Cyfoeth Naturiol Cymru
Natural Resources Wales

Environment Agency

Assessing new nuclear power station designs

Generic design assessment of Hitachi-GE's Advanced Boiling Water Reactor

Assessment report - AR01 Management arrangements

12 December 2016

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Natural Resources Wales is the largest Welsh Government Sponsored Body - employing 1,900 staff across Wales. We were formed in April 2013, largely taking over the functions of the Countryside Council for Wales, Forestry Commission Wales and the Environment Agency in Wales, as well as certain Welsh Government functions.

- Adviser: principal adviser to Welsh Government, and adviser to industry and the wider public and voluntary sector, and communicator about issues relating to the environment and its natural resources
- Regulator: protecting people and the environment including marine, forest and waste industries, and prosecuting those who breach the regulations that we are responsible for
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- Manager/Operator: managing seven per cent of Wales' land area including woodlands, National Nature Reserves, water and flood defences, and operating our visitor centres, recreation facilities, hatcheries and a laboratory
- Partner, Educator and Enabler: key collaborator with the public, private and voluntary sectors, providing grant aid, and helping a wide range of people use the environment as a learning resource; acting as a catalyst for others' work
- Evidence gatherer: monitoring our environment, commissioning and undertaking research, developing our knowledge, and being a public records body
- Employer: of almost 1,900 staff, as well as supporting other employment through contract work.

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Executive summary

Protective status	This document contains no sensitive nuclear information or commercially confidential information

Process and Information Document[1]	The following sections of Table 1 in our process and information document (P&ID) are relevant to this assessment: Item 2: A description of the requesting party's management arrangements and responsibilities for: • developing the design • managing the generic design assessment (GDA) project • establishing the method for identifying the best available techniques (BAT) and making sure they are used in the design • producing and maintaining the submission • ongoing communications with the regulators and responding to matters they raised during GDA • maintaining records of design and construction • controlling and documenting design modifications, both during and after completion of GDA • transferring information to potential operators and providing ongoing support to them throughout the reactor's life cycle

Radioactive Substances Regulation Environmental Principles[2]	The following principles are relevant to this assessment: MLDP1 – Establishing and sustaining leadership and management MLDP 2 – High standards of environment protection MLDP3 – Capability MLDP4 – Decision making MLDP5 – Learning from experience

[1] Process and Information Document for Generic Assessment of Candidate Nuclear Power Plant Designs, Version 2, Environment Agency, Mar 2013. http://webarchive.nationalarchives.gov.uk/20151009003754/https://www.gov.uk/government/publications/assessment-of-candidate-nuclear-power-plant-designs

[2] Regulatory Guidance Series, No RSR 1: Radioactive Substances Regulation – Environmental Principles, Version 2), Environment Agency, April 2010. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/296388/geho0709bqsb-e-e.pdf

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We have carried out this assessment of Hitachi-GE's (requesting party) quality assurance and management system arrangements for developing the design and producing the submission in accordance with the requirements of the Environment Agency's process and information document for generic assessment of candidate nuclear power plant designs (P&ID.) This is in order to give us confidence in the quality of the submission and to make sure processes are in place to transfer the technology to the future operator.

We have carried out this assessment out together with the Office of Nuclear Regulation (ONR). From the start of the generic design assessment (GDA) process, we have worked closely with ONR and Natural Resources Wales.

The report includes our findings from our preliminary assessment report (Lit 10001 Environment Agency, 2014) at Step 2 and follows the progress of development and improvements to the management arrangements through Step 3 into Step 4. It also includes evaluating processes that need to be in place at the end of the GDA process to support transferring technology to a future operator.

This assessment is limited to the UK Advanced Boiling Water Reactor (ABWR) GDA project quality plan and Hitachi-GE supporting documentation and the effectiveness of the implementation of the processes up to 5 August 2016. Hitachi-GE internal company processes were sampled, where applicable to the GDA process.

It includes reviews carried out in response to concerns raised by our assessors, such as effectiveness of training in requirements of UK legislation.

The quality of the information provided to the individual technical assessors is outside the scope of this assessment.

We are content that Hitachi-GE management arrangements for GDA are satisfactory and meet the requirements of the P&ID, and should ensure that the highest environmental standards are applied. This includes developed processes for transferring technology to a future operator.

We are working with ONR to develop a work plan, for the ongoing period up to the end of the GDA process. This will include meeting with Hitachi-GE management systems quality assurance (MSQA) staff and carrying out further sampling of evidence available in the UK and Japan, to keep compliance with the P&ID under review.

