfilled.

2.2 Standards and Criteria

11. The goal of the GDA Step 2 MSQA assessment is to reach an independent and informed judgment on the adequacy of and implementation of the RP's management system arrangements for the production of safety documentation and for meeting regulatory expectations. For this purpose, within ONR, assessment is undertaken in line with the requirements of the How2 Business Management System (BMS) document PI/FWD (Ref. 1). Appendix 1 of Ref. 1 sets down the process of assessment within ONR; Appendix 2 explains the process associated with sampling of safety case documentation.

12. In addition, the SAPs (Ref. 2) constitute the regulatory principles against which duty holders' safety cases are judged, and, therefore, they are the basis for ONR's nuclear safety assessment and have been used for GDA Step 2 assessment of the UK ABWR. The SAPs 2006 Edition (Revision 1 January 2008) were benchmarked against the IAEA standards (as they existed in 2004). They are currently being reviewed.

13. Furthermore, ONR is a member of the Western Regulators Nuclear Association (WENRA). WENRA have developed Reference Levels, which represent good practices for existing nuclear power plants, and Safety Objectives for new reactors.

14. The relevant SAPs, IAEA standards and WENRA reference levels are embodied and enlarged on in the Technical Inspection Guide (TIG) on MSQA (Ref. 3). This guide provides the principal means for assessing the MSQA aspects in practice.

2.2.1 Safety Assessment Principles

15. The key SAP (Ref. 2) applied within the assessment is SAP MS1 - Leadership (see also Table 1 for further details).

2.2.2 Technical Assessment Guides

16. The following Technical Inspection Guide (TIG) has been used as part of this assessment (Ref. 3):

- LC 17 - Management Systems NS-INSP-GD-017

2.2.3 National and International Standards and Guidance

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

- Relevant IAEA standards (Ref. 4):
  - The Management System for Facilities and Activities, Safety Standard, GS-R-3.

- WENRA references (Ref. 5):
  - Reactor Safety Reference Levels (January 2008).
- Other international standards (Ref. 19):
  - BS-EN-ISO9001:2008 – Quality Management Systems – Requirements.
  - BS ISO 10005:2005 – Quality Management Systems – Guidelines for Quality Plans.

2.3 Use of Technical Support Contractors

18. No technical Support Contractors were used for the MSQA assessment.

2.4 Integration with Other Assessment Topics

19. Early in GDA we recognised that during the project there would be a need to consult with other assessors from ONR and EA as part of the MSQA assessment process. We consider these interactions very important to identify shortfalls in the RP's management system arrangements, and, therefore, are key to the success of the project. Thus, from the start of the project, we made every effort to identify as many potential interactions as possible between the MSQA and other technical areas, with the understanding that this position would evolve throughout the UK ABWR GDA.

3 REQUESTING PARTY'S MANAGEMENT SYSTEM ARRANGEMENTS

20. This section presents a summary of the RP's Management Arrangements for GDA. It also identifies the documents submitted by the RP which have formed the basis of our assessment of the UK ABWR MSQA during GDA Step 2.

3.1 Summary of the RP's Management System Arrangements.

21. ONR expects the RP to have adequate management system arrangements to deliver good quality safety, security and environmental submissions and to deliver the expectations expressed in ONR and EA guidance documents (Ref. 12, 13 & 18). The RP submitted a quality management plan and complete suite of quality management procedures for GDA in December 2013. The processes covered by the GDA management arrangements are outlined below and were the focus for our MSQA assessment.

22. A quality management plan describes the overall project organisation, responsibilities and management system processes. The plan provides confidence that the regulatory expectations for GDA will be met.

23. Document control arrangements to ensure that safety, security and environmental documentation is appropriately; developed, peer reviewed, verified, approved and issued. This also includes the arrangements for acknowledging and responding to RIs ROs and RQs.

24. Design change control arrangements for the development of the UK ABWR design reference that ensure design changes are adequately controlled and have appropriate safety justification. Additionally, design change control also includes the arrangements for controlling design changes after the design reference point (DRP) and for obtaining regulatory approval to include the change in GDA.

25. Competence arrangements to ensure that the personnel developing, peer reviewing, verifying and approving safety, security and environmental submissions are suitably qualified and experienced to carry out their roles. This includes the competence of contractors providing services to the RP.

26. Hitachi-GE internal audit arrangements to evaluate the continuing suitability and effectiveness of the GDA arrangements and to promote continual improvement.

