



Assessing new nuclear power station designs

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

Assessment report - AR01
Management arrangements

December 2017

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Executive summary

Protective status	This document contains no sensitive nuclear information or commercially confidential information
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Process and information document¹	<p>The following sections of Table 1 in our process and information document (P&ID) are relevant to this assessment:</p> <p>Item 2: A description of the requesting party's management arrangements and responsibilities for:</p> <ul style="list-style-type: none">• 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
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Radioactive Substances Regulation Environmental Principles²	<p>The following principles are relevant to this assessment:</p> <p>MLDP1 – Establishing and sustaining leadership and management</p> <p>MLDP 2 – High standards of environment protection</p> <p>MLDP3 – Capability</p> <p>MLDP4 – Decision making</p> <p>MLDP5 – Learning from experience</p>
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We have carried out this assessment of Hitachi-GE's (the 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 (P&ID) for generic assessment of candidate nuclear power plant designs (Environment Agency, 2016). This is to give us confidence in the quality of the submission and to make sure processes are in place to transfer the technology to a future operator.

We have carried out this assessment together with the Office for 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 (Environment Agency, 2014) at Step 2 and follows the progress of development and improvements to the management arrangements through to 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.

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 produced a report of our findings in December 2016 in support of our preliminary consultations. We have continued to work with ONR during the remaining period up to the end of the GDA process. This report includes our findings from further sampling of Hitachi-GE management systems carried out up to the end of GDA.

After detailed assessment and action taken on our inspection findings we conclude that Hitachi-GE has good management arrangements in place to support its GDA 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 the BAT case for implementation at a site level.

In conclusion, we inspected Hitachi-GE's management system and provided advice to Hitachi-GE on UK regulatory expectations. We identified and implemented improvements on Hitachi-GE's systems during GDA, these include:

- ensuring the demonstration of best available techniques (BAT) was discussed and recorded within the design review process
- ensuring the discharges from the TGS (turbine gland steam) system were captured and Hitachi-GE analysed why these were missed from the initial source term
- ensuring Hitachi-GE developed an appropriate process to transfer information from Hitachi-GE to a future operator

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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) (Environment Agency, 2016). Where this report refers to safety, we are following Hitachi-GE's convention that this includes safety, environment and quality management.

This report identifies how we inspected Hitachi-GE's processes to allow us to assess 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 in 2 stages, as set out in our P&ID.

The first stage was an initial assessment of Hitachi-GE's management arrangements. The findings of our assessment was set out in our initial report (Environment Agency, 2014).

At that stage, we reviewed the GDA UK ABWR management arrangements with reference to the requirement of ISO 9000¹ and ISO 14000² series of standards and IAEA guidance (IAEA, 2006, 2006a and 2009).

We reviewed relevant key areas of Hitachi-GE's arrangements; the quality management plan (QMP) and the supporting process documents. These set out the expectations for quality control to ensure they met the requirements of our P&ID and Environment Agency Radioactive Substances Regulation Environmental Principles (REPs) (Environment Agency, 2010). We found these to be satisfactory.

We visited Hitachi-GE works offices in Japan to inspect selected records and determine how the GDA process was being implemented. We found arrangements generally satisfactory, and identified some areas that were subsequently improved during the GDA process.

In the second stage of our GDA assessment, we examined the processes in more detail, testing to make sure they complied with our requirements.

We examined a selection of documents, such as, independent verification and approval records, examples of design change records, including BAT in design. In addition, we were able to look at Hitachi-GE's competency and suitably qualified and experience personnel (SQEP) assessments.

We raised several Regulatory Queries (RQs) and Regulatory Observations (ROs). All ROs and RQs have been closed out and we discuss them in detail below.

We inspected Hitachi-GE's management system and provided advice to Hitachi-GE on UK regulatory expectations. We identified and implemented improvements on Hitachi-GE's systems during GDA, these include:

- ensuring the demonstration of best available techniques (BAT) was discussed, addressed and recorded within the design review process
- ensuring the discharges from the TGS (turbine gland steam) system were captured and analysis undertaken of why this discharge route was missed from the initial source term
- ensuring Hitachi-GE developed an appropriate process to transfer information from Hitachi-GE to a future operator

Hitachi-GE gave consideration to our recommendations and incorporated these into Hitachi-GE

¹ The ISO 9000 family of quality management systems standards is designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product or program. It deals with the fundamentals of quality management systems, including the seven quality management principles ; customer focus; leadership; engagement of people; Process approach; improvement; evidence based decisions and relationship management, upon which the family of standards is based.

