



Office for
Nuclear Regulation

Strategy for the Regulation of Replication on SZC

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Strategy for the Regulation of Replication on SZC

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Purpose

Sizewell C (SZC) is the first power reactor 'next-of-a-kind' (NOAK) deployment that ONR has had to regulate. There is therefore a need for ONR to define a strategy for regulation of replication which is proportionate and targeted but which recognises the legal requirements of SFAIRP. This strategy needs to provide inspectors with clarity on regulatory expectations and how these fit within our regulatory framework.

The purpose of this paper is to set out the proposed strategy for the regulation of the replication of Hinkley Point C (HPC) at SZC and to request the endorsement of the New Reactors Division (NRD) board for its implementation.

Following endorsement of this strategy by NRD board it will be submitted to the Technical Division board with a recommendation that it should form the basis of standalone regulatory guidance on expectations for a 'fleet-wide' approach to multi-site deployment of nuclear power plant designs, to sit alongside the ONR guidance on demonstration of As Low as Reasonably Practicable (ALARP) [Ref. 1].

Background

NNB GenCo (SZC) has undertaken work to produce project principles and a strategy to define and manage replication of HPC at SZC. This included a specific hold-point in 2021 for which a number of supporting documents were produced.

One such supporting document was an ALARP Position Paper. The aim of this paper was to demonstrate, at a holistic level, that *"design decisions made for HPC which were justified as delivering a risk that is ALARP for HPC, in general need not be re-opened / re-considered for SZC replicated plant"*. This was supported by a number of test cases which supported this position.

ONR assessed the documentation in support of this hold point. This assessment [Ref. 2] concluded that ONR had confidence that NNB will be able to present a safety case which demonstrates replication.

ONR then wrote to NNB (GenCo) SZC in January 2022 [Ref. 3] stating its support for the principle of replication, as follows:

"...ONR [has] confidence that the future safety case for SZC based on the replication of HPC, where appropriate and possible, should be able to demonstrate that the risks associated with the design can be reduced to a level that is ALARP. This conclusion is contingent on:

- *adequate resolution of matters identified as part of the ongoing nuclear site licence assessment;*

- *a more robust consideration and justification developed regarding any gaps between codes, standards and methodologies, for example, applied to HPC and proposed to be adopted by SZC, and current relevant good practice; and*
- *an adequate process developed and implemented to identify and consider options discounted at HPC, but that could be feasible for SZC due to different constraints.*

ONR's present level of confidence does not preclude regulatory engagement identifying design modifications as necessary due to factors currently unknown. However, as the overall nuclear safety risk to workers and members of the public from the HPC design is predicted to be low, based on our assessment of your replication justification and subject to adequate resolution of the above highlighted matters, ONR considers that it is unlikely that there will be significant challenge to replication.

Notwithstanding the views expressed in this letter, it remains ONR's expectation that the future SZC safety case will be produced consistent with the expectations in ONR's TAG 51 or be based on other principles or guidance giving an equivalent outcome, such that the replicated design can be demonstrated to reduce the level of risk ALARP."

Definition of Replication

Replication is a principle where a design and associated arrangements, supply chain, etc. is implemented in multiple instances. Usually, this is an iterative process where a design from a previous project is then used again at a new location. The extent of the design that can be replicated is limited to areas where the location (i.e. environment, external hazards, plot size etc) has no impact on the design.

ONR interpretation of replication in the context of fleet deployment is that it applies to replication of the as-built configuration design at the point of pre-commissioning, for the preceding 'in family' unit. So, in the case of SZC, the as-built configuration for HPC unit 2 will be replicated for SZC unit 3, unit 4 will be based on replication of unit 3, and so on.

Ultimately it is the role of the dutyholder to define the scope of replication, and therefore what is included and what is excluded in any specific implementation. ONR would expect the dutyholder to make available the rationale, strategy and scope of replication at an early project stage (e.g. during the licensing assessment for a NOAK deployment new site).