There are no assessment findings at this time.

Contents

1. Introduction

The purpose of this report is to provide our assessment of Hitachi-GE's (requesting party) quality assurance and management system arrangements for developing the design and producing the submission to meet the requirements of the Environment Agency's process and information document (P&ID).

This was to give us confidence in the quality of the submission and to make sure processes are in place to transfer the technology to the future operator.

We carried out the assessment out in 2 stages, as set out in our P&ID.

The first stage was an initial assessment of its arrangements. The findings of our assessment was set out in our Environment Agency/Natural Resources Wales initial report (Environment Agency, 2014).

We sampled the GDA UK ABWR management arrangements with reference to the requirements of ISO 9000, 14000 and 18000 series of standards.

We carried out a review of the Hitachi-GE quality management plan (QMP) and the supporting documents, which set out the expectations for quality control, and identified the requirements for compliance with our P&ID and how it met the Environment Agency Regulation Environmental Principles (REPs). We found these to be satisfactory.

We checked the process documents to make sure it identified the requirements of the P&ID relevant for this stage of the project and the Environment Agency REPs. We visited Hitachi-GE works offices in Japan to sample the records and take a view on how the process was being implemented. We found arrangements generally satisfactory, with some areas requiring improvement and further development.

In the second stage, we examined the processes in more detail, testing to make sure they complied with our requirements. We did this through correspondence, meetings in the UK and Japan and site visits to carry out further sampling of the processes at Hitachi-GE works offices in Japan. We raised several Regulatory Queries (RQ) and Regulatory Observations (RO). They have all now been closed out and we discuss them in detail below.

We provided our views to Hitachi-GE on processes to control design change and transfer technologies to future operators to enable them to develop processes to cover areas such as RO/Regulatory Issue (RI) commitment capture, and a process to capture changes to the pre-construction safety report (PCSR) which may affect Hitachi-GE's generic environmental permit (GEP) submission.

We provide the detail of our assessment below, which supports our conclusion that Hitachi-GE has adequate management arrangements in place to support its GEP submission to ensure high standards of environmental protection can be achieved.

Hitachi-GE also has well developed processes to support a future operator in taking forward the design and underpinning BAT case for implementation at a site level. It also has draft arrangements in place and is on track to develop these arrangements to complete the UK ABWR GDA project.

At the time of writing this report (5 August 2016), we do not have any assessment findings.

2. Assessment

We sampled Hitachi-GE's GDA management system in some detail during our initial assessment in 2013 to 2014 and concluded that it was suitable for controlling the content and accuracy of the information Hitachi-GE would provide for GDA in support of its GEP submission. We included this in our initial report (Environment Agency, 2014)

Hitachi-GE's submission describes the management system in:

- the GDA project plan
- the quality plan (for the UK ABWR GDA project)
- the compliance table for regulatory expectations
- GDA specific procedures

Hitachi-GE has a quality management system (QMS) that is certificated to ISO 9001:2008, and has developed specific management system arrangements for the GDA project.

The Hitachi-GE project plan (XD-GD-0015) sets out the objectives for the project, and describes Hitachi-GE leadership and accountability arrangements for providing the GDA, recognising the aim of environmental protection. It sets out the requirement to achieve this through the Hitachi-GE GDA project quality plan (GNQA13-0066).

The Hitachi-GE project control plan sets out how Hitachi-GE controls the development, review, internal independent review and approval of the safety, security and environmental submissions and meets the regulators' expectations for GDA. It also implements the requirements as set out in the compliance table for regulatory expectations document (GNQAA13-0518).

It provides a structure of documentation and processes to follow to make sure that the GDA project meets international standards and complies with Hitachi-GE's quality manual for nuclear business and how it relates to UK requirements. It sets out clear responsibilities at all levels within Hitachi-GE for controlling and providing information to the regulators for assessment. It recognises the specific need to demonstrate BAT within the design to support Hitachi-GE's submission of the GEP as set out in the summary of GEP submissions document (XE-DG-0094).

The quality plan specifies the requirement for the processes needed to support its application and the subsequent verification and internal auditing requirements. These requirements are set out in process quality control (PQC) plans for each work area. Hitachi-GE has divided the work up into project teams and 18 technical topic areas with dedicated subject matter experts to provide information to the regulators.

The list of processes developed to support the GDA process is set out in the list of references listed at the end of this assessment report.