² The ISO 14000 family of international quality management standards, that exists to help organizations (a) minimize how their operations (processes, etc.) negatively affect the environment (i.e., cause adverse changes to air, water, or land); (b) comply with applicable laws, regulations, and other environmentally oriented requirements; and (c) continually improve.

processes as appropriate.

We conclude that Hitachi-GE has good management arrangements in place to support its GDA 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 the BAT case for implementation at a site level.

2. Assessment

We reviewed selected elements of 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 its GDA submission (Environment Agency, 2014).

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 key controlling documents are:

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

The Hitachi-GE project plan (GA10-0501-0001-00001) 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 (GA70-1501-0005-00001).

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 (GA70-1501-0002-00001).

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 (GA91-9901-0019-0001).

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 ABWR design' (GA91-9901-0011-00001) and Hitachi-GE UK ABWR concept document (GA91-9901-0013-0001), which included information on designing for minimising the impact on the environment.
- The document 'Description of Hitachi-GE organisational capability, systems and management

arrangements' (GA91-9901-0016-00001) 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 (GA70-1501-0010-00001).

- We examined the documents 'Generic design development control' (GA70-1501-00002-00001), 'Design control and documentation' (GA70-1501-0003-00001) and 'Control of general document and records' (GA70-1501-00005-00001) 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' (GA70-1501-00009-001) and 'Control of non-conformance, corrective action and preventative action' (GA70-1501-0008-00001). 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)' (GA91-9901-0028-00001). We are content that it clearly identifies how our REPs are to be taken into account in the GDA process
- The processes for ensuring good communications are maintained was set out in the ONR document 'Generic design assessment interface arrangements', January 2015, Revision 3. (TRIM 2013/410878) and 'Communication, Reporting Lines and Distribution of Information in the GDA Organisation, 17 April 2015' (GA70-1501-0001- 00001-Rev 4)

We were, therefore, content that these processes were suitable for supporting the Hitachi-GE GDA submission

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 deliver 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). Records were generally 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 nuclear safety and the use

of best available techniques (BAT) are discussed and considered during design review meetings and how this is recorded and subsequently addressed.

- 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 was judged to be sufficient at that stage of the project. Hitachi-GE has since employed RWAs to support its GDA 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 to be implemented.

In October 2014, we and ONR visited Hitachi-GE's offices in Hitachi City, Japan.

- During the visit, meetings were held to clarify and agree how the UK ABWR reference design as discussed in 'Definition of design reference point' (GA91-9901-0017.00001) would be specified at the DRP and in the master document submission list (MDSL) (GA91-00011-0003-00001).
- 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 formally responded to Hitachi-GE our main findings in a joint Environment Agency and ONR RQ with Hitachi-GE to address the main findings of the visit (RQ-ABWR-0092).

Hitachi-GE 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. We required further evidence that consideration of BAT in the GDA design control process was adequately recorded. This was subsequently inspected and found to be satisfactory.

During the detailed assessment phase we advised Hitachi-GE on areas to improve its processes to demonstrate compliance. We gave them advice to help develop a new process for transferring technology from Hitachi-GE to future operators.

We also provided advice to Hitachi-GE to adapt the design change management processes and incorporate the ONR/Environment Agency '6-step process'. The 6-step process outlines the requirements that Hitachi-GE must follow to gain approval for a design change to be included in the GDA assessment process. This required Hitachi-GE to provide information on the scope and the safety and environmental categorisation of the proposed change.

Subsequently, we inspected the arrangements to ensure the process was being adequately implemented.

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.
- 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 a future operator to incorporate into its operating system. We are satisfied that Hitachi-GE:

- established a process for identifying and capturing the claims arguments and evidence (GA91-0512-0010-00001)
- developed a process to capture and implement 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

In October 2014, we reviewed Hitachi-GE's implementation of its processes for delivery of UK ABWR safety case and GEP submission. Topics covered included:

- early discussion on moving the safety case and BAT case to a future operators management 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 (XM-GD- e047c)

RO-ABWR-00057 was issued to address to address expectations for moving the safety case into the operating regime and for demonstrating that the constructed plant will be capable of being operated within safe limits by ensuring and assuring that safety claims and assumptions are realised in the final as-built design with the following actions:

Action1:

Hitachi-GE to develop a method of clearly identifying requirements and assumptions in the text of the safety case and supporting documents.