Scope

Applicability to ONR's Purposes

Nuclear safety

Replication applies to the nuclear safety purpose and may be justified where it can be demonstrated that replicated aspects reduce the level of risk ALARP.

Nuclear site health and safety (conventional health and safety) including life fire safety

Replication applies to the nuclear site health and safety purpose and may be justified where it can be shown that application of the 'Principles of prevention' (Management of Health and Safety at Work Regulations 1999 Schedule 1) indicates that changes in approach or design are not required.

Nuclear security

Replication applies to the nuclear security purpose and may be justified where it can be demonstrated that replicated elements achieve security outcomes.

Safeguards

Replication applies to the Safeguards purpose and may be justified where it can be demonstrated that replicated aspects achieve compliance with nuclear safeguards regulations.

Transport

Replication is not applicable to the transport purpose as this is not relevant to NOAK deployment.

Exclusions

Replication is generally limited to areas where the safety case and security plan for SZC is bounded by that for HPC. Areas where this isn't the case would not be within the scope of replication. Specific exclusions are likely to include, but may not be limited to:-

- differences in site geology, layout, topology and limitations;
- site specific design aspects, both construction design and nuclear safety design;
- site specific aspects of compliance arrangements for statutory regulations, e.g. Construction (Design and Management), Control of Major Accident Hazards;
- changes in supply chain, for example where a supplier for HPC is no longer available to enter into contract for SZC;
- external hazards case where the SZC site envelope is not bounded by HPC;
- any changes to the design basis threat;
- obsolescence issues;
- constructability, where this is influenced by topography, geology, site curtilage, access, restrictions on craneage, storage and laydown areas, changes in design of temporary works;

- the review of items within design risk register or application of learning from previous build, or usage experience, indicates that replication would no longer control risks to ALARP;
- changes in the sequencing of build or availability of material which impact on the site construction phase; and
- aspects of construction, improvements relating to how the design is constructed may give benefits without changing the ultimate design, which have already been realised in HPC unit 2 compared with unit 1.

Replication

Benefits

There are significant safety and operational benefits to be realised from replication and adopting a 'fleet approach'. Each NOAK implementation of the design can take operating experience (OPEX) from previous deployments to improve processes and learning from issues encountered with the design. This reduces the need for development of new approaches to design, procurement, construction, commissioning, testing and operation which not only have limited OPEX, but may introduce unforeseen risks.

Considerations

As time progresses, codes, standards and practices will evolve such that new techniques and methods may deliver safety benefits. Furthermore, OPEX may highlight shortfalls with existing designs that require resolution to achieve adequate safety and security performance. Hence, ONR's interpretation of what constitutes relevant good practice (RGP), and therefore how risks are reduced ALARP, will change accordingly. Whilst ALARP is not applicable to security, the use of RGP remains key in demonstrating that security outcomes are achieved. Dutyholders proposing to replicate an existing design are therefore expected to be cognisant of, and to give due consideration to, the evolution of RGP.

Should more than ten years elapse between the pre-commissioning design freeze of one unit and the pre-construction safety and security case of the next unit in the fleet, the licensee would be expected to undertake review of the design to be replicated, and its operation to ensure the safety and security case for the replicated design remains valid, that risks are reduced ALARP and security outcomes achieved. This is consistent with the requirement for licensees to undertake periodic safety reviews (PSR) every ten years, and the period of validity for the output of Generic Design Assessment (GDA).

Within the ten-year period it is considered unlikely that developments in RGP would significantly undermine the case for replication. Notwithstanding this, the dutyholder would still be expected to carry out a proportionate review and justify the approach to replication. For SZC this was provided in the ALARP position paper that was produced in 2021.

Challenge

The challenge for ONR and for inspectors is evaluating the balance between replication and seeking continuous improvement. Two perspectives on the regulation of replication have been discussed and considered; these are presented within Appendix A.

