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| **GDA Regulatory Observation** |
| **REGULATOR TO COMPLETE** |
| **RO unique no.:** | RO-RRSMR-001 |
| **Revision:** | 0 |
| **Date sent:** | 15/08/2023 |
| **Acknowledgement required by:** | 06/09/2023  |
| **Resolution Plan Agreement Required by:** | 04/10/2023  |
| **Record Reference:** | ONRW-2126615823-1136 |
| **Related RQ / RO No. and WiRED Ref:** (if any)**:** | N/A |
| **Observation title:** | Development of the generic E3S case |
| **Lead technical topic:**Project | **Related technical topic(s):**ChemistryCivil EngineeringControl & InstrumentationConventional Fire SafetyConventional Health and SafetyElectrical EngineeringEnvironment External HazardsFault StudiesFuel and CoreHuman FactorsInternal HazardsManagement for Safety and Quality AssuranceMechanical EngineeringNuclear Liabilities RegulationProbabilistic Safety AnalysisRadiological ConsequencesRadiological ProtectionSafeguardsSecuritySevere Accident AnalysisStructural Integrity  |
| **REGULATORY OBSERVATION:** |
| **Background**During Step 1 of the Generic Design Assessment (GDA) for the Rolls-Royce SMR design the Requesting Party (Rolls-Royce SMR Ltd) submitted information on its strategy and intentions regarding the development of their Environment, Safety, Security and Safeguards (E3S) case [1]. Concurrent with the development of the E3S case the RP continues to further develop its design. The RP is aiming to produce an integrated design and E3S case, which it is claimed will offer benefits in terms of clarity, integration and understanding impacts from any changes.Several notable aspects of the RP’s approach to development of their E3S case are:* The RP has chosen to develop its cases in a holistic manner across the E3S purposes, to demonstrate that the design will ‘protect people and the environment from harm’;
* Use of a document hierarchy, with the highest Tier 1 level comprising the E3S summary chapters supported by lower-level, more detailed, Tier 2 and 3 documents which contain arguments and evidence;
* The use of a rigorous Claim, Arguments and Evidence (CAE) structure to define the “golden thread” for the case;
* A combined systems engineering and analysis approach;
* Alignment to international guidance for safety cases, supplemented to include UK specific expectations and expanded to include the other E3S purposes;
* Derivation and management of functional and non-functional requirements; and
* Adoption of a range of digital tools to aid the production and control of the design and case.

At the end of Step 1 we reported that we were satisfied that the proposed E3S approach was logical, suitably structured and would give the RP means to direct the development of its design. We recognised the early production of clear strategies and the holistic approach to be good practices adopted by the RP.The first version of the Tier 1 E3S chapters [2] were submitted to the Regulators at the start of Step 2, and lower-level Tier 2 and 3 submissions continue to be provided in accordance with the agreed submission schedule for the Step. Through our assessment of these submissions, and interactions with the RP to date, we have identified that further work is needed by the RP for it to achieve its objectives for the E3S case during GDA. We are therefore seeking additional confidence that the RP has fully developed and is implementing suitable and sufficient procedures and controls to develop a Rolls-Royce SMR E3S case which will meet UK and international regulatory expectations and will be an enabler for future regulatory activities. Our view is that a fundamental part of this is to have a clear understanding of the strategy, objectives, scope and plan for development of the case and to embed this fully within the RP’s organisation and arrangements. **Relevant Legislation, Standards and Guidance**A documented safety case is a requirement of the Licence Conditions (LC) associated with holding a nuclear site licence, particularly LCs 23 [3] and 14 [4]. Safety documentation is also required under other legislation, such as relevant statutory provisions of the Health and Safety at Work etc Act 1974 (e.g. the Management of Health and Safety at Work Regulations 1999 and the Ionising Radiations Regulations 2017). Safety cases are also considered