Action 2:

Hitachi-GE to produce guidance to the authors of the safety case chapters on the method described in action 1. This guidance should include examples of the types of requirements and assumptions that should be identified

Action 3:

Produce the arrangements to show how the requirements and assumptions are captured in Technical Specifications

Hitachi-GE developed procedure GA91-0512-0010-00001 '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.

During 2015, we reviewed Hitachi-GE's development of the design change control process (GA70-1501-0002-00001) and obtained clarification of the design reference point for the UK ABWR.

We found the design change control process had developed to include regulators' specific requirements to assess the proposed change to ensure it was appropriate to include it within the scope of the GDA process.

In April 2015, we inspected the MSQA arrangements in preparation for moving to detailed assessment (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 inspected the process to transfer GDA environmental requirements to the future operator and the development of the master document submission list (MDSL) and design change process for the design reference point (DRP) to assess that environmental protection was being included in the 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 had been incorporated within the manual, so that information within the future GDA pre-construction safety case (PCSR) informed the GEP.

We summarised the findings of the visit in RO-ABWR-0058. The actions within this RO are detailed below:

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.

Action 2:

1. To resolve the non-conformities in role profiles and SQEP assessments found during the inspection:
2. 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.
3. Hitachi-GE to review the SQEP assessment for the human factors (HF) subject matter expert to make sure it is consistent with the SQEP assessment HF integration plan.
4. Hitachi-GE should review SQEP assessment coversheets to make sure they record and demonstrate that GDA staff have received the necessary GDA specific training.
5. 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. The regulators are satisfied the plan was appropriate and has been adequately implemented,

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 the PCSR needed to support the GEP was captured and available to the environmental assessment team.

- Hitachi-GE submitted 'Modification notice implementing procedure' (QGG-GD-0003) - Consistency management plan between GEP and PCSR.
- The process has a register of changes, which we have kept under review.

We reviewed this process and found it satisfactory

Further meetings were held to discuss:

- Progress on Hitachi-GE's response to RQ-ABWR-0665 safety case and BAT case training and the effectiveness of support from UK experts.
- Progress on implementing the procedure for the '6-step processes following DRP.'
- Handing over information in Hitachi-GE GDA modification notices to an operator (Horizon Nuclear Power).
- Responses to RO-ABWR-0058 were reviewed and considered to be complete.
- The process for the 'Technology transfer to licensee and operating regime (GA70-1502-0001-00001)' needed to consider decommissioning and would be available for individual topic assessment to be carried out.
- Hitachi-GE corrective action reports (CAR) reports produced during the period.

In April 2016, assessed 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 recommendations:

1. Review the target date specified for PCSR chapter leads to review impact of commitments made for the closure of 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 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.

All the actions from RQ-ABWR-0936 have been closed out satisfactorily.

We have reviewed the content of Chapter 4 of the generic PCSR (safety management throughout plant lifecycle), which describes how safety is managed within the other chapters. Hitachi-GE has included a sub-chapter to incorporate environmental considerations. We are content that this will make sure that information within the Hitachi-GE PCSR relevant to the GEP submission is managed, controlled and available.

Throughout the project, we have reviewed CAR reports on a regular basis. In May 2016, we noted that a significant corrective action had been raised in one of the technical topic areas, but not addressed. This related to a previously unidentified waste stream within the turbine gland steam system (TGS). A pathway for tritium release had not been identified as significant and had, therefore, not been incorporated in the source term, the proposed discharges and the dose assessment (RO-ABWR-0071).

