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| ONR Assessment Report  Generic Design Assessment of the Rolls Royce SMR – Step 2 project assessment |



ONR Assessment Report

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**Report Title**: Step 2 project assessment

**Authored by**: [Redacted]

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# Executive Summary

This report presents the outcomes of my project assessment of the Rolls-Royce Small Modular Reactor (SMR) as part of Step 2 of the Office for Nuclear Regulation (ONR) Generic Design Assessment (GDA). This assessment is based upon the information presented in version 2 of Rolls-Royce SMR Limited’s Environmental, Safety, Security and Safeguards (E3S) case chapters and supporting documentation. Rolls-Royce SMR Limited are the Requesting Party (RP) for this GDA.

ONR’s GDA process calls for a step-wise assessment, which increase in detail as the project progresses. The focus of my assessment in this step was towards the fundamental adequacy of the Rolls-Royce SMR design and safety case, and the suitability of the methodologies, approaches, codes, standards and philosophies which form the building blocks for the design and ES3 case.

The project assessment differs to other topic assessments conducted during Step 2 of the GDA. It is focused on aspects that are required to deliver the overall GDA assessment, but which cannot be assessed by individual or small groups of topics in isolation. It therefore includes aspects which underpin all or most of the topic assessments, and requires a high level of coordination at a project level. I targeted my assessment, in accordance with my assessment plan, at the content of most relevance against the expectations of ONR’s Safety Assessment Principles (SAPs), Technical Assessment Guides (TAGs) and other guidance which ONR regards as relevant good practice. I assessed the following aspects of the Rolls-Royce SMR E3S case:

* The overall approach and strategy for development of the generic E3S case, including integration of the purposes and alignment with the design as it matures
* Definition and control of the generic design, the change management process and implications for the E3S case
* The approach and impacts of modularisation within the generic Rolls-Royce SMR design
* The approach to demonstrating safety risks are reduced to As Low As Reasonably Practicable (ALARP), including consistency of application across the E3S case and optimisation with the other purposes

Based upon my assessment, I have concluded the following:

* The RP’s approach to development of the E3S case is ambitious, and if achieved would represent several areas of good practice. The RP has made some good progress in documenting and developing arrangements for this, including the use of a number of digital tools, and rolling these out within the wider organisation. Despite this I judge that there remains work to do to fully document the enablers for the E3S case, to ensure consistency and clarity across all the purposes and topics. This is particularly true for the Claims, Arguments and Evidence (CAE) approach, use of requirements and the DOORS® software tool to inform the case, and the intent for how the “golden thread” will be documented. There does remain further work needed by the RP to fully resolve Regulatory Observation (RO) RO-RRSMR-001, but I am confident that the RP can achieve this in a timely manner during Step 3.
* I am satisfied that the RP has met requirement [2.16] from guidance to requesting parties regarding setting a Design Reference Point (DRP) and establishing change management arrangements during Step 2. These represent a sound basis for controlling the design as part of Step 3 of the GDA. I expect to maintain oversight of the implementation of these processes, as the design continues to mature and changes are proposed by the RP.
* I judge that the RP should be able to demonstrate that modularisation of the generic design will be compatible with maintaining adequate safety, security and safeguards. The RP has also highlighted a number of potential benefits in its approach from an E3S case perspective which, if they can be substantiated, would provide strong justifications for the adoption of modularisation. There remains a large amount of substantiation work to underpin the use of the Modular Kit of Parts (MKoP). This includes matters relating to structural performance, seismic withstand, hazard barrier justification, management of interfaces and connections, and Examination, Inspection, Maintenance and Testing (EIMT). Improvements will be necessary to the E3S case for modularisation, to justify the relevant impacts, and to focus on the E3S implications including the overall justification and ALARP demonstration.
* The key duty in Great Britain (GB) health and safety legislation is for dutyholders to demonstrate that risks have been reduced to ALARP. This is also part of the RP’s own objectives for what the E3S case will demonstrate for its design. My assessment has given me confidence in the RP’s approach to address this duty. I am satisfied that the RP intends to present evidence in the E3S case that will allow ONR to make a judgement on whether it has demonstrated that the design reduces risk to ALARP during GDA.