in IAEA [5] [6] and WENRA [7] standards and guidance. ONR’s Safety Assessment Principles (SAPs) [8] contain specific principles relating to safety cases (SC.1 to 8) which are further expanded in the associated Technical Assessment Guide (TAG) NS-TAST-GD-051 [9].ONR approves the security plans produced by dutyholders under the Nuclear Industries Security Regulations (NISR) 2003 [10], to demonstrate that their security arrangements meet relevant legal obligations. IAEA guidance is available in the Nuclear Security Fundamentals [11]. ONR guidance is detailed in the Security Assessment Principles (SyAPs) [12] and associated TAGs [13].The Nuclear Safeguards (EU Exit) Regulations 2019 (NSR19) [14] require the submission to ONR of nuclear material accountancy and control plans (ACPs) and basic technical characteristics (BTC) submissions to demonstrate their compliance with legal requirements for safeguarding. ONR guidance is available in the TAGs [13].An environment case is used to demonstrate that the Environment Agency radioactive substances regulation (RSR): objective and principles [15] have been taken into account.During GDA, the RP is expected to produced generic versions of these cases, which will be used by a future licensee to inform their site-specific cases. This is detailed in the Regulators “Guidance to Requesting Parties” [16] [17].**Regulatory Expectations**There are numerous legal requirements which mean that an operator of a nuclear power plant must justify that their facility is safe, secure and minimises environmental impacts. For GDA, the Regulators “Guidance to Requesting Parties” requires the production and submission of relevant aspects of the environment, safety, security and safeguards cases for the generic design undertaking the GDA, as this forms the basis for the Regulators assessments. It is important that these cases should be complete, coherent, cogent and consistent – recognising that they will be refined and developed throughout the GDA. Production of such cases can be complex and time consuming. It therefore requires forethought to be given right throughout the production and development to ensure that the right people are involved at the right time, with a clear vision for what they are trying to achieve and demonstrate, and for how this will be documented and presented. The organisational arrangements that provide control and oversight also needs to be suitably rigorous and embedded within the RP. For Rolls-Royce SMR Ltd, who are also developing the design in parallel with their E3S case, there is the need to ensure that design and E3S activities are properly coordinated including across the various E3S purposes.Our main concerns over the development of the E3S case for the generic Rolls-Royce SMR design can be summarised as:* The status of the planning and arrangements to develop the E3S case are not fully mature and do not yet align with regulatory expectations for successful progression and completion of GDA;
* The overall objectives, strategy and scope of the E3S case has not been fully documented, and therefore it is not possible to demonstrate their completeness and adequacy;
* It is not clear whether the current gaps in the E3S case, including in the underlying CAE structure, have been identified and therefore what further work needs to be undertaken to resolve them;
* It is unclear how the E3S case will be managed to ensure it remains integrated with the development of the design and other key milestones; and
* The organisational arrangements to control the development have not yet been fully embedded in the RP and do not provide sufficient organisational control over the production and development of the E3S case.

In essence, we expect a more rigorous and considered level of planning and control over development of the E3S case moving forward, to enable a more proactive rather than reactive approach. There are two main areas where we expect further work to be undertaken to strengthen the RP’s activities:* Documenting the development of the E3S case in a clear and unambiguous manner. In particular, a strategy that includes the understanding of what still needs to be completed.
* Embedding the oversight, governance and control arrangements for the E3S case including how this interacts with the evolving design.