27. Purchasing arrangements to ensure that the suppliers of services for GDA are evaluated and selected appropriately and have the capability to perform the service to the required standard and quality.

28. Communication arrangements to ensure effective communications through the Joint Programme Office (JPO) in accordance with the interface arrangements (Ref 13)

3.2 Basis of Assessment: The RP's Documentation

29. The RP's management system documentation that has formed the basis for my GDA Step 2 assessment of the MSQA arrangements for the UK ABWR is:

- UK ABWR GA10-0501-0001-00001 - XD-GD-0015 - Rev 1 - GDA Project Plan. This document describes the overall arrangements for the GDA project.
- UK ABWR GA70-1501-0007-00001 - GNQA13-0066 - Rev 2 - Quality Management Plan (For UK ABWR GDA Project). This document describes the GDA projects organisational structure and a description of the management

arrangements, processes and documentations which form the basis for the GDA management arrangements.

- UK ABWR GA70-1501-0013-00001 - GNQA13-0518 - Rev 0 - Compliance Table for Regulatory Expectations. This document supplements the QMP and describes how regulatory expectations are fulfilled.
- UK ABWR GDA tracking sheet (Ref. 8).
- The RP's response to Regulatory Query (RQ) RQ-ABWR-0092 (Ref. 11)
- The RP's response to Regulatory Query (RQ) RQ-ABWR-0173 (Ref. 11)
- GNQA13-0199 Communication, Reporting Lines and Distribution of Information in the GDA Organization. (Ref.15)
- GNQA13-0215 Control of general documents and records. (Ref.15)
- GNQA13-0255 SQEP Requirements for HITACHI-GE and Supplier Personnel. (Ref.15)
- GNQA13-0201 Generic Design and Development Control. (Ref.15)
- GNQA13-0202 Design Change Control and Documentation. (Ref.15)
- GNQA13-0203 Purchasing Control. (Ref.15)
- GNQA13-0256 Control of Non-conformance, Corrective action, and Preventive action. (Ref.15)
- GNQA13-0257 Assessment of GDA arrangements (Internal Audits, Self assessment). (Ref.15)
- XD-GD-0001 GDA Document Control Manual. (Ref. 20)
- XD-GD-0016 Implementation Procedure for Readiness Review. (Ref.15)

30. In addition, in the response to RQ-ABWR-0092 (Ref. 11) the RP have submitted to ONR and EA for information a quality planning matrix showing how the regulators' expectations for Steps 3 and 4 of GDA will be fulfilled. Although we have not covered this report in our GDA Step 2 formal assessment, seeing it has been useful to start planning and preparing our GDA Step 3 work.

4 ONR AND EA ASSESSMENT

31. Our assessment has been carried out in accordance with ONR How2 BMS document PI/FWD, “Purpose and Scope of Permissioning” (Ref. 1).

32. Our GDA Step 2 MSQA assessment has followed the strategy described in Section 2 of this report

33. Our Step 2 assessment work has involved continuous engagement with the RP’s MSQA Subject Matter Experts (SME), i.e., Technical Exchange Workshops (one in Japan and one the UK) and an implementation inspection has been carried out at Hitachi Works in Hitachi City. We have also visited:

- Kashiwazaki Kariwa Units 6&7 ABWRs where we could tour the majority of the facility.

- Hitachi Works (reactor internals workshop), where they manufacture reactor components and we could see the quality arrangements and controls associated with manufacture.

34. During our GDA Step 2 assessment and inspection, we have identified some minor shortfalls in documentation which led to the issue of one Regulatory Query (RQ) to request the RP to provide information on the corrective actions carried out in response to the MSQA implementation inspection at the Hitachi Works in Japan. No Regulatory Observations (RO) were raised relating to MSQA during Step 2 of GDA.

35. Details of our GDA Step 2 assessment of the UK ABWR GDA MSQA arrangements including the areas of strength that we have identified, as well as the items that require follow-up and the conclusions reached, are presented in the following sub-sections.

4.1 The RP’s Management System Arrangements Documentation and Processes

4.1.1 Assessment

36. This assessment was carried out to determine if the RP’s management arrangements and processes could deliver good quality safety, security and environmental submissions and would fulfil the regulatory expectations for GDA which are expressed in the GDA Guidance to Requesting Parties (Ref. 12) and in the GDA Interface Arrangements (Ref 13).