Overall, based on my assessment to date, and subject to the provision and assessment of suitable and sufficient supporting evidence, I have not identified any fundamental safety shortfalls that could prevent ONR permissioning the construction of a power station based on the generic Rolls-Royce SMR design.

# List of Abbreviations

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| ALARP | As low As Reasonably Practicable |
| ASCE | Assurance and Safety Case Environment |
| BAT | Best Available Technique |
| C&I | Control and Instrumentation |
| CAE | Claim, Argument and Evidence |
| CKoP | Civil Kit of Parts |
| COTS | Commercial Off The Shelf |
| DAC | Design Acceptance Confirmation |
| DOORS | Dynamic Object-Oriented Requirements System |
| DR | Design Reference |
| DRP | Design Reference Point |
| E3S | Environment, Safety, Security and Safeguards |
| EIMT | Examination, Inspection, Maintenance and Testing |
| GB | Great Britain |
| GDA | Generic Design Assessment |
| HVAC | Heating, Ventilation and Air Conditioning |
| IAEA | The International Atomic Energy Agency |
| IMS | Integrated Management System |
| MDSL | Master Document Submission List |
| MEP | Mechanical, Electrical and Plumbing |
| MKoP | Modular Kit of Parts |
| MRI | Master Records Index |
| NPP | Nuclear Power Plant |
| NRW | Natural Resources Wales |
| OEM | Original Equipment Manufacturer |
| ONR | Office for Nuclear Regulation |
| OPEX | Operational Experience |
| PWR | Pressurised Water Reactor |
| RCP | Reactor Coolant Pump |
| RD | Reference Design |
| RDS-PP | Reference Designation System for Power Plants |
| RGP | Relevant Good Practice |
| RO | Regulatory Observation |
| RP | Requesting Party |
| RPV | Reactor Pressure Vessel |
| RQ | Regulatory Query |
| SAP | Safety Assessment Principle |
| SbD | Secure by Design |
| SG | Steam Generator |
| SMR | Small Modular Reactor |
| SSC | Structure, System and Component |
| TAG | Technical Assessment Guide |
| TSC | Technical Support Contractor |
| TSR | Technical Safety Review |
| WENRA | Western European Nuclear Regulators Association |

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# Introduction

1. This report presents the outcomes of my project assessment of the Rolls-Royce Small Modular Reactor (SMR) as part of Step 2 of the Office for Nuclear Regulation (ONR) Generic Design Assessment (GDA). This assessment is based upon the information presented in version 2 of Rolls-Royce SMR Limited’s Environmental, Safety, Security and Safeguards (E3S) case chapters (refs [1], [2], [3], [4] and [5]) and supporting documentation.
2. The project assessment differs to other topic assessments conducted during Step 2 of the GDA. It is focused on aspects that are required to deliver the overall GDA assessment, but which cannot be assessed by individual or small groups of topics in isolation. It therefore includes aspects which underpin all or most of the topic assessments, and requires a high level of coordination at a project level.
3. Assessment was undertaken in accordance with the requirements of the ONR’s Management System and follows ONR’s guidance on the mechanics of assessment, NS-TAST-GD-096 (ref. [6]). The ONR Safety Assessment Principles (SAPs) (ref. [7]), together with supporting Technical Assessment Guides (TAGs) (ref. [8]), have been used as the basis for this assessment.
4. This is a Major report (refer to NS-TAST-GD-108 (ref. [9])).
   1. Background
5. The ONR’s GDA process (ref. [10]) calls for a step-wise assessment of the Requesting Party's (RP) submissions with the assessments increasing in detail as the project progresses. Rolls-Royce SMR Limited is the RP for the GDA of the Rolls-Royce SMR design.
6. In April 2022 ONR, together with the Environment Agency and Natural Resources Wales (NRW), began Step 1 of the GDA for the generic Rolls-Royce SMR design. Step 1, which is the preparatory part of the design assessment process and mainly associated with initiation of the project and preparation for technical assessment in later steps, was successfully completed in 12 months.
7. Step 2 commenced in April 2023. This is the first substantive technical assessment step. The focus of ONR’s assessments in this step is towards the fundamental adequacy of the design and safety and security cases, and the suitability of the methodologies, approaches, codes, standards and philosophies which form the building blocks for the design and generic safety and security cases. The objective is to undertake an assessment of the design against regulatory expectations to identify any fundamental safety, security or safeguards shortfalls that could prevent ONR permissioning the construction of a power station based on the design.
8. Prior to the start of Step 2 I prepared a detailed Assessment Plan for the project assessment (ref. [11]). This has formed the basis of this assessment and was also shared with the RP to maximise openness and transparency.
9. This report is one of a series of assessments which support ONR’s overall judgements at the end of Step 2 which are recorded in the Step 2 Summary Report (ref. [12]).
   1. Scope
10. The assessment documented in this report is based upon the E3S case for the Rolls-Royce SMR as summarised in the E3S case chapters and supporting documentation.
11. The overall scope of the Rolls-Royce SMR GDA is described in (ref. [13]). Rolls-Royce SMR Limited has indicated that it intends to complete a three step GDA, with the objective of receiving a Design Acceptance Confirmation (DAC) from ONR and have aligned its GDA scope with this objective. The GDA scope defines the generic plant and layout and includes all systems, structures and components that are identified as being important to safety, security and safeguards, all modes of operation, and all stages of the plant lifecycle.
12. However, give the step-wise assessment during GDA, information has not been submitted for all aspects within the GDA Scope during Step 2. The following aspects of the E3S case are therefore out of scope of this assessment:

* Aspects related to the Rolls-Royce SMR approach to modularisation:
  + The site factory, which is a temporary structure that provides an environmental shelter to the Rolls-Royce SMR assembly area during construction;
  + The design, construction, and operation of the various factories which will build and supply the modules and components for the design; and
  + Aspects of modular transport and modular construction on site.

1. My assessment has considered the following aspects:

* The overall approach and strategy for development of the generic E3S case, including integration of the purposes and alignment with the design as it matures.
* Definition and control of the generic design, the change management process and implications for the E3S case.
* The approach and impacts of modularisation within the generic Rolls-Royce SMR design.
* The approach to demonstrating safety risks are reduced to As Low As Reasonably Practicable (ALARP), including consistency of application across the E3S case and optimisation with the other purposes.

# Assessment standards and interfaces

1. For ONR, the primary goal of the GDA Step 2 assessment is to reach an independent and informed judgment on the adequacy of a preliminary safety, security and safeguards case for the reactor technology being assessed.
2. ONR has a range of internal guidance to enable Inspectors to undertake a proportionate and consistent assessment of such cases. This section identifies the standards which have been considered in this assessment.
3. This section also identifies the key interfaces with other technical topic areas.
   1. Standards
4. The ONR Safety Assessment Principles (SAPs) (ref. [7]) constitute the regulatory principles against which the RP’s case is judged. Consequently, the SAPs are the basis for ONR’s assessment and have therefore been used for the Step 2 assessment of the Rolls-Royce SMR.
5. The International Atomic Energy Agency (IAEA) safety standards (ref. [14]) and nuclear security series (ref. [15]) are a cornerstone of the global nuclear safety and security regime. They provide a framework of fundamental principles, requirements and guidance. They are applicable, as relevant, throughout the entire lifetime of facilities and activities.
6. Furthermore, ONR is a member of the Western European Nuclear Regulators Association (WENRA). WENRA has developed Reference Levels (ref. [16]), which represent good practices for existing nuclear power plants, and Safety Objectives for new reactors (ref. [17]).
7. The relevant SAPs, IAEA standards and WENRA reference levels are embodied and expanded on in the TAGs (ref. [8]). The TAGs provide the principal means for assessing the project aspects in practice.
   * 1. Safety Assessment Principles (SAPs)
8. The key SAPs applied within my assessment are those associated with the regulatory assessment of safety cases (SC.1, SC.2, SC.4, SC.7 and SC.8), but I have also considered specific principles associated with Examination, Inspection, Maintenance and Testing (EIMT), ageing and degradation, and layout.
9. A list of the SAPs used in this assessment is recorded in Appendix 1.
   * 1. Technical Assessment Guides (TAGs)
10. The following TAGs have been used as part of this assessment:

* NS-TAST-GD-005 – Regulating duties to reduce risks to ALARP (ref. [18])
* NS-TAST-GD-051 – The purpose, scope and content of safety cases (ref. [19])
* NS-TAST-GD-096 – Guidance on Mechanics of Assessment (ref. [6])
  + 1. National and international standards and guidance