When replicating a facility for a NOAK deployment there are areas where the judgement of what was reasonably practicable may have moved on since previous deployments.

Inspectors should consider what impact any change would have on the overall risk of the facility, taking into account the level of the risk at the previous deployment in the fleet. Unless the change would have a notable and demonstratable impact on the overall risk of the facility, then it is likely it would be disproportionate for ONR to expend regulatory time and effort on these areas. Where this is the case inspectors should therefore not target and sample such aspects of replication in their assessment and engagement. This does not however remove the dutyholders' duty to ensure the facility reduces risk SFAIRP and achieve security outcomes.

In areas where it can be demonstrated that the change in risk would be notable, ONR would expect the licensee to reconsider the ALARP justification within its safety case and / or demonstration that security outcomes are achieved.

Adopting this risk informed, targeted approach to the regulation of NOAK deployments is aligned with our approach to enabling regulation [Ref. 5] and ensures that ONR fulfils our statutory obligations under the Regulators' Code [Ref. 6].

Continuous Improvement

ONR still expects a licensee to consider continuous improvement opportunities where there is little sacrifice associated with doing so where there is a notable risk benefit. Learning gained from areas such as supply chain, quality assurance and construction could provide reductions in risk whilst still delivering a replicated design.

Application to SZC

The EPR design has successfully undergone Generic Design Assessment (GDA) and has been subject to further regulatory scrutiny and assessment through the permissioning regime on the HPC project. NNB has demonstrated that the operational risk of the station is generally below the Basic Safety Objective (BSO).

As the overall level of risk from HPC is already judged to be acceptably low, unless there is a notable and demonstratable improvement on the overall station risk it is likely that any potential design changes would ultimately be demonstrated to be grossly disproportionate. It would therefore be disproportionate for ONR to push for or expect NNB GenCo (SZC) to expend significant effort in undertaking detailed assessments and analyses to demonstrate ALARP on a case-by-case basis.

Should inspectors identify areas where it can potentially be demonstrated that a change would result in a notable reduction in overall risk, a justification should be prepared by the inspector, giving explicit consideration to the impact of challenging replication and the inherent cost to safety in making unproven changes, for presentation to a governance panel for a decision to be made on whether this should be targeted, and regulatory time and effort allocated in this area.

Summary

ONR is supportive of the principle of replication and recognises that there are benefits to such an approach. However, it remains a regulatory expectation that the SZC safety case will be consistent with ONR's expectations, and the principle of replication should therefore be applied with due consideration given when changes to what is reasonably practicable would have a notable impact on the overall station risk. Replication does not however, remove a licensee's legal obligations including areas such as CDM, COMAH, SFAIRP and the HSWA.

Recommendation

The NRD board is requested to endorse this strategy for implementation on the SZC project.

It is recommended that this strategy is reviewed on a periodic basis, initially after 18-24 months.

References

1. Technical Assessment Guide – Guidance on the Demonstration of ALARP (As Low as Reasonably Practicable), Revision 11, November 2020, ONR, NS-TAST-GD-005
2. SZC Replication Strategy – Summary Assessment Report, February 2022, ONR, ONR-NR-AR-21-034, 2022/89864
3. Letter – Feedback on Replication of Hinkley Point C, January 2022, ONR, SZC504197N, 2022/2097
4. The Tolerability of Risk from Nuclear Power Stations, 1992, HSE, <http://www.onr.org.uk/documents/tolerability.pdf>
5. A guide to enabling regulation, ONR, August 2020, [A guide to enabling regulation \(onr.org.uk\)](#)
6. Regulators' Code, April 2014, Department for Business Innovation and Skills, [Regulators' Code - GOV.UK \(www.gov.uk\)](#)
7. Summary of replication workshop, 3 November 2022, CM9 2022/64524

Appendix A – Evaluation of Perspectives on Replication

Two differing perspectives on the regulation of replication have been put forward. These perspectives were presented at an internal workshop in November 2022 [Ref. 6] and can be summarised as follows:

Perspective one – ONR should expect NNB GenCo (SZC) to proactively and systematically seek out and evaluate all drivers for change that have arisen since HPC, in order to further reduce risk for SZC SFAIRP.