The RO-ABWR-0071 contained 6 actions for Hitachi-GE:

1. Provide details of the Turbine Gland Steam System including sources of steam, radionuclide content of steam, and discharge route(s)
2. Demonstrate that the design and operation of the Turbine Gland Steam System is consistent with the application of Best Available Techniques (BAT)
3. Demonstrate that the design and operation of the Turbine Gland Steam System reduces health and safety risks As Low As Reasonably Practicable (ALARP)
4. Provide information on the quantities of gaseous radioactive waste that will be discharged to the environment, either directly or indirectly, from the Turbine Gland Steam System. Provide any changes to the proposed discharge limits and radiological dose assessments related to

discharges from the Turbine Gland Steam System

5. Ensure that the relevant GEP and supporting GDA documentation, including the documentation related to resolution of the UK ABWR source terms (RI-ABWR-0001 and RO-ABWR-0006), are updated appropriately and are consistent with the response to this RO.
6. Carry out a review of discharge routes to the environment, and confirm if there are any other significant sources which are not already detailed in the GEP Rev E.

Hitachi-GE was also asked whether failing to identify the TGS 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 investigation found that processes had not been fully understood and followed. It made the necessary changes to and Hitachi-GE has updated the relevant process quality control plan (PQCs) accordingly.

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

We raised the issue of training as a possible cause of the omission. 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 the CAR was raised. Hitachi-GE provided evidence that further checks to test staff's understanding of the process had been carried out and that Radioactive Waste Advisers (RWAs) were used to support its staff.

In October 2016 we reviewed how Hitachi-GE was continuing to implement its processes in support of the GDA submission and meet the overall GDA programme and submit fit-for-purpose and right-first-time documentation to the GDA team assessment teams. We assessed the following 4 areas:

- programme management
- management of safety case interdependencies, including those affecting GEP submission
- programme risk management
- internal challenge

We presented our findings as RQ-ABWR-1233 and advised Hitachi-GE of the following recommendations identified by the inspection:

- Hitachi-GE to review key managerial or control documents 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:
 - the design reference point change management arrangements to ensure they cover all contingencies
 - 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 to provide information on the extent to which procedure the standard control procedure for identification and registration of assumptions, limiting conditions for operation (GA91-0512-0010-00001) 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.
- Hitachi-GE should consider whether document production could be improved based on learning from:
 - periodic analysis of the comments received during Hitachi-GE review/verification of documents
 - analysis of the relationship between the level of Hitachi-GE internal review/verification and feedback from UK regulators
- Hitachi-GE should determine:

- why there is no evidence that the expected review of design inputs was undertaken 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 adopting 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

In January 2017, Hitachi-GE provided a response plan to address these findings of RQ-ABWR-1233. Progress was monitored at regular meetings with Hitachi-GE. We are satisfied that Hitachi-GE has taken account of our findings.

We have assessed progress on the development and implementation of processes to transfer technology to a future operator and worked with ONR to ensure that Chapter 4 of the PSCR (safety management throughout plant lifecycle) captures the environmental requirements. We also continued to examine examples of design changes for inclusion of environmental issues, we found that these met our expectations.

We continued to work with ONR on the agreed plan to examine Hitachi-GE processes up to the end of GDA. The processes used to support the GDA GEP assessment has met our requirements set out in our P&ID document.

We have considered the responses from the public consultation carried out and they are set out in Table 2 below, along with our replies. We are satisfied that the observations raised by the public have been addressed within this assessment.

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 good leadership in to support of the UK-ABWR project. It has responded to emerging issues, by restructuring of engineering to provide steering group for safety case development, and has ensured environmental requirements are maintained to a high standard.

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

We held a public consultation on our preliminary GDA assessment findings, which ran for 12 weeks, from 12 December 2016 to 3 March 2017. We received a number of consultation responses, all of which have been published in full for everyone to view (Environment Agency, 2017a). Our replies to each point raised are presented within our decision document (Environment Agency, 2017b). However, points raised that were in GDA scope and relevant to Hitachi-GE management arrangements are summarised below:

Table 2. Summary of consultation responses and Environment Agency replies relevant to management arrangements