In response to this RO, Rolls-Royce SMR Ltd is requested to provide responses to several interrelated Actions related to development of their E3S case. The response to these Actions may be combined if considered appropriate by the RP.**References**[1] Generic Design Assessment of the Rolls-Royce SMR – Step 1 summary, ONRW-2019369590-1908, Report Issue No. 0, April 2023. [www.onr.org.uk/new-reactors/rolls-royce/reports/rolls-royce-smr-step-1-summary.docx](https://www.onr.org.uk/new-reactors/rolls-royce/reports/rolls-royce-smr-step-1-summary.docx) [2] Rolls-Royce SMR Tier 1 E3S chapters, Issue 1, April 2023. Available via <https://gda.rolls-royce-smr.com/documents> [3] ONR Technical Inspection Guide, LC 23 – Operating Rules, NS-INSP-GD-023, Issue No 6.2, April 2023. [www.onr.org.uk/operational/tech\_insp\_guides/ns-insp-gd-023.docx](https://www.onr.org.uk/operational/tech_insp_guides/ns-insp-gd-023.docx) [4] ONR Technical Inspection Guide, LC 14 – Safety Documentation, NS-INSP-GD-014, Revision 5, July 2019. [www.onr.org.uk/operational/tech\_insp\_guides/ns-insp-gd-014.pdf](https://www.onr.org.uk/operational/tech_insp_guides/ns-insp-gd-014.pdf) [5] IAEA Safety Standards, Safety Assessment for Facilities and Activities, General Safety Requirements No. GSR Part 4 (Rev. 1). [www.iaea.org](http://www.iaea.org)[6] IAEA Safety Standards, Format and Content of the Safety Analysis Report for Nuclear Power Plants, Specific Safety Guide No. SSG-61. www.iaea.org[7] WENRA Safety Reference Levels for Existing Reactors 2020, February 2021. [www.wenra.eu](http://www.wenra.eu) [8] Safety Assessment Principles for Nuclear Facilities, 2014 Edition, Revision 1, ONR, January 2020. [www.onr.org.uk/saps/saps2014.pdf](https://www.onr.org.uk/saps/saps2014.pdf) [9] ONR Technical Assessment Guide, The purpose, scope and content of nuclear safety cases, NS-TAST-GD-051, Issue 7.1, December 2022. [www.onr.org.uk/operational/tech\_asst\_guides/ns-tast-gd-051.docx](https://www.onr.org.uk/operational/tech_asst_guides/ns-tast-gd-051.docx) [10] The Nuclear Industries Security Regulations - Statutory Instrument 2003 No. 403. [www.legislation.gov.uk/uksi/2003/403/pdfs/uksi\_20030403\_en.pdf](http://www.legislation.gov.uk/uksi/2003/403/pdfs/uksi_20030403_en.pdf) [11] IAEA Nuclear Security Fundamentals series. [www.iaea.org](http://www.iaea.org)[12] Security Assessment Principles for the Civil Nuclear Industry, 2022 Edition, Version 1, ONR, March 2022. [www.onr.org.uk/syaps/security-assessment-principles.pdf](https://www.onr.org.uk/syaps/security-assessment-principles.pdf) [13] ONR Technical Assessment Guides. [www.onr.org.uk/operational/tech\_asst\_guides/index.htm](https://www.onr.org.uk/operational/tech_asst_guides/index.htm) [14] The Nuclear Safeguards (EU Exit) Regulations 2019 - Statutory Instrument 2019 No. 196. [www.legislation.gov.uk/uksi/2019/196/made](https://www.legislation.gov.uk/uksi/2019/196/made) [15] Radioactive substances regulation (RSR): objective and principles, December 2021. [www.gov.uk/government/publications/radioactive-substances-regulation-rsr-objective-and-principles/radioactive-substances-regulation-rsr-objective-and-principles](https://www.gov.uk/government/publications/radioactive-substances-regulation-rsr-objective-and-principles/radioactive-substances-regulation-rsr-objective-and-principles) [16] New Nuclear Power Plants: Generic Design Assessment Guidance to Requesting Parties, ONR-GDA-GD-006, Revision 0, October 2019. [www.onr.org.uk/new-reactors/onr-gda-gd-006.pdf](https://www.onr.org.uk/new-reactors/onr-gda-gd-006.pdf) [17] New nuclear power plants: Generic Design Assessment guidance for Requesting Parties. [www.gov.uk/government/publications/new-nuclear-power-plants-generic-design-assessment-guidance-for-requesting-parties](https://www.gov.uk/government/publications/new-nuclear-power-plants-generic-design-assessment-guidance-for-requesting-parties)  |
| **REGULATORY OBSERVATION ACTIONS** |
| **RO-RRSMR-001.A1 – E3S case strategy and forward plans**In response to this Regulatory Observation Action, Rolls-Royce SMR Ltd should:Document the on-going development of the E3S case in a defined development strategy that has a clear and unambiguous definition of the scope, content and development of the E3S case aligned to the various project milestones (design and GDA related) as it matures throughout GDA, with defined forward plans for aspects which require further development. **Regulatory Expectations**In responding to this Action, we are seeking a demonstration of the adequacy of the strategy and forward plans that are needed to develop the E3S case throughout GDA, as enablers to development of the final consolidated E3S case produced at the end