

REGULATORY OBSERVATION	
REGULATOR TO COMPLETE	
RO unique no.:	RO-ABWR-0014
Date sent:	22 September 2014
Acknowledgement required by:	13 th October 2014
Agreement of Resolution Plan Required by:	31 st October 2014
Resolution of Regulatory Observation required by:	<i>To be determined by Hitachi-GE Resolution Plan</i>
TRIM Ref.:	2014/334530
Related RQ / RO No. and TRIM Ref. (if any):	
Observation title:	UK ABWR Radiological Protection Safety Case: Project Plan and Delivery
Technical area(s) Radiation Protection & (Level 3 PSA)	Related technical area(s) Fault Studies PSA Internal Hazards External Hazards Reactor Chemistry Civil Engineering Human Factors Generic Environmental Permitting Radwaste & Decommissioning
Regulatory Observation	
Summary	
<p>The objective of this Regulatory Observation (RO) is to state ONR's expectations related to the development and delivery of the Radiological Protection safety case for the UK ABWR as part of the GDA submission. Hitachi-GE should develop and deliver a suitable and sufficient Radiological Protection safety case for UK ABWR in accordance with a detailed plan outlining specific Radiological Protection safety case tasks required to be completed and providing clarity on, and timings for, the deliverables. In response to the RO Hitachi-GE are requested to provide the UK ABWR Radiological Protection safety case documentation in a staggered but logical and timely fashion throughout GDA in accordance with the Radiological Protection safety case plan, and to keep the plan updated as the safety case and strategies evolve.</p>	
Background	
<p>ONR's Radiological Protection assessment during Step 2 of GDA for UK ABWR has concluded that the documents provided by Hitachi-GE form an adequate basis for further development of the UK ABWR safety case during Step 3 [1]. The Step 2 assessment was almost entirely based upon two sections of the Radiological Protection Pre-Construction Safety Report (PCSR), drafted as Preliminary Safety Reports (PSR) for Radiological Protection, and a report provided to the Environment Agency (EA) which provided a set of limited safety claims (assertions). As GDA progresses there is an expectation that the safety case will evolve to enhance, and expand, as necessary, the claims already made and to provide the arguments (reasoning) and evidence which underpin the safety of the UK ABWR design. This will mean that the safety case evolves to include a PCSR and a much wider range of supporting documents.</p> <p>Throughout Step 2, Hitachi-GE demonstrated that they have qualified, experienced and competent staff with technical expertise in Radiological Protection for BWRs, backed up by many years of engineering knowledge and design expertise for BWR technology. As such, ONR has no concerns over the capability of Hitachi-GE to demonstrate this in their GDA technical submissions. However, the UK regulatory regime is goal setting and</p>	

places a particular requirement on the duty holder (in this case, Hitachi-GE) to demonstrate that they have reduced risks So Far As Is Reasonably Practicable (SFAIRP). This has impacts on the safety case and how it is presented and it is this specific aspect, the development and delivery of a Radiological Protection safety case which meets UK requirements and expectations that this RO is seeking to address. A fundamental part of achieving this is to have a clear understanding of the strategy, objectives, scope and plan for development of the safety case.

Although it is for Hitachi-GE to define and produce the safety case for UK ABWR, guidance on ONR's expectations for a nuclear safety case is given in NS-TAST-GD-051 [2]. While this is generic guidance, it remains applicable to UK ABWR. Specific ONR expectations in relation to Radiological Protection are described in the SAPs [3] and in the relevant Radiological Protection Technical Assessment Guides (TAGs)[4].

While it is for Hitachi-GE to define and produce the safety case for UK ABWR, ONR have already identified a number of areas which will form part of our assessment sample during GDA, as defined in the Step 2 Assessment Report [1], Step 3 Assessment Plan [5] and presentations delivered during the end of Step 2 wrap up meeting in June 2014 [6]; it should be noted however that ONR is a sampling organisation, and therefore, the areas identified by ONR so far as requiring follow up or to be assessed during step 3, do not constitute all that is required for Hitachi-GE to have a complete and integrated safety case.

When comparing the above requirements and expectations to the current position of Hitachi-GE, the main concerns over the development of the Radiological Protection safety case for UK ABWR can be summarised as:

1. the overall objectives, strategy and scope of the Radiological Protection safety case have not been stated;
2. it is uncertain how the integration of the Radiological Protection aspects into the overall UK ABWR safety case will be managed to ensure that a coherent and proportionate safety demonstration will be provided;
3. the hierarchy of submissions that would constitute the Radiological Protection safety case and their structure do not appear to have been fully considered;
4. it is not apparent how the submissions identified so far will develop the overall Radiological Protection related aspects of the safety case; and
5. it is not clear how any Radiological Protection supporting documents produced will ultimately be used to support the PCSR.

In essence, the development of the Radiological Protection safety case appears to be a reactive, rather than proactive process at present and there is a need to enhance the level of planning and control over development of the safety case moving forward. These concerns mean that ONR requires additional confidence that Hitachi-GE has adequate arrangements in place to enable progress throughout steps 3 and 4 of GDA.

This RO is only concerned with the Radiological Protection safety case.

Regulatory Expectations

ONR consider that a suitable and sufficient Radiological Protection safety case is vital to ensuring that GDA for UK ABWR can be meaningfully progressed to expected timescales. In order to provide confidence that this can be achieved ONR consider that a strategy and project plan are key inputs to timely delivery of a high quality full scope Radiological Protection safety case for the UK ABWR, which is essential for the completion of GDA. The objective of this RO is to state ONR's expectations related to these areas, as part of the overall GDA submission.