37. During Step 1 of GDA the RP developed a QMP which described the GDA specific management system including organisational structure of the GDA project and the documented processes. During a visit to Japan in October 2013 (prior to commencing Step 2 of GDA) the regulators agreed to provide high level comments on draft documentation prior to formal issue to check if the RP’s quality assurance documentation required early in GDA fulfilled the regulators’ expectations. Comments were provided on the QMP (Ref.14) and the associated management system procedures (Ref.15). The most significant comment related to clearly demonstrating that the arrangements would fulfil regulatory expectations in the QMP.

38. The RP incorporated the comments into the QMP and associated management system procedures which were issued, on time, at the end of December 2013 ready for Step 2 of GDA. We formally assessed the adequacy of these arrangements for Step 2 of GDA against the standards and relevant good practice described in section 2.2 by carrying out a desktop review.

4.1.2 Strengths

39. The QMP provided evidence that the RP have carried out sufficient quality planning and that a suitable Quality Management System (QMS) had been developed for Step 2 of GDA.

40. The processes needed to produce good quality safety submissions and to meet regulatory expectations have been developed and documented in GDA specific procedures.

41. Adequate resources have been allocated to developing and maintaining the RP's management arrangements for the UK ABWR GDA.

4.1.3 Conclusions

42. The management arrangements assessed were judged to meet the requirements of the international QMS standards and other guidance identified in section 2.2. We considered the documentation was of a good standard and adequate for directing and controlling Step 2 of GDA. Our assessment therefore concluded that the arrangements were satisfactory and saw no reason why the ABWR GDA should not progress into Step 2 and beyond.

4.2 Implementation Inspection of the UK ABWR GDA MSQA Management Arrangements

4.2.1 Inspection

43. To confirm the implementation of the RP's GDA Management Arrangements ONR and EA carried out a joint inspection at the the RP Offices in Hitachi City, Japan in February 2014. The inspection was carried out over four days.

44. An inspection plan (Ref.16) was developed and the topics covered by the inspection were:

- Document Control;
- Design Control;
- Personnel competence;
- Audit arrangements;
- Purchasing;
- Communications;
- Quality Planning for Step 3 & 4 of GDA.

45. Our inspection assessed the RP's GDA Management System to ensure that adequate arrangements are in place. The RP is certificated to ISO 9001 and 14001 so our inspection concentrated on the processes to deliver the GDA.

46. The findings from our inspection were recorded in a joint intervention report (Ref.17). Key strengths and areas for improvement identified are discussed in the following sub-sections.

4.2.2 Strengths

47. Document control arrangements were of a good standard. The format and content of documents was suitably specified and arrangements were in place to submit documentation to the regulators' Joint Programme Office (JPO). A number of minor discrepancies were found and have been identified as areas for improvement below.

Records were well specified and kept. The inspection team judged the document control arrangements to be satisfactory.

48. Arrangements are in place for the review, independent verification and approval of safety and environmental documentation prior to submission to the Regulators. This was considered to be satisfactory.

49. The inspection found that the design change control arrangements for developing the UK ABWR Reference Design from a Japanese Reference Plant were satisfactory. The level of design review, verification and validation appeared appropriate. One important area for improvement was identified relating to how the impact on nuclear safety and the use of Best Available Techniques (BAT) are discussed and considered during design review meetings and how this is recorded in the minutes. The RP have taken improvement action. ONR and EA are currently monitoring and discussing the effectiveness of the action with the RP..

50. The RP have arrangements in place for requesting that design changes be included in GDA after the Design Reference Point (DRP) and for receiving regulatory agreement. These are in line with the six step process recommended by the Regulators.

51. Suitably Qualified and Experienced Person (SQEP) records were examined for the RP's staff, contractors and consultants and demonstrated that the personnel were competent for their roles. SQEP records were of a good standard. The team judged this to be satisfactory.

52. The control of suppliers included an approved suppliers list, supplier evaluation and a good standard of procurement documentation. Records for supplier evaluations were readily available and complete. The team judged these arrangements to be satisfactory.

53. Radioactive Waste Advisers (RWA) had not been appointed at the time of the inspection, however examination of role profiles indicated that training on EA requirements and the use of BAT had been given to key staff. This was judged sufficient at this stage of the project. The RP have plans to use RWAs in Step 3 and we may revisit this at a later date.

54. Independent assessment of the GDA process consisted of an audit programme. The first part of the programme for Step 2 of GDA had been completed and all corrective actions carried out and verified. These audits focussed on system requirements. Our inspection team made a recommendation to focus the next round of the RP's audits on GDA deliverables and to carry them out near the start of the step so as to allow time for corrective action.