1. I have considered the ONR technical guidance for GDA (ref. [20]), in particular sections 2.1 (ALARP), 2.6 (safety case) and those aspects related to the design reference and management of change under section 3.12 (management for safety and quality assurance).
2. The following international standards and guidance have been used as part of this assessment:

* IAEA, Format and Content of the Safety Analysis Report for Nuclear Power Plants, Specific Safety Guide No. SSG-61 (ref. [21])
* IAEA, Safety Assessment for Facilities and Activities, General Safety Requirements No. GSR Part 4 (Rev. 1) (ref. [22])
* WENRA, Safety Reference Levels for Existing Reactors 2020 (ref. [16])
  1. Integration with other assessment topics

1. To enable my assessment I worked closely with other topics (including the Environment Agency and NRW assessors) as part of my project assessment. Similarly, other assessors sought input from my assessment. These interactions are key to the success of GDA to prevent or mitigate any gaps, duplications or inconsistencies in ONR’s assessment.
2. By its nature the matters considered under my project assessment involved working with all of ONR’s topic areas.

## Use of technical support contractors

1. During Step 2 I engaged Technical Support Contractors (TSCs) to support the following specific aspects of my assessment of the Rolls-Royce SMR:

* Review of the impacts of modularisation on the generic Rolls-Royce SMR design. This contract provided external specialist support and advice on modularisation, as applied in nuclear and other industries, and sought to identify areas where this may impact on the safety, security or safeguards of the generic Rolls-Royce SMR design. The purpose of this contract was to help inform ONR’s assessment strategy and targeting of related matters during GDA, including beyond Step 2.

1. The TSC provided me with technical advice and supported my assessment, working under my close direction and supervision. It should be noted that all regulatory judgements have been made exclusively by ONR.

# Requesting party’s submission

1. Rolls-Royce SMR Limited submitted a series of E3S chapters, or summary reports, and other supporting references, which outline the E3S case for the generic Rolls-Royce SMR design. This section presents a summary of the RP’s E3S case for project aspects. It also identifies the documents submitted by the RP which have formed the basis of my project assessment of the Rolls-Royce SMR.
   1. Summary of the Rolls-Royce SMR design
2. The generic Rolls-Royce SMR design is a three loop Pressurised Water Reactor (PWR) with a target electrical power output of 470 MWe (from a thermal power of 1,358 MWth) and a design life of 60 years for non-replaceable components.
3. The Rolls-Royce SMR design has been developed by the RP based upon well-established PWR technology, in use all over the world. Innovation comes in the form of its modular approach to construction which would see the majority of the power station built in factory conditions and assembled on site. Modularisation is applied throughout the design including within the civil structures and by the use of frames which provide the internal structures and barriers and house the plant systems.
4. The reactor itself is of a typical PWR design, including a steel Reactor Pressure Vessel (RPV) holding fuel assemblies, Steam Generators (SG), Reactor Coolant Pumps (RCP) and piping, all held within a steel containment vessel. The reactor is equipped with a number of supporting systems for normal operations and a range of safety measures are present in the design to provide cooling, control criticality and contain radioactivity under fault conditions. Passive safety features are preferred to active components, reflecting the RP’s design philosophy.
5. The design is defined by a design reference detailed within the Design Reference (DR) report (ref. [23]).
   1. E3S case approach and structure
6. Rolls-Royce SMR Limited has chosen to develop its cases in a holistic manner, as an Environment, Safety, Security and Safeguards (E3S) case. The overall objective for the E3S case is to demonstrate that the design will “protect people and the environment from harm”.
7. This means that, although the case made for each of the E3S purposes (i.e. environment, safety, security and safeguards) will inevitably be different at the top level, it will draw upon common evidence outputs (as well as other non-common outputs) to substantiate each of the purposes. This is claimed to offer benefits in terms of clarity, integration and understanding impacts from any changes to the case.
8. The E3S case is being developed using a three-tier hierarchy and incorporating a Claim, Argument and Evidence (CAE) structure with the highest-level claims being derived from the RP’s own E3S principles. The highest level of the three tiers is the RP’s tier 1 E3S chapters, with the lower tiers providing more detailed arguments and evidence. This is illustrated in Figure 1.

