

## REGULATORY OBSERVATION

### REGULATOR TO COMPLETE

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<b>Observation title:</b>	Identification and Use of Operational Experience (OPEX) in the UK HPR1000 Generic Design and Safety Case
<b>Lead technical topic:</b>	<b>Related technical topic(s):</b>
6. Project	1. Chemistry 11. Human Factors 13. Management of Safety Quality Assurance 16. Radiological Protection 17. RadWaste, Decommissioning & Spent Fuel Management 21. Environmental

### ***Regulatory Observation***

#### **Background**

The effective utilisation of Operational Experience (OPEX) is a fundamental part of demonstrating the safety and security of a nuclear installation throughout its entire lifecycle – starting with the design. There are many sources of OPEX available to organisations, both internally and externally. OPEX may comprise: operational data/information, event reports, investigations, corrective actions, design modifications, research and development *etc.* ONR expect that available and relevant sources of OPEX should be: identified, analysed and used in the correct way, to ensure learning adequately underpins the entirety of the lifecycle of a nuclear facility, from construction, through to decommissioning.

As part of the Generic Design Assessment (GDA) of the UK HPR1000, the Office for Nuclear Regulation (ONR) and Environment Agency (EA)<sup>1</sup> have continued to consider the adequacy of the Requesting Party's (RP) approach to OPEX. The Regulators have assessed various submissions which are directly relevant to the RP's identification and use of OPEX, including: the production strategy for the Safety, Security and Environment Report (SSER), various chapters of the SSER, the safety case development manual, and a range of other supporting documentation [1 to 10].

The Regulators recognise UK HPR1000 is an evolutionary design and as described in [3], has already considered learning from key OPEX obtained from the Chinese domestic fleet of Pressurised Water Reactors (PWRs) and lessons learnt from the Fukushima accident – resulting in several design modifications.

<sup>1</sup> ONR and EA – for the purposes of this RO are collectively termed “The Regulators”.

It is also clear the RP's suite of processes and procedures developed for the UK context, to demonstrate the UK HPR1000 design will reduce relevant risks So Far As is Reasonably Practicable (SFAIRP<sup>2</sup>), captures the importance of the role of OPEX and provides relevant guidance [5 to 7].

The Regulators have continued to assess the UK HPR1000 SSER including: lower tier supporting documentation, how the RP has applied their processes and procedures to demonstrate risks are reduced to as low as reasonably practicable (ALARP) [5 to 7], and how OPEX has been identified and used. To date, ONR's assessments across several topic areas: chemistry, radiological protection, human factors and decommissioning, have revealed several important shortfalls which require action from the RP to address. These topic areas typically place a greater emphasis on using OPEX as a source of supporting evidence to make a robust demonstration of safety. Some of the gaps identified include:

- insufficient evidence of a systematic approach being applied to gather and use OPEX to support the demonstration of ALARP;
- a very narrow (sometimes too narrow) selection of OPEX – often limited to the RP's experience only; and
- insufficient justification being provided to support the RP's conclusions on the applicability of the OPEX considered and the links (i.e. referencing) to the safety case claims and arguments which the OPEX directly supports.

In addition, a more fundamental shortfall is that while OPEX is cited in the generic safety case and key safety arguments made, or conclusions drawn on the basis of that OPEX, the OPEX itself (i.e. the data) is often not presented in the documentation. This is best exemplified by the RP's approach to normal operational radiological source term(s), where reliance is placed on OPEX (data) collected from operational PWRs, but the documentation only presents a very narrow set of these data. ONR continues to influence the RP to address this gap and has recently sought some of the necessary clarifications by raising Regulatory Queries (RQs) [11]. So far, the RP has been unable to provide sufficient confidence this particular gap will be adequately addressed during GDA. The information provided clarifies the RP's working arrangements only; it does not commit to an approach to adequately capture and incorporate OPEX data currently absent from some generic safety case documentation [12].

Overall, ONR considers the shortfalls identified with the RP's approach to OPEX can be summarised as gaps in the:

- approach to identifying, justifying and using OPEX (i.e. scope); and
- what OPEX (including data) is presented in the generic safety case, and how.