We reviewed these documents at this early stage to be confident in the quality of the submission. This helped us decide to take a risk-based 'sampling' approach for the detailed assessment stage.

We sampled the Hitachi-GE quality management arrangements documentation below to establish whether suitable arrangements were in place:

- The basis of the UK ABWR design as set out in 'Genesis of design' (XE-GD-0083) and Hitachi-GE UK ABWR concept document (XE-GD-0088) included information on designing for minimising the impact on the environment.
- The document 'Description of Hitachi-GE organisational capability, systems and management arrangements' (XE-GD-0085) sets out the support of suitably qualified and experienced people (SQEP), whether in-house staff or contractors, for the project. This is set out in more detail in SQEP requirements for Hitachi-GE and supplier staff.

- We examined the documents ‘Generic design development control’ (GNQA13-021), ‘Design control and documentation’ (GNQA13-0202) and ‘Control of general document and records’ (GNQA13-0205) and found :
    - there is an appropriate level of verification, review and approval of design and submission documents in place, including those produced by contractors and the submission accurately reflects the design
    - the design has been developed taking environmental requirements for all power station life cycle stages into account
    - design changes are, and will be, controlled, evaluated for their impact on environmental matters, recorded and reflected in the submission
- We examined the documents ‘Assessment of GDA arrangements internal audits, self-assessment’ (GNQ13-0257) and ‘Control of non-conformance, corrective action and preventative action’ (GNQ13-0256). These showed that:
    - an adequate quality audit system is in place to make sure Hitachi-GE processes can be implemented successfully
- We reviewed the document ‘Consideration of and compliance with the radioactive substances regulation environmental principles (REPS) (XE-GD-0099). We are content that:
    - it clearly identifies how our REPs are to be taken into account in the GDA process
- The process for ensuring good communications are maintained were set out in the document ‘Generic design assessment interface arrangements’, January 2015, Revision 3.

We were, therefore, content that these processes were suitable for supporting the Hitachi-GE GEP submission. However, we planned to test how the processes were applied on a visit to Hitachi-GE works offices in Japan.

In February 2014, we and ONR visited Hitachi-GE’s offices in Hitachi City, Japan, for a 4-day joint assessment of how the management system worked in practice. The main objectives were to:

- check that Hitachi-GE has a QMS that provides organisational and procedural arrangements that adequately support production of the submissions
- establish that Hitachi-GE has implemented and continues to review arrangements that adequately control its GDA related activities
- inform the regulators' assessment of Hitachi-GE’s submission

We examined samples of the QMS procedures and other documentation, and held discussions with relevant staff. Hitachi-GE is certificated to ISO 9001 and 14001, so we carried out further sampling of the processes that will provide the GDA. These arrangements were generally of a good standard. Our main findings are summarised below:

- Document control arrangements were of a good standard. The format and content of documents were suitably specified and arrangements were in place to submit documentation to the joint programme office (JPO). We found a number of minor discrepancies. Records were well specified and kept. We judged the document control arrangements to be satisfactory.
- Arrangements are in place for the review, internal independent verification and approval of safety, security and environmental documentation before submission to the regulators. We considered these arrangements to be satisfactory.
- We found 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.
- We identified one important area for improvement, 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.

- We asked Hitachi-GE to put in place arrangements for requesting that design changes are included in GDA after the design reference point (DRP) and for receiving regulatory agreement to include within the GDA scope.
- We examined SQEP records for Hitachi-GE staff, contractors and consultants. These demonstrated that the staff were competent for their roles. SQEP records were of a good standard. We judged this to be satisfactory.
- The arrangements for 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. We judged these arrangements to be satisfactory.
- Radioactive waste advisers (RWAs) had not been appointed at the time of our site visit. However, examining role profiles indicated that training on our requirements and the use of BAT had been given to relevant staff. This is judged sufficient at this stage of the project. Hitachi-GE has since employed RWAs to support its GEP submission.
- Hitachi-GE has carried out an internal audit of its GDA processes in accordance with an audit programme.

The first part of the programme for ONR's Step 2 and our initial assessment had been completed and all changes made and verified. We noted that the Hitachi-GE audits focused on system requirements. We made a recommendation to focus the next round of audits on information to be provided for GDA and to carry out the audits near the start of the next stage of GDA, to allow time for any necessary changes.

In October 2015, we and ONR visited Hitachi-GE’s offices in Hitachi City, Japan.