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**Figure 1: Claim, Argument and Evidence (CAE) structure within the E3S hierarchy** (ref. [1])

1. The structure of the E3S case largely aligns with the IAEA guidance for safety cases, SSG-61 (ref. [21]), supplemented to include UK specific expectations and expanded to include the other E3S purposes.
   1. Summary of the requesting party’s E3S case for project related aspects
2. The aspects covered by the Rolls-Royce SMR E3S case relevant to the project assessment can be broadly grouped under four headings which are summarised as followed:
   * 1. Development of the E3S case
3. Chapter 1 of the E3S case (ref. [1]) provides an overview of the RP’s approach to development of its E3S case for the generic Rolls-Royce SMR design. The approach and structure is already described in Section 3.2. Other notable aspects of the case are that the RP is developing it in concert with the design, using an iterative approach, building upon safety analysis and as an integrated part of the existing engineering processes.
4. An important reference for development of the case is the E3S Case Route Map (ref. [24]), which presents the derivation of top-level claims and subsequent decomposition of sub-claims and arguments for each tier 1 chapter of the E3S case, linked to the lower tier 2 and 3 evidence that underpins them. In effect this summarises the “golden thread” the RP expects to present.
5. The demonstration of ALARP, and the corresponding optioneering and decision making arrangements are considered separately as part of my assessment.
   * 1. Design control and change management
6. Chapter 1 of the E3S case (ref. [1]) describes the RP’s arrangement for control of the design. These are based on the RP’s engineering processes, which ONR considered during Step 1 (see Section 4.1.5. and 4.1.6. of ref. [25]). The RP’s approach is that these form the basis for defining the design, as defined in the Design Reference (DR) report for GDA, and its change control process. The RP claims that Design Reference Point 1 (DRP1), which represents the fixed design declared during Step 2, is the basis for the tier 1 E3S chapters.
   * 1. Approach and impacts of modularisation
7. Chapter 14 of the E3S case (ref. [1]) contains the claim that the “modularisation approach minimises risks during manufacture, assembly, installation and commissioning”. The chapter itself contains little in the way of supporting arguments and evidence, which reside mainly within the tier 2 and 3 documents.

### Approach to demonstrating risks are reduced to ALARP

1. Chapter 24 of the E3S case (ref. [25]) provides the tier 1 summary of how the RP considers it has reduced risks to ALARP based on the extant E3S case information available at that time. The main claim made within Chapter 24 is that the “design permits construction, commissioning, operation, maintenance and decommissioning with risks and exposures reduced to ALARP”. Whilst the entire E3S case is relevant to the demonstration of ALARP, the main specific reference is the ALARP summary report (ref. [26]) which summarises the main optioneering and decisions taken in the design to date.
   1. Basis of assessment: requesting party’s documentation
2. The principal documents that have formed the basis of my project assessment of the E3S case are:

* Relevent tier 1 chapters of the E3S case covering introduction (ref. [1]), E3S objectives and design rules for Structures, Systems and Components (SSCs) (ref. [2]), civil engineering works and structures (ref. [3]), plant construction and commissioning (ref. [4]) and ALARP summary (ref. [5]).
* The suite of documents that detail the arrangements developed by the RP to govern the development of the E3S case, including during GDA (refs [27], [28] and [29]).
* The DR report which defines the first DRP for the generic design (refs [30] and [23]) and the associated change management process guidance (ref. [31]).
* The Modular Kit of Parts (MKoP) strategy report (ref. [32]) and the design definition documents for the MKoP frame (ref. [33]) and barriers (ref. [34]). I have also considered the reactor island architectural and layout summary report (ref. [35]) and the five more detailed layout reports for specific areas of the reactor island (refs [36], [37], [38], [39] and [40]) given the strong relationship between adoption of the MKoP and plant layout.
* The ALARP summary report (ref. [26]) provides details of how the RP considers that the generic design reduces risk based upon the latest design and E3S case.

# ONR assessment

* 1. Assessment strategy

1. My assessment strategy, as defined in my assessment plan (ref. [11]) differed for each of the four distinct themes that I assessed.

