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| **GDA Regulatory Observation** | |
| **REGULATOR TO COMPLETE** | |
| **RO unique no.:** | RO-RRSMR-002 |
| **Revision:** | 0 |
| **Date sent:** | 24/08/23 |
| **Acknowledgement required by:** | 15/09/2023 |
| **Resolution Plan Agreement Required by:** | 13/10/2023 |
| **Record Reference:** | ONRW-2126615823-1172 |
| **Related RQ / RO No. and CM9 Ref:** (if any)**:** | N/A |
| **Observation title:** | PSA Project Plan and Integration |
| **Lead technical topic:**  Probabilistic Safety Analysis | **Related technical topic(s):**  External Hazards  Fault Studies  Internal Hazards  Radiological Consequences  Severe Accident Analysis |
| **REGULATORY OBSERVATION:** | |
| **Background**  The Generic Design Assessment (GDA) of the Rolls-Royce Small Modular Reactor (SMR) started in April 2022. The Rolls-Royce SMR design is currently mid-way through Step 2 of the GDA.  Rolls-Royce SMR Ltd. has indicated their intention to develop, within GDA timescales, a full-scope modern-standards Probabilistic Safety Analysis (PSA) to demonstrate risks are As Low As Reasonably Practicable (ALARP) and to support risk informed design development of the Rolls-Royce SMR.  Prior to GDA starting, Rolls-Royce SMR Ltd. used PSA to inform early design decisions such as the optimal number of steam generators. This represented good practice. The PSA was updated in line with the design until around 2018. Since this time the development of the PSA has been more limited, such that by the start of GDA there was a gap between the PSA model and the latest design reference. The extent of the PSA is also limited in that it only covers reactor internal events at power for intact circuit faults and loss of coolant faults. It does not cover other fault types, shutdown states, fuel handling, fuel storage, hazards, level 2 PSA or level 3 PSA.  Early in GDA Rolls-Royce SMR Ltd. submitted a scope and submission plan [1] which laid out the expected deliverables for Step 2 and Step 3 of GDA. According to this plan the internal events at power PSA would be rebuilt and updated in line with the design during Step 2. The PSA model is to be symmetric which is a positive development. The plan also established the intent that, during Step 3, Rolls-Royce SMR Ltd. would submit internal events shutdown state PSA, internal and external hazards PSA for all plant states, plus fuel route and fuel handing PSA. Level 2 and level 3 PSA would also be submitted in Step 3 to establish the off-site consequences for all the aspects listed above.  The PSA Development Strategy [2] has been submitted by Rolls-Royce SMR Ltd. and assessed by ONR. The purpose of the document is to outline the development of the PSA throughout the rest of GDA.  Assessment of this document, and discussions with Rolls-Royce SMR Ltd., have revealed gaps in the following areas:   * The integration of PSA into the wider safety case is not clear * There is no discussion on how the hazards PSA will be developed * The strategy does not describe how the radiological risks to on-site workers will be evaluated * The significant sources of radioactivity that the PSA will model are not described * No details are provided on how the PSA for fuel handling will be developed * The interface with Rolls-Royce SMR’s Severe Accidents Analysis team is not clear, and the plans for development of the level 2 and 3 PSA are not detailed * The computer codes to be used for transient analysis, severe accident analysis and level 3 PSA are not identified * Deliverables in Step 3 were not addressed consistently within different sections * Description of resourcing of the PSA team is limited, and there is no indication of how the scope of step 3 will be delivered   A modern standards PSA of sufficient scope to inform the design and demonstrate risks have been reduced ALARP is anticipated to be a key component of the final safety case submission provided by Rolls-Royce SMR Ltd. to achieve the standards required for a Design Acceptance Confirmation. However, the extant PSA development strategy does not provide sufficient details on what will be delivered in Step 3 of GDA to achieve this goal.  **Relevant Legislation, Standards and Guidance**  The guidance provided in this RO is based on the following international and national guidance:   * IAEA General Safety Requirements Part 4 [3], * IAEA Specific Safety Requirements Part 2-1 [4], * WENRA Safety Reference Levels for Existing Reactors – Part O [5] * IAEA Specific Safety Guide 3 on Level 1 PSA [6], * IAEA’s TECDOC 1854 on attributes of PSA [7], * ONR’s Safety Assessment Principles [8] * ONR’s Technical Assessment Guide on Probabilistic Safety Analysis [9].   **Regulatory Expectations**  **Project Planning**  International expectations [3] [6] [7] and ONR guidance [9] states that a good quality PSA project plan is key to timely delivery of a high-quality full scope PSA. For the Rolls-Royce SMR a high-quality full scope PSA is essential for the completion of GDA. The objective of this Regulatory Observation is to state ONR’s expectations related to the development of the PSA for the Rolls-Royce SMR as part of the GDA submission.  Rolls-Royce SMR Ltd. should develop and deliver the Rolls-Royce SMR PSA in accordance with a detailed programme, which should be reflected in the Project Plan requested in Action A1 of this RO, outlining specific PSA tasks required to be completed. The plan should include timings for the deliverables and the resources required to deliver them. The PSA documentation should be delivered to ONR in a phased and logical manner in order to facilitate assessment. As many of the future applications as possible should be identified, as these will affect the approach to be used in the individual tasks.  The PSA modelling and deliverables should be developed in accordance with Quality Assurance (QA) plans and procedures to ensure that the PSA model and documentation is robust and of high quality.  Actions A1 and A2 below address these aspects.  **PSA Integration with the wider project**  In accordance with Safety Assessment Principle (SAP) FA.10 [8], “Suitable and sufficient PSA should be performed as part of the fault analysis and design development and analysis”. In particular, the PSA TAG [9] states that a “PSA should be suitable and sufficient to inform that the risks associated with the design and operation of the facility, as well as changes in risk associated with any modification to plant or operation, are and will remain ALARP”.  In order for the PSA to be developed to this standard, a set of inputs and outputs from the PSA are required. The inputs are design information and transient analysis from other disciplines within the project. The outputs are PSA results that can identify the radiological risks associated with the design. Once PSA results are available they can be fed back into the design process to establish if these risks are ALARP, if further analysis is required or if further safety improvements can be made to the design.  Up to this point in Step 2 of the Rolls-Royce SMR GDA it is not clear that the PSA is sufficiently integrated into the safety case to ensure that the PSA team are receiving the inputs they require, nor that other aspects of the safety case are making use of the results that a PSA can provide.  Action A3 below addresses this aspect.  In accordance with SAP FA.14 [8], PSA should be used to inform the design process and help ensure the safe operation of the site and its facilities. Up to this point in the GDA it is not clear to ONR how the PSA is being used to risk inform the design. Whilst there is attendance from the RR SMR PSA team and their sub-contractors at design review meetings for systems reaching Design Reference (DR) 1 and DR3, the lack of an up to date PSA model means that the PSA team can only provide limited inputs to the process. There is a risk that Rolls-Royce SMR Ltd. continue to develop their design without adequate PSA input. This could lead to an unbalanced design and design changes later in the process. Rolls-Royce SMR Ltd. should establish how the PSA will be used to inform the design process as the design develops.  Action A4 below addresses this aspect.  **References**  [1] GDA Scope and Submission Plan for Probabilistic Safety Assessment, Rolls-Royce SMR Ltd., Revision 1.0, December 2022, 2023/7986.  [2] PSA Development Strategy, Rolls-Royce SMR Ltd., Revision 1, March 2023, 2023/20545.  [3] 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)  [4] IAEA Safety Standards, Specific Safety Requirements No. SSR-2/1 (Rev. 1) Part 2-1, [www.iaea.org](http://www.iaea.org)  [5] WENRA Safety Reference Levels for Existing Reactors 2020, February 2021. [www.wenra.eu](http://www.wenra.eu)  [6] IAEA Safety Standards, Specific Safety Guide 3 – Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants, 2010. [www.iaea.org](http://www.iaea.org)  [7] IAEA-TECDOC-1804, Attributes of Full Scope Level 1 Probabilistic Safety Assessment (PSA) For Applications In Nuclear Power Plants, October 2016. [www.iaea.org](http://www.iaea.org)  [8] Safety Assessment Principles for Nuclear Facilities, Revision 1, January 2020, www.onr.gov.uk/SAPS/index.htm  [9] Technical Assessment Guides. Probabilistic Safety Analysis NS-TAST-GD-030 Revision 7, ONR, June 2019. [www.onr.org.uk/operational/tech\_asst\_guides/index.htm](http://www.onr.org.uk/operational/tech_asst_guides/index.htm) | |
| **REGULATORY OBSERVATION ACTIONS** | |
| **RO-RRSMR-002.A1 – PSA Project Plan**  In response to this Regulatory Observation Action, Rolls-Royce SMR Ltd should:   * Provide a Rolls-Royce SMR PSA project plan to cover GDA. This should include the following:   + A detailed scope for the PSA for the totality of the three step GDA it has asked the regulators to undertake, including a clear statement of any exclusions, including aspects that would be developed post-GDA.   + A complete list of the PSA objectives, applications and definition of the requirements of the PSA to fulfil these.   + The identification and justification of the computer code(s) that will be used for the Level 1, Level 2 and Level 3 PSA Rolls-Royce SMR PSA (including supporting calculations).   + Clarity on the expected scope of the hazards PSA, including how PSA hazards screening will inform the rest of the hazards scope of work.   + Clarity on how the radiological risks to on-site workers will be evaluated.   + Clarity on which radioactive materials (e.g. nuclear fuel, nuclear waste etc.) and locations (reactor, fuel handling, fuel storage etc.) will be considered in the PSA.   + Definition of the PSA tasks required to be completed during GDA (including the tasks already completed or ongoing).   + Identification of the various procedures, PSA models and reports which will be produced or updated during the development of the Rolls-Royce SMR PSA, for all the PSA tasks and PSA applications.   + A detailed work programme including all planned deliverables. This should identify which design reference points (DRP) will be modelled and how any gap between the final GDA DRP and the final GDA PSA will be managed. The human resources required to deliver this programme should also be identified.   Resolution required by: To be determined by the Rolls-Royce SMR Ltd. Resolution Plan. | |
| **RO-RRSMR-002.A2: PSA Quality Assurance Plan and quality assurance procedures**  In response to this Regulatory Observation Action, Rolls-Royce SMR Ltd should:   * Submit to ONR the relevant Rolls-Royce SMR PSA QA plans and procedures that detail the necessary level of QA for each PSA task, including those that require involvement of other departments.   Resolution required by: To be determined by the Rolls-Royce SMR Ltd Resolution Plan. | |
| **RO-RRSMR-002.A3: Integration of PSA into the wider safety case**  In response to this Regulatory Observation Action, Rolls-Royce SMR Ltd should:   * Demonstrate how the PSA is integrated into the wider safety case, including the analysis and engineering disciplines. This should highlight both inputs to the PSA (e.g. claims related to transient analysis, performance analysis, human reliability analysis) and where evidence from the PSA will be used to support the safety case (e.g. Optioneering reviews, demonstration of a balanced design etc.) in line with the expectations of Technical Assessment Guide 30 on PSA [9]. * Set out how the PSA will used to inform, complement, support and strengthen the demonstrations across the safety case that radiological risks have been reduced ALARP in the design.   Resolution required by: To be determined by the Rolls-Royce SMR Ltd. Resolution Plan. | |
| **RO-RRSMR-002.A4: Integration of PSA into the design**  In response to this Regulatory Observation Action, Rolls-Royce SMR Ltd should:   * Demonstrate how the PSA is integrated into the development of the generic design. The criteria for when PSA should be used, and when it is justified for it not to be used, should be clearly laid out.   Resolution required by: To be determined by the Rolls-Royce SMR Ltd. 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)**:** |  |