55. The RP was considering how it will meet the expectations given in ONR's Guidance to Requesting Parties (Ref. 12) and EA's Process and Information Document (Ref. 18) for Steps 3 and 4 of GDA and agreed to produce a table showing how it plans to meet them.

56. During the inspection additional meetings were held to clarify and agree the format and content of the UK ABWR Reference Plant and Design Reference and the contents of the Master Document Submission List (MDSL). The RP suggested a 'Design Reference Document List / Reference Plant' document listing approximately 2000 plant and system descriptions and drawings as the basis for the Design Reference. This document would also indicate the Japanese reference plant from which the UK ABWR systems are developed. ONR and EA team were content with the proposal.

4.2.3 Areas for Improvement (AFI)

57. Our inspection found 10 areas for improvement which are listed below in order of safety and environmental significance:

- AFI 1 - The Generic Design Development Procedure GNQA13-0201, section 4.4, (2) d & h. states that two purposes of the design review process are to consider the impact of the design change on nuclear safety and how BAT will be utilised. The RP stated that its design reviews meet these requirements. However, the minutes and other design review documents which were examined and discussed during the inspection did not record or demonstrate that nuclear safety or BAT had been considered by the design review meeting. Our inspection concluded that the RP should review the compliance with procedure GNQA13-0201, section 4.4, (2) d & h and determine if the design review meetings adequately consider:

  - the impact of the design change on nuclear safety and if the change will adversely affect nuclear safety;
  - if the change will utilise BAT to control discharges or potential discharges to the environment.

  The RP must ensure that discussions relating to the above are recorded in the design review meeting minutes.

- **AFI 2 -** All sections of the UK ABWR Preliminary Safety Report (PSR) were individually verified and approved. It was unclear whether the top level signature on the front of each document only confirmed that each section had been individually verified or if it also indicated that the PSR had been verified as a complete document and found fit for purpose. The RP should confirm the purpose of these signatures.
- **AFI 3 -** Procedure GA-9105-120003-0001 (RQ response procedure) was in draft at the time of the review. The RP stated that it is using this draft procedure to control the RQs recently issued by the regulators. We recommended that this procedure should be formally approved and issued as soon as possible.
  In addition, the inspection team noted that the workflow diagram in the procedure did not show how partial responses to RQs are processed and recommended that this information should be included in the procedure before issuing. We also recommended that similar procedures should also be approved and issued for ROs and Regulatory Issues (RI).
- **AFI 4 -** Procedure GA-9105-120003-0001 (RO response procedure), in draft at the time of the inspection, contains reference to an informal exchange of draft ROs with ONR and EA. The interface arrangements between the regulators and the RP (Ref. 13) (Workflow in Paragraph 78) states “Drafts of the ROs and Resolution Plans will be discussed by all parties during their development.” We recommended that Procedure GA-9105-120003-0001 should be consistent with the Interface Arrangements and state that drafts of the ROs and Resolution Plans will be discussed by all parties during their development, rather than referring to an informal exchange of draft ROs.
- **AFI 5 -** The RP 2013 audits concentrated on assessing compliance with IAEA’s GS-R-3 requirements which are listed in the QMP. To ensure that GDA regulatory expectations will be met we recommended the RP to focus the next audits on the GDA deliverables which are specified in the guidance documents. The audits should also follow a graded approach and be targeted on the areas of greatest safety, security or environmental significance. The RP should review its GDA audit plan to address the points in this regard raised by our inspection team.

- **AFI 6 –** At the time of conducting our Step 2 MSQA inspection GDA audits were programmed towards the end of each step. This purpose was to use the audit results to confirm readiness to move to the next step; however this audit strategy will not identify problems early in the process. The regulators would encourage audits to be planned earlier in each step so that problems are identified early leaving time for corrective action. It may also be appropriate to audit periodically throughout the longer steps. We recommended the RP to review its GDA audit programme to address the regulators' recommendations in this regard..
- **AFI 7 -** The front sheets of safety case and environmental documents should be amended to contain a signature for the completion of the review stage in addition to the existing signatures for independent verification and approval.
- **AFI 8 –** Our inspection identified that the RP's submission tracking sheet did not include RQs, ROs, RIs and other documents provided to regulators for information (e.g. MSQA procedures and resolution plans). The definitions section (2) in the Interface Arrangements states that the tracking sheet should contain these documents. We recommended the RP to retrospectively add the existing RQs, ROs and other documents provided to ONR and EA (for example MSQA procedures) to the submission tracking sheet and ensure such documents are included in the future.
- **AFI 9 -** The RP's Document Control Manual (XD-GD0001) did not make reference to the procedures for handling sensitive nuclear information or commercially sensitive information. Users of this document need to be fully aware of the information contained in these procedures as they may be handling such information during GDA. We recommended the RP to make reference to the two procedures in its Document Control Manual.
- **AFI 10 -** The RP should include in its Document Control Manual the arrangements for controlling the GDA contact list.