* My strategy for assessment of the RP’s approach and strategy for development of the generic E3S case evolved when I found it necessary to raise Regulatory Observation (RO) RO-RRSMR-001 (ref. [41]) early in Step 2. I therefore focused on the RP’s responses to this RO. As part of this I also undertook a team intervention to test the implementation of the E3S case arrangements.
* For definition and control of the generic design, my assessment was targetted towards the requirement [2.16] from Guidance to Requesting Parties (ref. [10]) to judge the adequacy of the declared design reference and the RP’s arrangments that maintain control of this. I therefore chose to sample the DR report and the associated change management processes applied by the RP. It was not possible to assess the application of these to any design changes, as none were declared during Step 2.
* My assessment aimed to identify any E3S related impacts arising from the approach to modularisation, and to judge the overall adequacy of the associated parts of the E3S case. I sought to identify any fundamental concerns over this novel aspect of the design. To do so I sought information on the RP’s methodology, what Relevent Good Practice (RGP) it had utilised, design details and what aspects will need substantiating to evidence the E3S case.
* I targetted the methodology the RP uses to demonstrate safety risks are reduced to As Low As Reasonably Practicable (ALARP). I sampled the approach and examples of design decisions within the ALARP summary report, to form a view on whether the method is consistent with ONR’s guidance.

1. In addition to the above, my assessment plan also identified a number of other related matters. These are not included in this report. These are described below, along with the rationale for their exclusion.

* No changes to the GDA Scope (ref. [13]) were made by the RP during Step 2. Therefore the assessment undertaken during Step 1 remains valid and the GDA scope is sufficient to undertake a meaningful assessment of the generic Rolls-Royce SMR design. It is consistent with previous GDAs that have achieved a DAC.
* The RP initiated an IAEA Technical Safety Review (TSR) of the generic Rolls-Royce SMR design during Step 2. However, this was not completed in time for any outcomes to be considered as part of my assessment. I will consider this further in Step 3.
* A number of activities are management activities, necessary for a GDA, but not relevant to assessment. These are reported as part of the Step 2 Summary Report (ref. [12]). These include oversight of:
  + the Master Document Submission List (MDSL);
  + the implementation of the improvement actions identified in the RP’s gap analysis and readiness review from Step 1;
  + consolidation activities needed at the end of Step 2 (to ensure clarity on the basis for the Step 2 GDA Statement)​; and
  + responses to public comments​ received.
  1. Assessment
     1. Development of the E3S case

1. During Step 1 ONR assessed information on the RP’s strategy and intentions regarding the development of its E3S case (ref. [25]). At the end of Step 1 ONR reported that it was satisfied that the proposed E3S approach was logical, suitably structured and would give the RP means to direct the development of its design. The early production of clear strategies and the holistic approach were cited as good practices adopted by the RP.
2. Throughout Step 2 the RP has continued to develop both the design and E3S case, which it claims to be delivered in an integrated manner. Version 1 of the tier 1 E3S chapters were submitted to the Regulators at the start of Step 2, and lower-level tier 2 and 3 submissions were provided in accordance with the agreed submission schedule for the step. Version 2 of the E3S chapters (in May 2024) were updated to reflect the progress made during Step 2 (and hence are consistent with the Step 2 assessments). In totality these documents represent the E3S case for the generic Rolls-Royce SMR design.
3. With support from across the ONR assessment topics and in coordination with the Environment Agency, I have assessed the RP’s approach, progress and delivery of the E3S case. This included us undertaking two “E3S health checks”, in June 2023 (ref. [42]) and February 2024 (ref. [43]), to determine the regulator’s overall views on the adequacy of the E3S case based upon the characteristics described in the safety case TAG, NS-TAST-GD-051 (ref. [19]). These characteristics are equally applicable to security, safeguards and environmental purposes.
4. In addition to the safety case SAPs, I have also considered the guidance provided in section 2.6 of ONR technical guidance for GDA (ref. [20]), IAEA SSG-61 (ref. [21]), requirements 1 to 5, 19, 20 and 22 to 23 of IAEA GSR Part 4 (Rev. 1) (ref. [22]) and Issue N of the WENRA safety reference levels (ref. [16]). These relate to the production, scope, content, maintenance and use of the safety case.
5. Chapters 1 (ref. [1]) and 3 (ref. [2]) of the E3S case provide summary information on the RP’s approach to development of its E3S case. Several notable aspects of the RP’s approach are:

* The RP has chosen to develop its cases in a holistic manner across the E3S purposes;
* 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 CAE structure to define the “golden thread” for the case;
* A combined systems engineering and analysis approach;
* Alignment to IAEA guidance for safety cases (ref. [21]), 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.

