REGULATORY OBSERVATION		
REGULATOR TO COMPLETE		
RO unique no.:	RO-UKHPR1000-0048	
Revision:	0	
Date sent:	30/07/20	
Acknowledgement required by:	20/08/20	
Agreement of Resolution Plan Required by:	To Be Agreed	
TRIM Ref:	2020/228260	
Related RQ / RO No. and TRIM Ref: (if any):	RO-UKHPR1000-0021 (CM09 2019/358870) RQ-UKHPR1000-0674 (CM09 2020/117581)	
Observation title:	Equipment Qualification for Mechanical Engineering Based Structures Systems and Components	
Lead technical topic:	Related technical topic(s):	
14. Mechanical Engineering	 Control & Instrumentation Electrical Engineering Fault Studies Management of Safety Quality Assurance Severe Accident Analysis Structural Integrity 	

Regulatory Observation

Background

Equipment Qualification (EQ) is a fundamental expectation of ONR's safety assessment for nuclear facilities; contributing to reducing relevant risks so far as is reasonably practicable (SFAIRP).

ONR is currently undertaking a phased Generic Design Assessment (GDA) of the UK HPR1000 reactor. During GDA the Requesting Party (RP) has provided information describing how EQ is performed for the generic design. ONR has undertaken a sample assessment the UK HPR1000 EQ methodology [Ref. 1] and supporting documents [Ref. 2 and 3] and identified several gaps against EQ relevant good practice (RGP), as described in ONR's Safety Assessment Principles (SAPs) [Ref. 4]. More specifically, ONR requires evidence of:

- Arrangements that ensure only suitably qualified and experienced people (SQEP) undertake activities: establishing, verifying, implementing, or preserving EQ.
- Arrangements that ensure auditable documented evidence of EQ will be available at all stages of the plant lifecycle. ONR SAP EQU.1 (Qualification procedures).
- A systematic approach being applied to establish a range of conditions (both normal operational and accident), for which EQ is required.
- Conservative derivation of safety function performance and necessary safety considerations for SSCs including 'mission times'.
- Adequate arrangements to deliver and demonstrate configuration control during manufacture of SSCs.
- Monitoring requirements to identify when re-assessment of qualified life is required.
- Evidence of adequate arrangements to preserve EQ.

Appropriate assessment of operating experience (OPEX) to support EQ.

This Regulatory Observation (RO) has therefore been raised to:

- Explain ONR's regulatory expectations;
- Seek improvements in the RP's processes/procedures to ensure robust EQ for the UK HPR1000 generic design can be achieved; and
- Seek a robust demonstration of the RP's EQ processes/procedures, as applied to the mechanical engineering discipline.

Relevant Legislation, Standards and Guidance

UK Law:

- Health and Safety at Work Act 1974; and
- Management of Health and Safety at Work Regulations 1999.

ONR Safety Assessment Principles [Ref. 4] - http://www.onr.org.uk/saps/saps2014.pdf:

- SAP EQU.1 Qualification procedures;
- SAP EMT.3 Type testing;
- SAP EMT.4 Validity of equipment qualification;
- SAP EMT.5 Procedures
- SAP EMT. 6 Reliability claims;
- SAP ERL.1 Form of claims;
- SAP ERL.2 Measures to achieve reliability;
- SAP EAD.1 Identification of requirements; and
- SAP EAD.2 Lifetime margins.

ONR Technical Assessment Guides - http://www.onr.org.uk/operational/tech_asst_guides/index.htm:

- NS-TAST-GD-057 Design Safety Assurance [Ref. 5];
- NS-TAST-GD-098 Asset Management [Ref. 6].

Regulatory Expectations

In responding to this RO, the RP should provide adequate evidence to demonstrate robust EQ in the following areas:

EQ Procedures:

- Provide confidence that a SSC will deliver the required safety function during normal operations, maintenance, fault, and accident conditions commensurate with its safety classification for the duration of its operational life;
- Ensure only SQEP perform duties delivering EQ in all stages of the SSC lifecycle; and
- Ensure configuration control of documented evidence for the SSC's qualified life is available during:
 - o Design;
 - o Verification testing;
 - Manufacture;

- Installation;
- o Commissioning; and
- Examination, maintenance, inspection and testing (EIM&T).

EQ Requirements:

- A systematic approach, clearly linked to the requirements identified by the safety case (for example
 using the fault and/or engineering schedules and identified safety properties), should establish design
 parameters for which SSCs should be qualified, including:
 - Environmental conditions in which plant must operate ("mild" and "harsh"*);
 - Operational conditions;
 - Ageing and degradation;
 - Mission times* where specific SSC performance requirements are required; and
 - Examination, maintenance, inspection and testing requirements to preserve qualified life.