- During the visit, additional meetings were held to clarify and agree how the UK ABWR reference design as discussed in ‘Definition of design reference point’ (XE-GD-0109) would be specified at the DRP and in the master document submission List (MDSL) (XE-GD-0158).
- Hitachi-GE suggested a ‘Design reference document list’ or ‘reference plant’ document listing approximately 2000 system descriptions and drawings as the basis for the design reference. This document would also indicate the Japanese reference plant from which the UK systems were developed. We and ONR indicated that we were content with the proposal.
- The development of the MDSL was reviewed throughout the project and this will continue until we decide whether to issue a statement of design acceptability (SoDA), as this is an important document in supporting a SoDA.

We recorded the details of the visit in a joint report (ONR-GDA-IR-13-001, Revision 0) and recorded the main 2 findings as areas for improvement:

- Hitachi-GE should include the arrangements for controlling the GDA contact list in the document control manual.
- Hitachi-GE should retrospectively add the existing RQs, ROs and other documents, for example management surveillance and quality assurance procedures to the submission tracking sheet and make sure it includes these documents in the future.

We raised a joint Environment Agency and ONR RQ with Hitachi-GE to address the main findings of the visit (RQ-ABWR-0092).

Hitachi-GE has responded to the requirements of the RQ. After considering Hitachi-GE’s responses we concluded that these were adequate for the purpose of GDA assessment, but that we will require further evidence that consideration of BAT in the GDA design control process would be adequately recorded. This was subsequently sampled at a later visit in October to Japan and found to be satisfactory.

During the detail assessment phase we continued to work with Hitachi-GE to improve its processes. We gave them advice to help develop a new process for transferring technology from Hitachi-GE to future operators.

We also discussed developing the Hitachi-GE design change management processes to incorporate the ONR / Environment Agency '6-step process'.

- The 6-step process is an administrative process that outlines the requirements that Hitachi-GE must follow to gain approval for a design change to be included in the GDA assessment process.
- Hitachi-GE must provide information on the scope, safety and environmental categorisation of the proposed change and an initial assessment on the impact of the change.
- The regulators would then decide whether they could accept the proposed change to the scope of the GDA.

We agreed a work plan, to include discussions via videoconferencing and meetings in the UK and Japan.

- This included site visits to Hitachi-GE works offices in Japan to further sample the process and assess how the processes had bedded in.
- Notes of the meetings were kept and are referenced in the table of references at the end of this report.
- Updated process documents were submitted and are included in the list of references.
- Comments were supplied by e-mail and discussed at the meeting and actions were agreed.
- Process documents were issued to use when all parties agreed that they were fit for purpose

We reviewed the results of Hitachi-GE's quality assurance audits and corrective actions carried out in response to these audits.

- These were catalogued in meeting materials supplied for discussion. Corrective action reports were provided in English and discussed at each meeting and continually monitored to make sure processes were being implemented correctly.
- After considering Hitachi-GE's response to RQ-ABWR-0173, we reviewed the design review process in more detail and found that improvements were needed to make sure that it captured both the elements of the design required to support nuclear safety impact and BAT in the summary sheet.
- Hitachi-GE revised the process to include our requirements.

During 2014, we focused on the processes that Hitachi-GE needed to develop to make sure that the requirements underpinning the BAT case were captured and available for future operator to incorporate into its operating system (QGG-GD-0001). Hitachi-GE needed to:

- establish a process for identifying and capturing the claims arguments and evidence (XD-GD-0042)
- develop a process to capture this through Hitachi-GE's company processes, not specific to GDA, in the technical specification and surveillance documents Hitachi-GE would provide to a future operator

We have examined both and provided comments to Hitachi-GE.

In October 2014, we visited Hitachi-GE works offices for a workshop with the MSQA team and other engineers as part of the ongoing dialogue with Hitachi-GE.

This allowed us to review the safety and BAT arguments, and understand how Hitachi-GE's processes were used to support the development of the UK ABWR safety case and GEP submission and how Hitachi-GE implemented them to meet modern standards and international good practice. Technical topics covered included:

- early discussion on moving the safety case and BAT case to the operating system
- incorporating BAT requirements into the design review process
- results of Hitachi-GE's audits
- RQ, RO and RI process and commitment capture
- review of quality system non-conformances
- reference design and DRP and summary of design review
- review and update the UK ABWR QMP

We were content that the Hitachi-GE design review process adequately captured the requirement for BAT assessments to be carried out and documented.

During 2015, we reviewed Hitachi-GE's progress to develop the design change control process (GNQA13-0201) and obtained clarification of the design reference point for the UK ABWR.