of Step 3. This should provide an adequate description of what the case is expected to contain and the approach that is being taken to manage and produce this, including links to other related processes. The information provided should clearly demonstrate that a suitable and sufficient E3S case will be produced and continually developed throughout GDA, which is likely to meet UK regulatory expectations and facilitates the production of a subsequent site-specific E3S case by the future licensee post GDA.We expect that the response to this Action should include information on, amongst other matters considered relevant by the RP:* The documented E3S strategy, including how this is supported by associated processes and approach. Collectively this should provide information on the objectives, scope and purpose for the overall E3S case and how this will be cascaded into individual documents at all levels of the E3S hierarchy;
* The integration of the overall strategy with any secondary strategies, such as those which may be produced at a topic, system or process level;
* Clear identification and definition of technical, design and E3S interfaces, and a description of how they are being effectively managed;
* The definition of the architecture of safety case documentation, demonstrating how the different levels and types of documentation, and the arguments and evidence contained therein, will be produced and linked together to cover the full scope, interactions and content of the E3S case;
* How the E3S case is used to inform and influence the design, and vice versa;
* The means to ensure that the E3S case remains consistent with, and comprehensively addresses the agreed GDA Scope;
* How the E3S case maintains alignment with the developing design, including the arrangements for definition and control of the Design Reference;
* The definition of what work still remains to be done, either in design or E3S case justifications, and the documentation of this into clear forward action plans;
* How the development of the E3S case is linked to other key Rolls-Royce SMR engineering processes, such as requirements management and the gated definition reviews;
* The integration of digital tools, used to aid the production of the case and design, into the strategy and development;
* How learning from previous safety case experience, and relevant national and international guidance, has been incorporated into the above strategy; and
* How progress will be measured, reviewed and controlled and how the success (in terms of adequacy, quality, suitability etc.) of the outputs will be measured.

Resolution required by '*to be determined by Rolls-Royce SMR Limited Resolution Plan*' |
| **RO-RRSMR-001.A2 – E3S processes, governance and oversight**In response to this Regulatory Observation Action, Rolls-Royce SMR Ltd should:Demonstrate the adequacy of their organisational arrangements to support the development of the E3S case for GDA. This should include roles and responsibilities, relevent processes, governance and oversight of the case.**Regulatory Expectations**In response to this Action, we are seeking clarity over the ownership and direction for the E3S case (the “controlling mind”), how this interacts with the ongoing design work and confidence that the development approach is suitably embedded throughout Rolls-Royce SMR Ltd.We expect that the response to this Action should include information on, amongst other matters considered relevant by the RP:* The organisational arrangements, roles and associated responsibilities and authorities related with the development of the E3S case;
* The arrangements for ensuring management oversight of the development of the E3S case by individuals with authority and influence to ensure the effective implementation of the strategy;
* The arrangements to ensure that suitably qualified and experienced environment, safety, security and safeguard case professionals are used to provide advice on and support development of the E3S case at all levels within the RP;
* Those arrangements which provide governance of the E3S case outputs, including how they are planned and undertaken to ensure they deliver appropriate E3S outcomes;
* How E3S processes are linked to associated engineering activities, including the defined gated review process;
* Any training undertaken / planned to authors or other individuals who have a role in producing the E3S case;
* Any independent or peer review activities and processes that may be employed; and
* How any third-party inputs for the E3S case will be specified, controlled, managed and integrated.

Resolution required by '*to be determined by 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)**:** |  |