Consultation Response	Details of response (as received)	Environment Agency reply
ABWR-02	A high standard of protection for people and the environment should be ensured. It is important for communities in the locality of an ABWR that the scrutiny and maintenance of quality of management systems employed is ongoing to provide confidence in their effectiveness (for example during construction, operation and decommissioning).	In GDA we assessed the Hitachi-GE management arrangements for the design of the UK-ABWR reactor. We noted that Hitachi is certified to ISO-9001 and ISO -14001 and that it has systems in place to ensure the design includes high standards of environmental performance of its reactor. It will be for the future operator to work with Hitachi-GE to ensure that the reactor is operated to high environmental standards. This will be enforced through an EPR permit, for which the operator will need to apply to the environmental regulator (the Environment Agency in England and Natural Resources Wales in Wales)
ABWR-09	Article 126 of Consultation Document, 12/12/16. Does Hitachi-GE operate a “lessons learned register” including remedies to capture information from relevant operational incidents occurring at	In GDA, Hitachi-GE prepared a pre-construction safety case (QGI-GD-0008) Chapter 4.4.1 that sets out how safety and the environment will be managed throughout the plant lifecycle. It states:

	<p>other nuclear power stations in Japan and worldwide?</p> <p>Article 128 of Consultation Document, 12/12/16. Does Hitachi-GE provide a formal technical service to operators during the operational life cycle of its existing BWR's and, if so, are the operator(s) of the proposed UK ABWR's committed to take up such a service?</p>	<p>"Hitachi-GE will establish the organisation and system to support the Licensee and to implement effective safety, environment and security management over the entire Plant Lifecycle of UK ABWR, in order to achieve a high level of safety while maintaining configuration control and structural integrity of the plant design.</p> <p>Throughout the plant lifecycle, ultimate responsibility for safety rests with the Licensee who shall be supported by Hitachi-GE. However, Hitachi-GE has a key responsibility as Vendor, Constructor, Contractor and the enduring role of Responsible Designer. The most important aspect of safety management from a Hitachi-GE perspective is to harmonise the management arrangements between Hitachi-GE and the Licensee in an effective way so that the Licensee is able to fulfil the responsibility for safety in the nuclear power station. Safety in each phase of the Plant Lifecycle and the responsibility for activities affecting the environment are clarified in the coordinated management arrangements for both Hitachi-GE and the Licensee.</p> <p>During the GDA process, the coordination of the management system of Hitachi-GE and that of Licensee would be required with regard to procurement engineering activities related to Long Lead Items such as reactor pressure vessels and reactor containment vessels"</p> <p>It also states.</p> <p>"Hitachi-GE supports the Licensee in providing practical technical information required for preparing a site specific PCSR and environmental report. Hitachi-GE will continue to assist the Licensee during the Plant Lifecycle, as required, to ensure that the Licensee is able to satisfy requirements for safety and the environment. In addition, Hitachi-GE can advise and support the Licensee during plant operation. Hitachi-GE is active in sharing operational experience and</p>
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		<p>knowledge as well as knowledge gained from the electrical power industry in Japan and outside Japan, other designers / operators and non BWRs to help ensure lessons learned are taken account of in future projects".</p> <p>As stated in our consultation, the claims/ arguments/evidence capture process supports the safety and environment cases and will ensure knowledge transfer to a future operator. We are confident that this includes learning from experience and that Hitachi-GE, in its role of responsible designer, will be able to support a future operator to maintain high standards of environmental protection for the UK-ABWR.</p>
ABWR-28	The design is fundamentally flawed with a number of long-term issues inadequately addressed.	<p>In GDA, we assessed the Hitachi-GE management arrangements for the design of the UK-ABWR reactor. We noted that Hitachi-GE is certified to ISO-9001 and ISO-14001 and that it has systems in place to ensure the design includes high standards of environmental performance of its reactor. Hitachi-GE has provided good quality technical information to our individual assessors. This has been assessed and our views on the environmental performance are presented within our consultation document. It should be noted that any future operator will require an EPR 2016 permit to operate. Any outstanding information outside the scope of GDA or that is identified as an Assessment Finding will be addressed during the determination process, before the environmental regulator (the Environment Agency in England and Natural Resources Wales in Wales) will issue a permit.</p>

5. Conclusion

We have reviewed the key areas of Hitachi-GE's arrangements: the quality management plan and its supporting documents. We reviewed the effectiveness and the implementation of the processes and arrangements. Our assessment includes reviews carried out in response to concerns raised by the regulators' technical assessors. It also takes into account responses made as part of our public consultation.