The design change control process was developed to include regulators' specific requirements to assess the proposed change (RO-ABWR-0025) to see if it is appropriate to include it within the scope of the GDA process.

In April 2015, we visited Hitachi-GE works offices to carry out further sampling of the MSQA arrangements in preparation for moving to ONR Step 3 of the GDA process. We summarised our findings in a joint RO, RO-ABWR-0058.

This included a review of:

- SQEP (BAT and safety case) training and competencies for UK requirements
- RO / RI resolution process and commitment capture process
- MSQA arrangements for ONR's Step 3 assessment
- a review of non–conformances and corrective action reports

We supported ONR on a specific requirement to look at the arrangements in place for control and instrumentation work being carried out at Hitachi-GE's OMIKA works for the diverse design of control systems. This included assessing whether the teams working on the project were in accordance with ONR requirements that the teams working on the project were adequately physically separated during their work.

We discussed and sampled the process to transfer GEP requirements to the future operator as outlined in Hitachi-GE's response to RQ-ABWR-0044; the development of the MDSL and DRP design change process.

We reviewed progress on the development and implementation of the '6-step process.'

We reviewed the safety case development manual to look at how information to support GEP submission requirements could be incorporated within the manual, so that information within the future GDA pre-construction safety case (PCSR) could inform the GEP.

We summarised the findings of the visit in RO-ABWR-0058.

Action 1

1. Hitachi-GE should review the arrangements for GDA specific training against the regulators' expectations to determine if the training is providing Hitachi-GE GDA staff with enough

knowledge so they can produce good quality GDA submissions for the UK ABWR. Hitachi-GE should then take appropriate action.

2. Hitachi-GE to review internal audit checklists to make sure the effectiveness of GDA specific training is adequately assessed by internal audits. Further meetings and videoconferences with Hitachi-GE discussed progress status of MSQA related RO-ABWR-0058 and Hitachi-GE closure plans.

Action 2

To resolve the non-conformities in role profiles and SQEP assessments found during the inspection;

1. Hitachi-GE should review the role profile for the Departmental Manager responsible for the Class 1 RPS to make sure it adequately describes the qualifications and experience required for the role. Hitachi-GE should also review the SQEP assessment and make sure it correctly identifies the nuclear safety significance of the role
2. Hitachi-GE to review the SQEP assessment (674195008) for the human factors (HF) subject matter expert to make sure it is consistent with the SQEP assessment in the response to RO-ABWR-0005 and the HF integration plan
3. Hitachi-GE should review SQEP assessment coversheets 310800272 and 310790164 to make sure they record and demonstrate that GDA staff have received the necessary GDA specific training
4. Hitachi-GE should also check and review other role profiles and SQEP assessments to determine if they contain similar shortfalls and take appropriate corrective action as necessary

Action 3

1. Hitachi-GE to develop a method for capturing and logging commitments to update the safety case when RO or RI actions have been completed and ONR has agreed that the RO or RI can be closed subject to the safety case being updated. This method should also be applied to RQ responses when appropriate

Action 4

1. consider improvements to the readiness review report so that it captures and takes credit for planned improvements

Hitachi-GE produced a resolution plan for RO-ABWR-0058, which it submitted to the regulators who monitored its progress to satisfactory completion.

Hitachi-GE developed procedure XD-GD-0042 ‘Standard control procedure for identification and registration of assumptions, operating limits and conditions in response to our RO-ABWR-0057.

- This allowed a process for transferring requirements to the operator to be developed in support of a site-specific BAT case.
- We reviewed this process to make sure that it included our environmental requirements and found it satisfactory.

Our meetings with Hitachi-GE identified a need to capture changes to the generic pre-construction safety report (PCSR) chapters and make sure that any information within PCSR needed to support the GEP was captured and available to the GEP assessment team.

- Hitachi-GE submitted ‘Modification notice implementing procedure’ (QGG-GD-0003) - Consistency management plan between GEP and PCSR.

- We reviewed this process and found it satisfactory.
- The process has a register of changes, which we have kept under review.

Further meetings were held to discuss:

- progress on Hitachi-GE's response to RQ-ABWR-0665 safety case training and adequate support from UK experts
- progress on implementing the procedure for the '6-step process' following DRP
- handing over information in Hitachi-GE GDA modification notices to Horizon Nuclear Power
- progress on RQ-ABWR-0792 relating to a response to ONR's safety case inspection of January 2016 and a response date of end of May 2016 was agreed
- responses to RO-ABWR-0058 were reviewed and considered to be to be complete
- the process for the 'Technology transfer to licensee and operating regime' needed to consider decommissioning
- Hitachi-GE corrective action reports (CAR) reports produced during the period. There have been few raised and Hitachi-GE was tasked with identifying the proportion raised by internal audits. This would be discussed at a later meeting.