Perspective two – HPC has been demonstrated as being a low-risk plant and so ONR should expect NNB GenCo (SZC) to target those areas where there is a demonstrable, material and measurable positive net benefit to risk reduction.

These perspectives are explained further in the following sections.

Perspective One

- Much time has passed since the design and specification on which HPC is based were developed. Over that time a lot has changed in terms of knowledge and understanding of the design, capability, OPEX, codes, standards, etc.
- Site specific needs for SZC are already driving change from the HPC design. It is therefore accepted that SZC will not be a duplicate of HPC. The question is therefore how much it will change, and how that change will be controlled.
- Safety and replication are linked, but replication does not guarantee safety; it is a foundation for safety.
- The fact that HPC will have reduced risks SFAIRP does not necessarily mean that SZC will reduce risks SFAIRP if it replicates HPC. Legally, and technically, as time moves on from HPC, the concept of SFAIRP requires SZC to consider changes for risk reduction/safety improvement.
- SZC should focus on safety rather than focusing on replication. To reduce risks SFAIRP, SZC should proactively seek out, and then properly evaluate, all drivers for change from the HPC foundation.
- A strong intelligent customer (IC) function is required that is alert to all changes since the original design and build. The default for the IC function should be in favour of safety rather than in favour of avoiding deviation from replication.
- Generally, the time between the original, 'first-of-a-kind' (FOAK) facility and the replicated NOAK is important because of changes over that time, and thus the licensee should think more about how it replicates whilst keeping risks SFAIRP, particularly if significant time has passed.

Perspective one recommends that ONR's strategic approach to the replication should be to expect a licensee to adopt 'proactive intelligent replication', which recognises the legal standard that what is designed and build must reduce risks SFAIRP. Fundamentally, the SFAIRP duty requires the licensee to consider whether there have been improvements on the FOAK in the time since it was designed and specified.

The licensee must have a strong intelligent customer function that is alert to all changes since the original design and build, and evaluates those changes properly in favour of safety rather than in favour of avoiding any deviation from replication.

Perspective Two

- The UK EPR design has already successfully completed GDA, and has been subject to thorough regulatory scrutiny since GDA, resulting in further improvements. Through this ONR has judged that the operational risk of HPC has been demonstrated to be generally below the BSO, or in the tolerable region.
- SZC is based on an iteration of the HPC design from 2018, and SZC has made a commitment to take into account future changes to the HPC design.
- There is OPEX for SZC not only from HPC but also from FA3, OL3 and Taishan. Fully replicated systems will in effect have been through three phases of commissioning prior to implementation at SZC. There is therefore a safety benefit to be realised from through-life sharing of OPEX, knowledge and learning.
- There is no legal requirement for dutyholders to meet RGP.
- Generally, deviations from replication will be in areas where different site geology/ topology/ external hazards necessitate a change from the HPC design.
- Changes to design or construction methods could negate the benefits of OPEX from HPC and elsewhere. Potential deviations from replication should be challenged by SZC to ensure safety is the primary focus (i.e. as opposed to 'doing it quicker and cheaper').
- Any new developments since HPC will by definition be novel and untested in the industry, with little or no OPEX to underpin them. Given the risks for HPC are judged to be acceptably low, any improvements for SZC would therefore be unlikely to significantly reduce risk of the site overall.
- The guidance in TAG 5 expects ONR to *"look at the design holistically and be guided by overall safety rather than focussing on incremental changes ... the requirement is to reduce risks ALARP and this refers to the overall outcome rather than seeking to narrowly apply ALARP to each individual aspect"*.