The persistence of these gaps means that in some circumstances, ONR is unable to undertake a complete and meaningful assessment, until these data are presented. ONR needs to have sufficient confidence that OPEX supporting the generic safety case is: appropriate, complete, and has not been unduly constrained; to be able to judge whether the UK HPR1000 generic design has taken account of all relevant learning, and ultimately whether relevant risks will be reduced SFAIRP. Similarly, the EA considers this is also applicable to underpinning the demonstration of Best Available Techniques (BAT).

### **Relevant Legislation, Standards and Guidance**

The themes of OPEX, learning, and learning organisation span a wide range of ONR's guidance, available standards and applicable legislation. There are many sources of guidance which cover ONR's expectations in undertaking assessment and inspection regulatory functions, covering areas such as: leadership and management for safety, regulatory assessment of safety cases and periodic review (PSR) of safety cases. Some of these are not directly relevant to a GDA (for example PSR); however, the principles still broadly apply to the production of a generic safety case.

ONR's Safety Assessment Principles [13] (SAPs) contain a section pertaining to leadership and management for safety. SAP MS.4 covers learning:

- *“Lessons should be learned from internal and external sources to continually improve leadership, organisational capability, the management system, safety decision making and safety performance”.*

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<sup>2</sup> The terms SFAIRP and As Low As Reasonably Practicable (ALARP) are used inter-changeably and effectively have the same meaning.

SAP SC.7 addresses safety case maintenance, including PSRs. Paragraph 110 is written in the context of PSRs, however, the principle still applies to the consideration of OPEX at the design stage:

- *“Reviews of incidents, operating experience and other sources of information should not be restricted to the facility or site in question. They should include similar facilities or equipment and also a wider range of nuclear and non-nuclear experience, both nationally and internationally.”*

There are also several related Technical Assessment Guides (TAGs) directly applicable to the RP’s organisational arrangements to support the development of the generic safety case:

NS-TAST-GD-005, *Guidance on the Demonstration of ALARP* [14]:

- Annex 2 contains guidance on ALARP for proposed new civil nuclear reactors:
- *“The demonstration should set out how known problem areas (e.g. identified from Operational Experience Feedback (OEF), improved analysis, or improving standards) have been addressed and how and why the particular solution chosen was arrived at.”*

NS-TAST-GD-050, *Periodic Safety Reviews* [15]:

- *“Learning organisation:*
- *Does the organisation actively seek out and act upon external sources of learning (including non-nuclear sectors)?*
- *Is there an integrated approach to organisational learning (pulling together lessons from internal and external events, investigations, evaluations, organisational changes etc.)?”*

NS-TAST-GD-051, *The Purpose, Scope and Content of Safety Cases* [16]:

- Figure 2, which covers safety case documentation structure, lists operational experience data within the document hierarchy.

The EA also have expectations relevant to OPEX captured in their principles and guidance documents:

Radioactive Substances Regulations – Environmental Principles (REPs) [17]:

- Fundamental Principle G requires use of the best scientific knowledge;
- Fundamental Principle H requires consideration of uncertainties and the use of the precautionary principle;
- MLDP3 – Capability – requires that sufficient relevant information is available to those who make decisions;
- MLDP4 – Decision making - requires effective decision making including ensuring that relevant information, including data and opinion, is sought, considered and used to inform decisions that might affect the environment and that the quality of the of data and opinions are evaluated;
- MDLP5 – Learning from Experience – requires organisations should learn from their own and others’ experience so as to continually improve their ability to protect the environment;
- RSMDP4- Methodology for Identifying BAT - The process to identify the best available techniques should be transparent such that sufficient information is provided to confirm the validity of all data used. Additionally, the process to identify the best available techniques should use good data and all data should be at a level of detail that ensures that it is fit for purpose;
- RSMDP6 – Application of BAT – requires decisions should be informed by relevant guidance and good practice, wider experience and developments, e.g. at facilities elsewhere; and
- ENDP7 – Reliability – requires that adequate reliability and availability for environment protection measures should be demonstrated by suitable analysis and data.

The EA’s expectations of the REPs are expanded on in [18].

### **Regulatory Expectations**

Based on the relevant standards and guidance outlined above, there are two main objectives driving this RO. Objective 1 is for ONR to seek assurances the RP has robust arrangements in place to: identify, capture and justify the applicability of relevant OPEX to the UK HPR1000 design. Specifically, The Regulators expect greater clarity on:

- The RP's processes which control (i.e. decision making, etc.) and provide oversight of the: specification, management, analysis and integration of different sources of OPEX into the generic safety case.
- Details of the methods and approaches RP personnel follow to justify the applicability, or otherwise, of OPEX and links to the generic design i.e. how the safety case submissions should treat and take account of OPEX, especially in the demonstration of ALARP.
- How sources of relevant international OPEX external to the RP are identified, analysed and used; and
- How relevant OPEX arising from non-nuclear sectors is identified and considered.