In April 2016, we visited Japan to review and assess how Hitachi-GE was implementing processes in support of the GDA submission.

Technical topic areas included:

- effectiveness of Hitachi-GE GDA specific training
- implementing of role profiles and SQEP assessments
- implementing the commitments capture process
- implementing requirements and assumptions management process
- design review and change process
- managing GEP submission
- DRP change control
- record keeping arrangements
- understanding and implementing safety case development manual

We presented the findings to Hitachi-GE as RQ-ABWR-0936. It raised 5 observations and recommendations:

1. Review the target date specified for PCSR chapter leads to review impact of commitments made for the closure of RQ-ABWR-0661 to make sure enough time is allowed for implementing changes into its chapters after this review.
2. Define the word 'operable', as used in the statement of requirements and assumptions.
3. Amend procedure 'instruction for 6-step process' (QGG-GD-0002) to include a justification for selecting change categorisation.
4. Submit change UKABWR-NDCP-0032 and at least 2 subsequent category C or D changes to the ONR for technical assessment of the justification of categorisation.
5. Provide a list of the 4 batches of changes to the DRP that Hitachi-GE and the regulators agreed before introducing the '6-step process'. List to include change title, description of change, whether change is completed or the expected completion date, when and how it is communicated to the ONR and the Environment Agency.

These actions have now been closed out satisfactorily.

We have reviewed the content of Chapter 4 of the generic PCSR, which describes how safety is managed within the other chapters. Hitachi-GE has agreed to include a sub-chapter to incorporate environmental considerations. We are content this will make sure that information within the Hitachi-GE PCSR, used for GEP submission is controlled.

Throughout the project, we have reviewed CAR reports on a regular basis and found that actions were closed out in a satisfactory way and tended to be minor, with one exception.

In May 2016, we noted that a significant corrective action GDA-CAR-0050 had been raised in one of the technical topic areas. This related to identifying a previously unidentified waste stream within the turbine gland steam (TGS) system. A pathway for tritium release had not been identified as significant and had, therefore, not been incorporated in the discharges and dose assessment.

Hitachi-GE was tasked with reviewing the process, to identify whether failing to identify the waste stream was due to a failure in the process or its implementation. It was asked to present the results as a root cause analysis. Hitachi-GE has now checked and reviewed this and made the necessary changes.

We reviewed the results of the root cause analysis and identified that the processes had not been implemented correctly. Hitachi-GE identified the following 3 corrective measures:

1. Clarify the implementing condition of release amount evaluation as the evaluating condition setting process for release of radioactivity amount in the UK radiation exposure evaluation design PQC.
2. Clarify the implementing condition of dose evaluation as the evaluating condition setting process for release of radioactivity amount in the UK radiation exposure evaluation design PQC.
3. Clarify the process to obtain the detailed information of all release routes (generation source, route, release end) with potential release from the system design engineer in the evaluating condition setting process for release of radioactivity amount for UK radiation exposure evaluation design PQC.

We have assessed the actions raised by the CAR as part of this report and they will be assessed by the relevant Environment Agency technical assessor.

We also raised the issue of training as a possible cause of the omissions. On further investigation however, it was revealed that the omissions had taken place before training in UK requirements had taken place and the work had not been revised until CAR was raised. Hitachi-GE provided evidence that further checks to test staff's understanding of the process had now taken place and that RWAs were used to support its staff.

We are content that Hitachi-GE has adequate processes in place to support the remainder of the GDA process. We are planning further meetings and site visits to carry out further sampling of the processes between 2016 and 2017 and the end of the GDA process, to make sure that Hitachi-GE processes continue to develop to support completion of the GEP submission and maintain control of the design changes and supporting developments to the PSCR/GEP BAT case.

3. Compliance with Environment Agency requirements

Table 1. Compliance with Environment Agency requirements.