To provide assurance of how EQ is achieved and demonstrated in the UK HPR1000 generic design, the RP should provide suitable and sufficient evidence to demonstrate how their EQ procedures and requirements are applied for the following SSCs:

- RIS (safety injection system)
 - Medium head safety injection (MHSI) pump;
 - o Residual heat removal exchanger; and
 - o In-containment Refuelling Water Storage Tank (IRWST) strainer;
- RCS (reactor coolant system) including:
 - Control rod drive mechanism (CRDM);
 - Pressure relief valve:
 - o Severe accident dedicated valves (SADV); and
 - Reactor coolant pump (RCP);
- DCL (main control room air conditioning system) including:
 - HEPA filter;
- EPP (containment leak rate testing and monitoring system) including:
 - Personal airlock and equipment hatch;
- ASG (emergency feed water system) including:
 - Containment isolation valves:
- VVP (main steam system) including:
 - Main steam isolation valve.
- LHP/LHQ/LHR: Emergency Power Generation including:
 - Emergency Diesel Generator.

NOTE:

- A) The RP should consider the use of flow diagrams in its explanations.
- B) The RP should explain how the generic safety case will be updated.

*Glossary

- Equipment Qualification refers to the generation and maintenance of evidence to assure that equipment will operate on demand to meet system performance requirements.
- Harsh environment/conditions refers to locations within nuclear installations that experience significant changes in environmental conditions as a consequence of a postulated initiating event.
- *Mild environment/conditions* refers to locations within nuclear installations in which environmental conditions will not degrade beyond those that occur during normal operational states.
- Mission time refers to a specific duration for which a SSC has to perform its function.
- Qualified life refers to the period of time for which adequate performance of an SSC can be
 demonstrated for a specific set of service conditions. N.B. at the end of its 'qualified life', the SSC shall
 be capable of delivering its safety function.

References

- 1. Equipment Qualification Methodology (GHX80000003DOZJ03GN), Revision A, May 2019 (CM09 Ref. 2019/156180).
- 2. Technical Specification for Medium Head Safety Injection Pumps (GHX45200006DNHX44DS), Revision B, January 2020 (CM09 Ref. 2020/21930).
- 3. Qualification Requirements for RIS Medium Head Safety Injection Pumps (GHX45200011DNHX44DS), Revision A, October 2019 (CM09 Ref. 2019/318804).
- 4. ONR Safety Assessment Principles 2014 Edition, Revision 1, January 2020, http://www.onr.org.uk/saps/saps2014.pdf.
- 5. ONR Nuclear Safety Technical Assessment Guide, Design Safety Assurance, NS-TAST-GD_057, Revision 5, http://www.onr.org.uk/operational/tech_asst_guides/ns-tast-gd-057.pdf.
- 6. ONR Nuclear Safety technical Assessment Guide, Asset Management, NS-TAST-GD-098, Revision 1, http://www.onr.org.uk/operational/tech_asst_guides/ns-tast-gd-098.pdf.

Regulatory Observation Actions

RO-UKHPR1000-0048.A1 - Equipment qualification processes and procedures

In response to this Regulatory Observation Action (ROA), the RP should demonstrate how:

- EQ RGP requirements are managed for each stage of the UK HPR1000 lifecycle;
- EQ arrangements satisfy ONR's view of EQ RGP; and
- Any EQ RGP shortfalls identified are to be addressed, and by when.

The response to this ROA may be combined with any other ROA under this RO, if deemed appropriate.

Resolution required by 'to be determined by General Nuclear System Limited Resolution Plan'

RO-UKHPR1000-0048.A2 - Demonstration of equipment qualification requirements

In response to this ROA, the RP should:

- Demonstrate how safety case EQ requirements, for the SSC's identified in this RO, are addressed by the design and achieved in practice. The response should demonstrate that a conservative approach has been used to determine the qualified life of SSCs taking account of:
 - o Functional and non-functional safety considerations:
 - Environmental conditions in which plant must operate (i.e. "mild" and "harsh"*);
 - o Operational conditions;

- Ageing and degradation;
- o Mission times where specific SSC performance requirements are required; and
- EIMT to preserve EQ.

The response to this ROA may be combined with any other ROA under this RO, if deemed appropriate.

Resolution required by 'to be determined by General Nuclear System Limited Resolution Plan'

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REQUESTING PARTY TO COMPLETE		
Actual Acknowledgement date:		
RP stated Resolution Plan agreement date:		