Objective 2 for the RO is about ensuring the UK HPR1000 generic safety case integrates OPEX in an appropriate way. The Regulators expect to see evidence of:

- A demonstration of the robust application of the RP's arrangements described under Objective 1, in a sample of safety case submissions. This should include updates to the RP's suite of documentation defining and justifying normal operational radiological source term(s), to ensure OPEX (data) is appropriately captured and integrated.

As noted in the background section, the shortfalls raised in this RO have been identified in technical topics where OPEX makes a significant contribution to safety case evidence. ONR expects the RP's approach to addressing Objective 2 to align with these technical topics, in order to provide a demonstration of the robust application of their arrangements. ONR also expects the RP to take due account of any links to related ROs, for example [19 and 20].

ONR recognises there are sometimes other considerations, such as a commercial factors or intellectual property rights (IPR) etc., which could constrain the availability of sources of OPEX and how it is used. These constraints should be clearly identified and explained, including a description of how they have been addressed.

For clarity, the scope of this RO is *not* seeking a response which provides an "event-by-event" analysis of international OPEX.

### **References**

- [1] *GDA Project UK HPR1000: SSER Development Strategy*, HPR-GDA-REPO-0071, Rev. 001, September 2019, General Nuclear System Limited; CM9 2019/367052;
- [2] *GDA Project UK HPR1000: Safety Case Development Manual*, HPR-GDA-REPO-0110, Rev. 000, September 2019, General Nuclear System Limited; CM9 2020/62311;
- [3] *UK HPR1000 GDA Project: Pre-construction Safety Report Chapter 2, General Plant Description*, HPR/GDA/PCSR/0002, Rev. 001, February 2020, General Nuclear System Limited; CM9 2020/13619;
- [4] *UK HPR1000 GDA Project: Pre-construction Safety Report Chapter 33, ALARP Evaluation*, HPR/GDA/PCSR/0033, Rev. 001, February 2020, General Nuclear System Limited; CM9 2020/14002;
- [5] *GDA for UK HPR1000:ALARP Methodology*, GDA-REC-CGN-001428 GHX00100051DOZJ03GN, Rev. B, May 2018, China Nuclear Power Design Co. Ltd; CM9 2018/181415;
- [6] *GDA for UK HPR1000:ALARP Demonstration Instruction*, GHX00100119DOZJ03GN, Rev. A, January 2020, China Nuclear Power Design Co. Ltd; CM9 2020/11295;
- [7] *GDA for UK HPR1000:Holistic ALARP Demonstration Report*, GHX00100071KPGB03GN, Rev. A, December 2019, China Nuclear Power Design Co. Ltd; CM9 2019/370389;
- [8] *GDA for UK HPR1000:HPR1000 R&D History*, GHX99980001DXZJ01MD, Rev. C, January 2020, China Nuclear Power Design Co. Ltd; CM9 2020/12209;
- [9] *UK HPR1000 Pre-construction Environment Report Chapter 3, Demonstration of BAT*, HPR/GDA/PCER/0003, Rev. 001, February 2020, General Nuclear System Limited; CM9 2020/14822;
- [10] *UK HPR1000 Pre-construction Environment Report Chapter 6, Quantification of Discharges and Limits*, HPR/GDA/PCER/0006, Rev. 001, February 2020, General Nuclear System Limited; CM9 2020/14809;
- [11] RQ-UKHPR1000-0713; RQ-UKHPR1000-0716; RQ-UKHPR1000-0717; April 2020, ONR; CM9 2017/407871;
- [12] Letter from GNSL to ONR and EA, *Use of EDF OPEX in Source Term Area for UK HPR1000 GDA – Arrangements and Process in place within the General Nuclear System*, HPR/GDA/LETT/0036, September 2019, General Nuclear System Limited, CM9 2019/283036;
- [13] *Safety Assessment Principles for Nuclear Facilities*, 2014 Edition, Rev. 1, January 2020, ONR, CM9 2019/367414;
- [14] ONR Nuclear Safety Technical Assessment Guide, *Guidance on the Demonstration of ALARP*, NS-TAST-GD-005, Rev. 10, December 2019, ONR, CM9 2019/315236;