In conclusion, we inspected Hitachi-GE's management system and provided advice to Hitachi-GE

on UK regulatory expectations. We identified and implemented improvements on Hitachi-GE's systems during GDA, these include:

- ensuring the demonstration of best available techniques (BAT) was discussed and recorded within the design review process
- ensuring the discharges from the TGS (turbine gland steam) system were captured and analyse why these were missed from the initial source term
- ensuring Hitachi-GE developed an appropriate process to transfer information from Hitachi-GE to a future operator

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

We are content that Hitachi-GE's management arrangements are satisfactory and meet the requirements of the P&ID (Environment Agency, 2016).

References

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Environment Agency, 2017a	Assessing new nuclear power station designs. Generic design assessment of Hitachi-GE Nuclear Energy Limited's UK Advanced Boiling Water Reactor. Responses to GDA consultation for the UK ABWR. LIT10656, July 2017. https://www.gov.uk/government/consultations/gda-of-hitachi-ge-nuclear-energy-ltds-uk-advanced-boiling-water-reactor
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IAEA, 2006	The management system for facilities and activities, GS-R-3.
IAEA, 2006a	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.

Hitachi-GE documentation

Document Number	Title
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

Document Number	Title
GA70-1501-0008-00001_Rev 2	Control of Non-conformance, Corrective Action and Preventative Action, 20 November 2014
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
GA70-1501-0004-00001_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
GA70-1501-0006-00001_Rev 1	Compliance table for Regulatory expectations, Jan 2014
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
GA91-9901-0016-00001_Rev_0	Description of Hitachi-GE organisational capability, systems and management arrangements, December 2013
GA91-9901-0011-00001_Rev 1	Genesis of ABWR design, December 2013
GA91-9901-0013-00001_Rev 1	Hitachi-GE UKABWR Concept design, December 2013
GA91-9901-0017-00001_Rev A	Definition of design reference point, December 2013

Document Number	Title
GA70-1502-0001-00001_Rev 0	Technology Transfer to License and Operating Regime, 8 August 2016
GA91-9901-0028-00001_ Rev A	Consideration of and compliance with Radioactive substances regulation environmental principles (REPS), December 2013
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
GA10-0512-0002-00001_Rev 0	Document Linkage Management Plan, 24 April 2014
XGG-GD-0002	Instruction for implementation of ONR “6 step process”
QGG-GD_0003.	Modification notice implementing procedure’ - Consistency management plan between GEP and PCSR.

Notes of meetings

Document Number	Title
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-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
XM-GD-E228	UK ABWR GDA MSQA L4 Step-3 Inspection Meeting - 20 April 2015
XM-GD-E332	L4 GDA - MSQA Step-3 Workshop - 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 Workshop - 17 December 2015
XM-GD-E534	L4 GDA - MSQA Step-4 Workshop - 21 January 2016
XM-GD-E553	L4 GDA - MSQA Step-4 Workshop - 29 February 2016
XM-GD-E593	L4 GDA- MSQA Step 4 Workshop - 23 March 2016
XM-GD-E643	L4 GDA - MSQA Step-4 Workshop - 19 May 2016
XM-GD-E698	L4 GDA- MSQA Step 4 Workshop - 1 July 2016
XM-GD-E875	L4 GDA-MSQA Step 4 Workshop - Feb 2017
XM-GD-E905	L4 GDA – MSQA Step 4 workshop - March 2017
XM-GD-EA23	L4 GDA – MSQA Step 4 workshop - July 2017

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
RO-ABWR-0071	Turbine gland steam system discharges and BAT
R0-ABWR- 0936	April 2016 MSQA Inspection of UK ABWR
RQ-ABWR-0092	MSQA inspection of UKAB WR
RQ-ABWR-0665	Training and support for Safety Case Steering Group

RQ-ABWR-0792

Response to ONR's Safety Case Inspection

RQ-ABWR-1233

October 2016 MSQA Inspection of UK ABWR

List of abbreviations

Abbreviation	Details
ABWR	Advanced Boiling Water Reactor
ALARP	As low as reasonably practicable
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
MSDL	Master document submission list
MSQA	Management systems quality assurance
ONR	Office for Nuclear Regulation
P&ID	Process and information document
PCSR	Pre-construction safety report
PQC	Process quality control
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
SoDA	Statement of design acceptability
SQEP	Suitably qualified and experienced personnel
TGS	Turbine gland steam system

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