P&ID Table 1 Section or REP	Compliance comments
MLDP1 – Establishing and Sustaining Leadership and Management	Hitachi-GE has shown full commitment to the project quality plan and restructuring of engineering to provide steering group for safety case development, and has recognised environmental requirements.
MLDP 2 – High Standards of Environment Protection	Hitachi-GE design development processes have clear requirement to take environmental requirements (BAT) into decision making process. Processes incorporate requirements for design to meet high environmental standards
MLDP3 – Capability	Significant training given to engineers on BAT. Employment of UK RWA professionals for advice.
MLDP4 – Decision Making	Hitachi-GE processes identify clear decision making processes. Regular auditing of processes and outputs is carried out.
MLDP5 – Learning from Experience	Hitachi- GE has sought relevant advice on UK compliance from UK partners and incorporated UK professionals to provide advice and guidance.

4. Public comments

No comments have been received regarding Hitachi-GE management arrangements.

5. Conclusion

This assessment is limited to the PQP and Hitachi-GE's supporting documentation and the effectiveness of the implementation of the processes up to 5 August 2016. It includes reviews carried out in response to concerns raised by the regulators' technical assessors and includes areas such as effectiveness of training in requirements of UK legislation.

The quality of the information provided to the individual technical assessors is outside the scope of this assessment, as it is considered by appropriate technical topic assessment reports.

We are content that that Hitachi-GE's management arrangements are satisfactory and meet the requirements of the P&ID.

Hitachi-GE has developed processes for transferring technology to a future operator, which include systems for identifying environmental requirements.

We are also working with ONR to develop a work plan for the ongoing period up to the end of the GDA process. This will include meeting with Hitachi-GE MSQA staff and further sampling of processes in UK and Japan to keep compliance with the P&ID under review.

There are no assessment findings at this time.

References

Author	Reference
Environment Agency, 2010	RSR: Management arrangements at nuclear sites, version 2.
Environment Agency, 2014	UK ABWR GDA preliminary assessment report, Lit10001.
IAEA, 2006	The management system for facilities and activities, GS-R-3.
IAEA, 2006	Application of the management system for facilities and activities, GS-G-3.1
IAEA, 2009	The Management System for Nuclear Installations, GS-G-3.5
ISO, 9000	The ISO 9000 family of international quality management standards, www.iso.org.
ISO,14000	The ISO 14000 family of international quality management standards, www.iso.org.
ISO,18000	The ISO 18000 family of international quality management standards, www.iso.org.

Hitachi-GE documentation

Document Number	Title
GA10-1001-0001-00001_Rev 7	Documents control manual, 3 December 2015
GA70-1501-0002-00001_Rev 11	Generic Design Development Control, 5 August 2016
GA70-1501-0001-00001-Rev 4	Communication, Reporting Lines and Distribution of Information in the GDA Organisation, 17 April 2015
GA70-1501-0003-00001_Rev 5	Design Change Control and Documentation, 08 April 2015
GA70-1501-0008-00001_Rev 2	Control of Non-conformance, Corrective Action and Preventative Action, 20 November 2014

Document Number	Title
GA70-1501-0009-00001_Rev 4	Assessment of GDA Arrangements (Internal Audits Self-Assessment), 7 December 2014
GA70-1501-0010-00001_Rev 4	SQEP Requirements for HITACHI-GE and Supplier Personnel, 2 February 2016
GA91-7108-0001-00001_Rev 0	GDA technical Justification for: Ultrasonic End of Manufacturer Inspection of the ABWTR RPV Shell Welds, 28 November 2014
GA70-1501-0002-00001_Rev 11	Generic Design Development Control, 5 August 2016
GA70-1501-0003-00001_Rev 5	Design Change Control and Documentation, 8 April 2015
GA70-1501-0004-00001_Rev 3	Purchasing Control, 14 November 2014
GA70-1501-0005-00001_Rev 3	Control of general documents and records, 14 November 2014
GA70-1501-0007-00001_Rev 6	QUALITY MANAGEMENT PLAN (For UK ABWR GDA Project), 16 April 2015
GA91-0011-0003-00001_Rev 8	Master Document Submission List (MDSL), 22 August 2016
GA91-0512-0006-00001_Rev 2	Managing Commitments made to Regulators on GDA Submissions, 26 August 2015
GA91-1104-0002-00001_Rev 3	Design Reference for UK ABWR, 7 July 2016
GA91-0511-0003-00001_Rev 0	Standard Assumption Register, 28 November 2014
GA70-1502-0001-00001_Rev 0	Technology Transfer to License and Operating Regime, 8 August 2016
GA91- 9201-0003-00170_Rev 0	Process to review the UK ABWR PSA to reflect design modification and process to capture, track and review assumptions (Response to RQ-ABWR-0160), 3 September 2014
GA91-0512-0010-00001_Rev 0	Standard Control Procedure for Identification and Registration of Assumptions, Limiting Condition for Operation, 30 October 2015