- [15] ONR Nuclear Safety Technical Assessment Guide, *Periodic Safety Reviews (PSR)*, NS-TAST-GD-050, Rev. 7, July 2017, ONR, CM9 2019/47761;
- [16] ONR Nuclear Safety Technical Assessment Guide, *The Purpose, Scope and Content of Safety Cases*, NS-TAST-GD-051, Rev. 6, December 2019, ONR, CM9 2019/82006;
- [17] Radioactive Substances Regulation – *Environmental Principles Regulatory Guidance Series*, No. RSR1. V.2 April 2010, EA. <https://www.gov.uk/government/publications/radioactive-substances-regulation-environmental-principles>
- [18] Radioactive Substances Regulation – *Management Arrangements for Nuclear Sites*, V.2, April 2010, EA. <https://www.gov.uk/government/publications/rsr-management-arrangements-for-nuclear-sites>
- [19] Regulatory Observation RO-UKHPR1000-0004, *Development of a Suitable and Sufficient Safety Case*, Rev. 0, September 2018, ONR, CM9 2018/255957;
- [20] Regulatory Observation RO-UKHPR1000-0035 *Optimisation of Collective Occupational Radiation Exposure for the UK HPR1000*, Rev. 0, March 2020, ONR, CM9 2020/93581.

## **Regulatory Observation Actions**

### **RO-UKHPR1000-0044.A1 – Arrangements for identifying, capturing and justifying the applicability of relevant OPEX**

In response to this Regulatory Observation Action (ROA), the RP should provide information on the documented arrangements which:

- Define and explain the approach and associated process(es) which control how different sources of OPEX (*i.e.* internal, external and international) are: identified, captured and analysed. The approach to identifying and using external, international OPEX, should be especially robust.
- Explain the method(s) or approach(s) RP personnel follow to justify the applicability, or otherwise, of OPEX, and the arrangements which control how this justification and the OPEX (data) itself, are presented and used in the generic safety case.
- Explain how dependencies or interfaces between technical topics, and/or safety case submissions *etc.*, which rely on similar or the same sources of OPEX are identified, together with a description of how they are managed, to ensure consistency.
- Identify and justify any specific constraints which may impact on the availability of any particular sources of OPEX and how they have been addressed; and
- Explain how learning from relevant non-nuclear sectors is considered and captured.

The response to this ROA should consider interfaces with the RP's existing suite of relevant documentation or arrangements to produce the generic safety case, and how or whether any of these documents need updating to integrate the information requested. The information should provide an adequate description of a robust set of arrangements for controlling the use of OPEX in the generic safety case.

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

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

### **RO-UKHPR1000-0044.A2 – Demonstration of suitable and sufficient integration of relevant OPEX into the UK HPR1000 generic safety case**

The information provided to respond to this ROA should seek to provide an adequate demonstration of the robust application of the arrangements described under ROA1. Specifically, it should seek to provide ONR with confidence that safety case submissions dealing with normal operational radiological source term(s) appropriately capture and integrate OPEX (data). Based on the response to ROA1 above, in response to this ROA, the RP should provide information to:

- Identify the technical topics/areas *etc.* with the greatest reliance on the use of OPEX.
- Define and explain any gaps identified in the application of the RP's extant arrangements for controlling the use of OPEX in the generic safety case – including the steps being taken to address them. Impacted technical topics, areas, submissions *etc.* should be clearly identified, listed, and a plan for when any identified gaps will be addressed, provided to The Regulators.
- Based on the above, provide a sample of technical submissions to The Regulators, to demonstrate the practical application of the arrangements which control the use of OPEX in the generic safety case:

- Identify the various submissions (i.e. topic reports, support studies, ALARP and BAT demonstrations etc.) that will be provided, together with a programme for delivery to ONR. The sample should include all impacted submissions in the normal operational radiological source term(s) topic.
- Provide a short explanation to justify which aspect(s) of the arrangements each submission will demonstrate.

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

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

**REQUESTING PARTY TO COMPLETE**

<b>Actual Acknowledgement date:</b>	
<b>RP stated Resolution Plan agreement date:</b>	