REGULATORY OBSERVATION

REGULATOR TO COMPLETE

RO unique no.:	RO-ABWR-0016
Date sent:	16 September 2014
Acknowledgement required by:	07 October 2014
Agreement of Resolution Plan Required by:	*28 November 2014*
Resolution of Regulatory Observation required by:	*26 June 2015*
TRIM Ref.:	2014/253045
Related RQ / RO No. and TRIM Ref. (if any)**:**	
Observation title:	Mechanical Engineering Design Process Arrangement
Technical area(s) Mechanical engineering	**Related technical area(s)** Conventional safety Structural integrity Civil engineering Control and instrumentation Electrical MSQA

Regulatory Observation

Summary

This mechanical engineering regulatory observation is cross cutting and is being raised to ensure Hitachi-GE establishes and implements a robust, consistent and auditable design process for all its structures, systems and components (SSCs) important to safety.

Assessment Observation

Through technical discussion the requesting party (RP) has provided an adequate level of assurance that its adopted design process incorporates an embedded valve selection arrangement. I consider this to be aligned with my expectations.

However, my assessment has identified that the RP design process arrangements do not set out any design principles, rules, considerations and selection criteria for the following sampled components:

1. flexible and temporary hoses; or
2. heat exchangers.

Through discussion the RP has explained it achieves a robust and consistent approach across the various plant systems by applying its design review process to a developed concept. I consider this approach has the potential for the various system teams to optioneer different solutions for the same application.

Assessment and engagement with the RP has not provided an appropriate level of assurance that it has established a sufficiently robust structured design process for its UK ABWR. I consider this falls short of my regulatory expectations. The implementation of a well structured design process is the foundation to establishing the audit trail to demonstrating a SSC:

1. is suitable for the purpose for which it is to be used; and
2. has been adequately optioneered by suitable and sufficient risk assessment to demonstrate the suitability of the SSC; a requirement of UK health and safety legislation (Regulation 3(1) of the Management of Health & Safety at Work Regulations 1999).

I acknowledge the RP's proposal to capture the above aspects within its proposed design documentation for the UK ABWR. However, I consider the flexible and temporary hoses plus heat

exchangers are only examples of where I judge the RP's design process is not fully aligned with my regulatory expectations. I consider the RP's design process arrangement should set out design principles, rules, and selection criteria for all equipment important to safety in advance of optioneering a concept.

I consider this regulatory observation to be cross-cutting and of interest to:

1. conventional safety;
2. structural integrity;
3. civil engineering;
4. MSQA;
5. control and instrumentation; and
6. electrical.

In conclusion I consider:

1. the RP's design process is not fully aligned with my regulatory expectations;
2. the RP has provided some limited assurance of its adequacy and robustness;
3. the RP should establish and implement a robust, consistent and auditable design process across the various systems and for all the plants SSCs; and
4. a GDA can not be concluded without the assessment observation being adequately addressed in an auditable manner.

Regulatory Expectations

It is a regulatory expectation that the RP establishes and implements a robust, consistent and auditable design process. The adopted design process arrangement should:

1. align with the expectations set out in ONR Design safety assurance technical assessment guidance (Ref. TAST/057). In addition, take account of other applicable UK legislation that may also impose requirements onto a specific SSC; examples of such include, but not limited to the:
    a. Provision and use of Work Equipment Regulations (PUWER) 1998;
    b. Confined Spaces Regulations 1997;
    c. Manual Handling Operations Regulations 1992; and
    d. Lifting Operations and Lifting Equipment Regulations 1998.
2. set out the design principles, rules and selection criteria for all mechanical engineering SSCs important to safety in advance of initial design optioneering; and
3. set out the foundation to establishing the audit trail to demonstrating a mechanical engineering SSC:
    a. is suitable for the purpose for which it is to be used; and
    b. has been adequately optioneered to demonstrate an SSC health and safety risks have been reduced SFAIRP.

Although this regulatory observation is focussed on mechanical engineering, it is cross-cutting and has potential broader application. The RP should consider this potential broader application as part of its resolution plan.

Regulatory Observation Actions

The RP is expected to:

1. generate a resolution plan that will:
    a. present its detailed strategy to implement a robust design process for optioneering its mechanical engineering SSCs';
    b. define and scope the planned activities;
    c. include a controlled programme identifying: planned activities; deliverables; milestones; timescales and resource requirements; and

d. provide the audit trail to its proposed design process arrangement. 2. define all the UK applicable, guidance and legislation; 3. identify all the applicable mechanical engineering SSCs; 4. examine and review its extant design process arrangement against the stated expectations; 5. make available to ONR the examination and review conclusions and recommendations; 6. if appropriate: a. raise design changes; and b. update its design process arrangement; the UK ABWR safety case; SSCs' design and substantiation; 7. provide progress updates to ONR through the planned engagements; and 8. make available any appropriate updated process arrangements and documents for ONR assessment.	
Actual Acknowledgement date:	
RP stated Resolution Plan agreement date:	