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| **GDA Regulatory Observation** |
| **REGULATOR TO COMPLETE** |
| **RO unique no.:** | RO-RRSMR-005 |
| **Revision:** | 0 |
| **Date sent:** | 04/12/2024 |
| **Acknowledgement required by:** | 08/01/2025 |
| **Resolution Plan Agreement Required by:** | 05/02/2025 |
| **Record Reference:** | ONRW-2126615823-5198 |
| **Related RQ / RO No. and CM9 Ref:** | RO-RRSMR-001 (ONRW-2126615823-1136) |
| **Observation title:** | Internal hazards safety case scope and delivery  |
| **Lead technical topic:**Internal Hazards | **Related technical topic(s):**Civil Engineering Life fire safetyConventional health and safetyMechanical EngineeringElectrical EngineeringFault Studies |
| **REGULATORY OBSERVATION:** |
| **Background**The overall objective of the Generic Design Assessment (GDA) is stated within ONR’s guidance to requesting parties [Ref.1], which is to “*provide confidence that the proposed design is capable of being constructed, operated and decommissioned in accordance with the standards of safety, security and environmental protection required in GB*”. Rolls-Royce SMR Limited, the Requesting Party (RP), started Step 3 of their GDA in August 2024. ONR’s guidance [Ref. 1] states the intent of ONR’s step 3 assessment is to undertake a detailed assessment of the RP’s design and supporting generic safety and security case against regulatory expectations. To facilitate this the RP is expected to produce a comprehensive safety case, that is intelligible, with a clear trail from claims, through the arguments, to the underpinning evidence that substantiates that the design is safe. Rolls-Royce SMR Limited has indicated its intention to develop, within GDA timescales, a full-scope Internal Hazards (IH) safety case for the generic design, which will form part of the wider arguments to demonstrate risks are (or are capable of being) reduced to As Low As Reasonably Practicable (ALARP). ONR’s assessment during Step 3 will be risk-informed, targeted and proportionate, in line with our guidance [Ref. 2], and we will sample the overall case on this basis [Ref.3], within the defined GDA Scope [Ref. 4]. Prior to the commencement of Step 3, we agreed a submission plan with the RP [Ref.5] which should allow us to undertake our assessment of the IH aspects of the case during Step 3 [Ref.6]. This was informed by our understanding of the design, the safety claims made by the RP and the RP’s plans for substantiation. This relies on the RP maturing the design and undertaking detailed IH analysis in a timely and integrated manner. The RP has continued to mature and develop its generic design, including aspects that will inform the IH safety case, such as modularisation and layout, and this will continue. Engagements have been held with the RP [Ref.7, Ref.8] to understand and gain confidence that the RP has adequate plans and controls in place to enable production of the full-scope comprehensive safety case, alongside the evolving design and refining of the claims and supporting analysis. These engagements have not provided us with sufficient confidence in this regard and we have identified potential gaps regarding:* The overall scope of the intended IH safety case that will be produced during GDA.
* The extent of safety case claims the RP intends to make on various safety measures across the design to eliminate and/or mitigate hazards.
* The extent of hazard analysis to be undertaken.
* The integration of the maturing design and layout to support the identification of hazards and associated analysis.
* The provision of the safety measures and how the associated safety claims will be substantiated.
* Clarity of the times scales to achieve the intended GDA design maturity such as plant layout upon which the hazards analysis will be based.