Perspective two therefore recommends that ONR's strategic approach to the regulation of replication should be to expect the licensee to target those areas where there is a demonstrable, material and measurable positive net benefit to risk reduction.

Where risks have already been demonstrated to be at or below the BSO ONR would not devote regulatory resource to seeking further improvement, and inspectors should instead focus on considering the validity of the arguments presented. However, this does not remove the duty on the licensee to reduce risks SFAIRP.

Evaluation

Objectives of the Strategy

Any regulatory strategy should balance the need to ensure licensees satisfy their duties under the law and ONR’s regulatory expectations, with the need to meet our commitment to enabling regulation and our obligations under the Regulators’ Code. It is considered that the strategy for regulation of replication should have the following objectives:

- Ensures licensees meets their legal duty to reduce risks SFAIRP.
- Ensures an appropriately systematic approach to considering opportunities to further reduce risk.
- Provides an enabling approach with meets the principles of enforcement:
 - proportionate – action related to the level of risk;
 - targeted – focusing regulatory attention on areas of most serious risk;
 - consistent – similar approach to managing similar risks; and
 - transparent – being clear on what we expect the licensee to do and also what we do not expect them to do.
- Ensures an efficient and effective use of regulatory and licensee resource.

Evaluation

The below table presents the evaluation of the two perspectives against the above criteria.

Table 2 – evaluation of replication perspectives

Objective	Perspective one	Perspective two
Satisfies SFAIRP duty	<p>Expects the licensee to proactively evaluate <u>all</u> drivers for change to demonstrate SFAIRP.</p> <p>Recognises that replication may be the outcome in most cases but expects justification on case-by-case basis.</p>	<p>Recognises that HPC is judged to be acceptably low-risk.</p> <p>Expects the licensee to evaluate changes which could give rise to significant reduction in risk, and cases there the NOAK case is not bound by the FOAK.</p>

		Legal duty to reduce risks SFAIRP remains.
Systematic approach to identifying change	Expects intelligent customer function to be alert to <u>all</u> changes since the FOAK and thoroughly evaluate them.	Expects the licensee to systematically target drivers for change where there is a <u>significant, demonstrable and measurable</u> reduction on the holistic site risk.
Proportionate	Expects <u>all</u> drivers for change to be proactively identified and thoroughly evaluated, rather than adopting a risk-informed approach.	Expects due consideration to be given to potential drivers for change, with priority given to those that would result in significant risk reduction.
Targeted	Expects <u>all</u> drivers for change to be considered independently of the level of risk, rather than adopting a risk informed approach.	Places the focus on areas where the NOAK case is not bound by the FOAK, and on changes that will give rise to significant, demonstrable risk reduction.
Consistent	Judges that replication of the FOAK does not necessarily mean the NOAK will be ALARP. Risk that ONR is seen as applying different expectations in similar circumstances.	Recognises that the FOAK has been judged to be acceptably low-risk and places the focus on areas where there is a material change in the risk profile between the FOAK and NOAK.
Transparent	Expects <u>all</u> drivers for change to be proactively and thoroughly evaluated. Risk that ONR is seen as seeking 'gold-plated' solutions.	Expects a graded approach to the identification of drivers for change, with focus placed on areas where there is a material change in risk profile between the FOAK and the NOAK.
Effective and efficient use of resource	Increases the burden on the licensee and reduces the focus on areas of greatest risk. Risks expending resource on evaluating changes which have a negligible reduction in holistic risk. Significant regulatory resource required to ensure expectations are being met.	Expects resource to be focused on areas that give rise to significant improvements in risk, and where replication is not possible (i.e. due to site-specific aspects or material changes in risk profile between the FOAK and NOAK). Allows ONR to take a proportionate, risk-informed approach to regulation of the NOAK.

Recommendation

From the above evaluation it is judged that perspective two best satisfies the identified objectives and it is therefore recommended that this be taken forward as the strategy for regulation of replication at SZC.