In response to this RO, Hitachi-GE are requested to provide the strategy and plan for delivery of the UK ABWR Radiological Protection safety case documentation, and to subsequently provide this in a staggered, but logical, and timely fashion. ONR recognise that such plans are liable to change, and hence there is an on-going requirement to review and update these throughout GDA. These aspects is described further below:

- **Strategy:** Development of a safety case can be a complex process, requiring forethought and planning. It is important therefore that a strategy for the process exists, which considers matters such

as the objectives, scope, interactions, structure and outputs from the work. In essence this is the framework which defines the development of the safety case.

- **Plan:** The primary function of the plan is to ensure that the strategy is enacted, ensuring that the purpose, objectives and scope are clearly understood at the outset of the project and these are developed into a set of deliverables and submissions which together, constitute the full scope of the safety case. At the highest level should be the PCSR which summarises and presents the safety case at a high level, below which sit the full suite of supporting documents which constitute the arguments and evidence to support the safety claims. Both the supporting organisation and the resources producing the safety case, either within Hitachi-GE or from external support organisations, are a key part of the planning process. The plan should include consideration of both technical and specific safety case production resource, as they are not always the same and may constrain the plan, as well as any required translation / interpretation resource.

References:

- [1] ONR-GDA-AR-14-01, GDA Step 2 Assessment of the Radiological Protection Aspects of Hitachi GE's UK Advanced Boiling Water Reactor (UK ABWR).
- [2] Technical Assessment Guides. The purpose, scope, and content of nuclear safety cases, NS-TAST-GD-051, Revision 3, ONR, July 2013.
- [3] Safety Assessment Principles for Nuclear Facilities. 2006 Edition Revision 1. HSE. January 2008.
- [4] Technical Assessment Guides. NS-TAST-GD-005 – ONR Guidance on the demonstration of ALARP; NS-TAST-GD-002 – Radiation shielding; NS-TAST-GD-004 – Fundamental principles; INS-TAST-GD-038 – Radiological protection; NS-TAST-GD-043 – Radiological analysis normal operation; and NS-TAST-GD-045 – Radiological analysis fault conditions.
- [5] ONR-GDA-AP-14-011 Step 3 Assessment Plan for Radiological Protection.
- [6] ONR presentation during the step 2 wrap-up meetings, 12/13 June, TRIM Ref. 2014/308425

Regulatory Observation Actions

RO-ABWR-0014.A1 - Hitachi-GE to provide their strategy for development of the Radiological Protection elements of the UK ABWR Safety Case

REGULATORY EXPECTATIONS

Hitachi-GE are requested to provide the UK ABWR Radiological Protection safety case strategy. This should provide an adequate description of what the Radiological Protection safety case for UK ABWR is expected to contain and the approach that is being taken to manage and produce this. The Radiological Protection safety case strategy may need to be updated throughout GDA as new information becomes available and changes occur. Any significant changes to the strategy should be agreed with ONR prior to implementation and the updated version should be submitted to ONR.

RESOLUTION REQUIRED BY: 28/11/2014. The response to this ROA1 may be combined with other actions under this RO if considered appropriate

RO-ABWR-0014.A2 - Hitachi-GE to provide a project plan for delivery of the Radiological Protection elements of the UK ABWR safety case

REGULATORY EXPECTATIONS

Hitachi-GE are requested to provide a plan for delivery of the Radiological Protection elements of the UK ABWR safety case to define in detail how the strategy identified in ROA1, will be enacted. ONR expect that this should include the following:

- Definition of the Radiological Protection safety case tasks required to be completed during GDA (including any tasks already completed or ongoing).
- Identification of the various reports (e.g. PCSR, topic reports, basis of safety case, etc) which will be produced with clear presentation of their hierarchy and interfaces.
- The timeline for production of the deliverables, including their submission date to ONR.
- Any specific constraints or assumptions which may impact on the plan.
- Any interfaces with other technical areas or topics.

The plan should cover both steps 3 and 4 of GDA. The plan should be updated and submitted to ONR at regular intervals throughout GDA as new information become available and changes occur. Any significant changes to the Radiological Protection safety case project plan (e.g. changes in the tasks, the deliverables or the planned delivery dates) should be agreed with ONR prior to implementation.

ONR recognise that the entirety of documentation which supports the Radiological Protection safety case for UK ABWR may be large, therefore the plan may be restricted to the PCSR and those submissions which are a primary reference to this, and/or containing key supporting arguments and evidence.

ONR would expect all items identified in the plan to be submitted to ONR in a logical and timely manner.

RESOLUTION REQUIRED BY: To be determined by the Hitachi-GE Resolution Plan. The response to this ROA2 may be combined with other actions under this RO if considered appropriate.

RO-ABWR-0014.A3 - Hitachi GE to allocate suitably qualified and experienced resources to develop the UK ABWR Radiological Protection safety case:

REGULATORY EXPECTATIONS

Hitachi-GE are requested to provide information on the resources allocated to develop the UK ABWR Radiological Protection safety case in terms of manpower and qualifications and experience (Hitachi-GE staff and, if relevant, technical support contractors) required to complete each of the tasks identified in the UK ABWR Radiological Protection safety case project plan, including expertise in writing safety cases, and including translators and interpreters as required.

RESOLUTION REQUIRED BY: To be determined by the Hitachi-GE Radiological Protection Resolution Plan.

RO-ABWR-0014.A4 - Radiological Protection safety case deliverables:

REGULATORY EXPECTATIONS

Hitachi-GE are requested to provide the reports identified in the UK ABWR Radiological Protection safety case project plan, which will constitute the totality of the UK ABWR Radiological Protection safety case, in a staggered, logical and timely fashion.

RESOLUTION REQUIRED BY: To be determined by the ABWR Radiological Protection safety case project plan

-REQUESTING PARTY TO COMPLETE

Actual Acknowledgement date:	
RP stated Resolution Plan agreement date:	