These gaps, at this stage of GDA undermine our confidence that the RP can demonstrate that the relevant claims within the IH safety case will be identified and adequately substantiated during GDA. ONR are therefore seeking further details on the scope and control of the generic IH safety case. This is to gain confidence that the safety case will have sufficient depth and breadth to demonstrate that all internal hazards are identified, screened and analysed. The safety case should also detail the provision of adequate safety measures which provide defence in depth demonstrating the risks from internal hazards are as reduced to ALARP. **Relevant Legislation, Standards and Guidance**The guidance provided in this RO is based on ONR's Safety Assessment Principles (SAPs) [Ref.9], Technical Assessment Guides (TAG) NS-TAST-GD-051 Issue 7.1 [Ref.10] and NS-TAST-GD-014 Issue 7.1 [Ref.11], which highlight the need to identify and analyse internal hazards, put in place adequate safety measures and provide an internal hazards safety case, that demonstrates that the risks are shown to have been reduced as low as reasonably practicable (ALARP). Furthermore ONR guidance (SAP FP.4, ONR-TAST-GD-051) states that a safety case is required to provide sufficient articulation of the safety case claims, arguments and evidence to demonstrate that hazards that pose a nuclear safety risk have been eliminated, minimised and mitigated, through the application of a robust assessment process and implementation of adequate safety measures. In addition, further good practice methodologies for structuring a safety demonstration can be found in Chapter 1 of the TF SCS common position document [Ref.12].These regulatory expectations are captured within the following relevant SAPs; SC.2, SC.3, SC.4, EKP.1, EKP.3, ELO.4, EHA series, ECS.2, EDR.2, EDR.4, ESS.1, ESS.2, FA.1, FA.2 and FA.8. **Regulatory Expectations**In line with the expectations detailed above, ONR expects the RP to provide confidence that its internal hazards scope is sufficient to deliver the required evidence for the various safety case claims required to demonstrate the risks from internal hazards are ALARP. **References**[1] ONR, Guidance to Requesting Parties on the Generic Design Assessment (GDA) process for safety and security assessments of new Nuclear Power Plants (NPP), Issue 1, August 2024, ONR-GDA-GD-006. [www.onr.org.uk/media/iexmextu/onr-gda-gd-006.docx](http://www.onr.org.uk/media/iexmextu/onr-gda-gd-006.docx) [2] ONR, Risk-informed and targeted engagements (RITE), Issue 2, May 2024, ONR-RD-POL-002. [www.onr.org.uk/media/z5mnnigr/onr-rd-pol-002-risk-informed-and-targeted-engagements-rite-policy.docx](http://www.onr.org.uk/media/z5mnnigr/onr-rd-pol-002-risk-informed-and-targeted-engagements-rite-policy.docx) [3] ONR, Guidance on Mechanics of Assessment, Issue 1.2, December 2022, NS-TAST-GD-096. [www.onr.org.uk/media/kb5h2fex/ns-tast-gd-096.docx](http://www.onr.org.uk/media/kb5h2fex/ns-tast-gd-096.docx) [4] Rolls-Royce SMR Limited, GDA Scope Document, Issue 2, January 2023, SMR0002183. (ONRW-2019369590-7694)[5] Rolls-Royce SMR Limited, Generic E3S Case Scope and Deliverable Document – Internal Hazard, Issue 1, April 2024, SMR0011049. (ONRW-2019369590-8703)[6] ONR, Generic Design Assessment of the Rolls-Royce SMR – Step 3 Internal Hazards assessment plan, Issue 1, July 2024. (ONRW-2126615823-3009)[7] ONR, L4 Layout and Modularisation Meeting, 15th October 2024, ONR-NR-CR-24-543. (ONRW-201936959-15250)[8] ONR, Internal hazards L4 Meeting 11, 28th October 2024, ONR-NR-CR-24-521. (ONRW-2019369590-14860)[9] ONR, Safety Assessment Principles for Nuclear Facilities, 2014 Edition, Revision 1, January 2020. [www.onr.org.uk/media/pobf24xm/saps2014.pdf](http://www.onr.org.uk/media/pobf24xm/saps2014.pdf) [10] ONR, The Purpose, Scope, And Content of Safety Cases, Issue 7.1, December 2022, NS-TAST-GD-051. [www.onr.org.uk/media/kc0fgwwk/ns-tast-gd-051.docx](http://www.onr.org.uk/media/kc0fgwwk/ns-tast-gd-051.docx) [11] ONR, Internal Hazards, Issue 7.1, December 2022, NS-TAST-GD-014. [www.onr.org.uk/media/lrnfqbg1/ns-tast-gd-014.docx](http://www.onr.org.uk/media/lrnfqbg1/ns-tast-gd-014.docx) [12] Licensing of safety critical software for nuclear reactors – common position of international nuclear regulators and authorised technical support organisations, Rev 2024, [www.onr.org.uk/media/i2anr3nd/24-09-common-position-2024-revision-1.pdf](http://www.onr.org.uk/media/i2anr3nd/24-09-common-position-2024-revision-1.pdf)  |
| **REGULATORY OBSERVATION ACTIONS** |
| **RO-RRSMR-005.A1:** **Information required to provide confidence that the delivery of the** **Internal Hazards safety case is achievable within GDA timescales and demonstrate the safety case outcomes will be meaningful.**In response to this Regulatory Observation Action, Rolls-Royce SMR Limited should:* Provide the necessary detailed information for the Internal Hazards aspects of the safety case that will be produced during GDA. The overall objective of which is to provide confidence that the stated intent of a full-scope IH safety case will be produced. This should include the following:
	+ A detailed scope for the IH safety case that the RP expects to produce during GDA, including a clear statement of any exclusions, including aspects that would be completed post-GDA.
	+ Clarity of safety case structure and content, including the claims, arguments and evidence that the RP intends will form the framework of the safety demonstration. This should cover the full breadth and depth of the case that will be produced during GDA, including all claims on the identified safety measures to mitigate or minimise the impact of internal hazards, relevant activities (such as hazard analysis, optioneering and test results) and the justification of ALARP.
	+ Definition of the tasks required to be completed during GDA to deliver this scope and provide inputs to the IH case and substantiation evidence (including the tasks already completed or ongoing).
	+ A detailed work programme including all planned outputs to deliver the tasks detailed above. This should explain how the maturing design (including the plant layout) will be managed as part of the inputs, and how any differences in design baseline will be managed.
	+ Information on the scope and content of documents that have been agreed to be submitted to ONR during Step 3 (of relevance to IH). This should include any known omissions or further work that will be expected on those documents, such that it is clear what the intended end-point will be during GDA. This includes factors such as the design basis, assumptions and maturity of information that underpins those submissions.

Resolution required by *‘to be determined by the Rolls-Royce SMR Limited Resolution Plan’* |

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| **REQUESTING PARTY TO COMPLETE** |
| **Actual Acknowledgement date** (dd/mm/yy)**:** |  |
| **RP stated Resolution Plan agreement date** (dd/mm/yy)**:** |  |