4.2.4 Resolution of Non-conformities

58. Following our inspection, we raised RQ-ABWR-0092 (Ref. 10) requesting the RP to provide information on the corrective actions that would be taken in response to the 10 AFIs raised by the inspection team, and the timescales for completing the actions.

59. The RP's response to the RQ (Ref. 11) identified suitable corrective action for each AFI and stated that the corrective actions for all 10 AFIs had been completed. The response also included sufficient evidence for the regulators to verify that the actions had been taken. All the AFIs from our inspection have therefore been closed out.

4.2.5 Items that Require Follow-up

60. We decided that, given its safety and environmental significance of AFI 1, it would be prudent for the regulators to verify the effectiveness of the RP's corrective action for this AFI. RQ-ABWR-0173 (Ref. 11) was issued seeking further information to verify the effectiveness of the improvement action taken. The RP have responded and provided evidence which clearly shows the process is implemented. However, some further dialogue is needed to ensure the information recorded by the new process is adequate. This will be done in Step 3.

4.2.6 Conclusions

61. Our inspection concluded that the RP have developed and implemented a suitable management system for the GDA project which, based on the sample taken, should ensure that the regulators' expectations for GDA are fulfilled and that the safety,

security and environmental documentation submitted to ONR and EA has been adequately reviewed and independently verified.

62. Our inspection did not find any instances where expected management arrangements or processes were not in place but it did identify a number of areas for improvement which have now been addressed by the RP.

4.3 Comparison with Standards, Guidance and Relevant Good Practice

63. In Section 2.2 above we have listed the standards and criteria we have used during our GDA Step 2 assessment of the UK ABWR MSQA to judge the adequacy of the GDA management system arrangements. Our overall conclusions in this regard can be summarised as follows:

- SAPs: The expectations in SAP MS.1 – Leadership have been fulfilled. Table 1 provides further details.
- The relevant expectations for management systems in ONR's TIG (Ref. 3) have been fulfilled by the RP's GDA management arrangements.
- The RP's management arrangements were also assessed against international QMS standards (Ref 4 & 19) and were found to fulfil the requirements of these standards.

4.4 Interactions with Other Regulators

64. The MSQA assessment and inspection was carried out jointly by ONR and EA. All assessment and inspection activities were planned, carried out and reported jointly. This included the joint MSQA implementation inspection carried out at the RP's Offices in Japan.

5 CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

65. The RP have developed suitable and sufficient management system arrangements to adequately control the development and production of safety, security and environmental documentation for the GDA of the UK ABWR. A good standard of quality planning has been carried out and the management arrangements contain adequate instructions and guidance to ensure that the regulators expectations are fulfilled during Step 3.

66. Overall, I see no reason, on MSQA grounds, why the UK ABWR should not proceed to Step 3 of the GDA process.

5.2 Recommendations

67. My recommendations are as follows:

- Recommendation 1: The UK ABWR should proceed to Step 3 of the GDA process.
- Recommendation 2: A Step 3 MSQA assessment plan should be developed to ensure the RP have adequate management system arrangements for Steps 3 and 4 of GDA.

6 REFERENCES

1 *ONR How2 Business Management System. BMS: Permissioning – Purpose and Scope of Permissioning*. PI/FWD – Issue 3. August 2011 (Please note that PI/FWD was superseded by NS-PER-GD-014 Issue 4 in July 2014) www.hse.gov.uk/nuclear/operational/assessment/index.htm.

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Table 1

Relevant Safety Assessment Principles Considered During the Assessment

SAP No and Title	Description	Interpretation	Comment
MS 1- 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.	This principle sets out the requirements for a Quality Management System (QMS).	Addressed in Section 4 of this report. The need for a QMS has been recognised from the outset and been developed by Hitachi-GE.