Document Number	Title
GA10-0512-0002-00001_Rev 0	Document Linkage Management Plan, 24 April 2014

Site visit reports

Document Number	Title
ONR-GDA-IR-13-001_Rev 0	ONR. 14 February 2014 MSQA Inspection Intervention Report
ONR-GDA-AR-15-014_Rev 0	GDA Step 3 Assessment of the Management for Safety and Quality Assurance of Hitachi GE's UK Advanced Boiling Water Reactor (UK ABWR), approved 3 November 2015.
ONR-NR-CR-16-114_Rev 1	GDA Inspection 2016

Notes of meetings

Document Number	Title
XM-GD-E593	L4 GDA- MSQA Step-4 workshop- 23 March 2016
XM-GD-A039	SME Meeting Specific to technical topic – MSQA -10- October 2013
XM-GD-A204	MSQA Meeting - 30 June 2014
XM-GD-E014	L4 GDA MSQA Step-3 Technical Exchange Workshop - 10 Sept 2014
XM-GD-E047-a	UK ABWR GDA L4 MSQA Rev0 Step 3 Tech Workshop - 06 Oct 2014
XM-GD-E047-b	UK ABWR GDA MSQA Step-3 Oct Technical Meeting - 07 Oct 2014
XM-GD-E047-c	UK ABWR GDA L4 MSQA Step-3 Oct Tech Workshop - 07-09Oct 2014
XM-GD-E129	UK-ABWR-GDA MSQA R02 - L4 Step3 Video Conference - 05 Dec 2014
XM-GD-E153	UK-ABWR-GDAMSQA L4 -Step 3 Jan Video Conference - 28 Jan 2015
XM-GD-E227	UK ABWR GDA MSQA Step-3 Workshop - 16 March 2015

Document Number	Title
XM-GD-E228	UK ABWR GDA MSQA L4 Step-3 Inspection Meeting - 20 April 2015
XM-GD-E332	L4 GDA - MSQA Step-3 Work Shop - 29 June 2015
XM-GD-E347	UK ABWR GDA L4 MSQA Step 3 Workshop - 11 August 2015
XM-GD-E384	UK ABWR GDA L4 MSQA Step 3 Workshop - 18 September 2015
XM-GD-E414	- MSQA Meeting - 20 October 2015
XM-GD-E439	Level 4 GDA MSQA Step 4 Workshop - 20 November 2015
XM-GD-E502	L4 GDA - MSQA Step-4 Work Shop - 17 December 2015
XM-GD-E534	L4 GDA - MSQA Step-4 Work Shop -21 January 2016
XM-GD-E553	L4 GDA - MSQA Step-4 Work Shop- 29 February 2016
XM-GD-E593	L4 GDA- MSQA Step 4 Workshop-23-March 2016
XM-GD-E643	L4 GDA - MSQA Step-4 Work Shop-19 May 2016
XM-GD-E698	L4 GDA- MSQA Step 4 Workshop- 1 July 2016

Regulatory Observations and Regulatory Queries

RO or RQ	Title
RO-ABWR-0057	Hitachi-GE's development of arrangements for the safety case to be met in practice
RO-ABWR-0058	Step 3 MSQA Improvement Actions
RQ-ABWR-0447	Process to Process to transfer GEP requirements to future operator
RQ-ABWR-0665	Training and support for Safety Case Steering Group
RQ-ABWR-0792	Response to ONR s Safety Case Inspection

List of abbreviations

Abbreviation	Details
ABWR	Advanced Boiling Water Reactor
BAT	Best available techniques
CAR	Corrective action report
DRP	Design reference point
GDA	Generic design assessment
GEP	Generic environmental permit
ISO	International Standards Organisation
JPO	Joint programme office
MSQA	Management systems quality assurance
ONR	Office for Nuclear Regulation
P&ID	Process and information document
PQC	Process quality control
PCSR	Pre-construction safety report
QMP	Quality management plan
QMS	Quality management system
QP	Quality plan
REP	Regulation environmental principles
RI	Regulatory Issue
RO	Regulatory Observation
RQ	Regulatory Query
RWA	Radioactive waste adviser

Abbreviation	Details
SoDA	Statement of design acceptability
SQEP	Suitably qualified and experienced personnel
TGS	Turbine gland steam system

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