1. The scope and approach to development of the generic E3S case is ambitious, and if it can be delivered to the RP’s own high standards it would represent good practice in a number of areas. To ensure this vision is delivered requires 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.
2. In August 2023, based on assessment and interactions with the RP to date, I did not have sufficient confidence that the RP had fully developed and implemented suitable and sufficient procedures and controls to develop an E3S case which will meet UK and international regulatory expectations, and would be an enabler for future regulatory activities. An important input to this view was the E3S health check from June 2023 (ref. [42]) which identified that although the overall structure and approach appeared sound, common deficiencies across the topics were found regarding immaturity of some information, lack of clarity over forward plans and undeveloped links between topics, design and E3S case.
3. As a consequence RO-RRSMR-001 was raised (ref. [41]). This detailed a number of related aspects where further work was required, summarised into two Actions regarding documenting the development arrangements and embedding the arrangements for oversight, control and governance. The RP’s resolution plan (ref. [44]) identified newly produced arrangements for the development of the E3S case, internal training and an inspection by its own assurance function. I also agreed that ONR (working jointly with the Environment Agency) would undertake our own intervention to assess the implementation of the arrangements. The responses to RO-RRSMR-001 therefore formed the basis for the Step 2 assessment.

#### Arrangements for development of the E3S case

1. The three documents submitted in response to the RO (refs [27], [28] and [29]), in combination with the E3S Case Route Map (ref. [24]), provide the holistic set of arrangements that the RP contend govern its development of the E3S case. Their scope extends beyond GDA, albeit details in these areas are limited given the uncertainities in future deployment plans at this time. I have not assessed those aspects beyond GDA, but consider it positive that the RP has actively considered this.
2. The E3S case development and management arrangements (ref. [27]) describes the RP’s overall approach, replacing and updating the E3S case development strategy assessed during Step 1. The document contains information regarding a number of facets of the RP’s methodology, explains the links between different tools and clarifies the integration of the working practices. Importantly it does cover matters such as the use of CAE, how design and E3S case maturity are related and the digital tools used to help the RP in producing the case. As the head document to provide the means to understand the arrangements at this higher level, I consider it a reasonable document. It has added significant clarity and value for the developers of the E3S case, and within the wider RP organisation. As described further below, it is more akin to a high level summary, and does not describe some of the more practical aspects needed in detail.
3. The E3S requirements and analysis arrangements (ref. [28]) describes how the RP expect the design to be influenced via requirements and analysis derived as part of the development of the E3S case. This includes “E3S requirements” derived from the RP’s own E3S principles (ref. [45]) and analysis inputs such as hazard identification and fault schedule development. It also considers the other E3S purposes aside from safety. The document itself is a high level summary, but cites a large number of subordinate standards for each area. A consequence of this lack of detail means that it is likely to be of limited value to an individual user. Overall, I consider it provides an adequate description of the key inputs at an overarching project level.
4. The regulatory affairs group functional manual (ref. [29]) documents the roles, responsibilities and governance of that group and supersedes the E3S Management Manual assessed during Step 1. The scope is wider than GDA, but it does detail the activities undertaken to support development of the E3S case and the organisation of the group. It is notable however that it, by definition, does not include the other areas of the RP’s organisation – notably engineering. It also does not reflect the regulatory facing organisation that we interact with (which is composed from a mixture of this group and engineering, but with specified and defined roles).
5. Taken together these documents represent a significant improvement to the RP’s documented arrangements. They provide much greater clarity over a number of the detailed points raised in the Actions under RO-RRSMR-001. I am content that, as documented, they provide a valuable definition of the type of information and structure the RP expects the case to contain, as well as the approach that is being taken to manage and produce this, including links to other related processes. I am expecting that they will continue to mature throughout GDA, but they are sufficient now to suggest that a suitable and sufficient E3S case could be produced which is likely to meet UK regulatory expectations. Details of development and activities necessary post GDA are still to be finalised, but there is sufficient to suggest that the RP has started to consider how they could enable the production of a subsequent site-specific E3S case by the future licensee.
6. However, there are some prominent aspects missing from these responses that were expected as part of the RO:

* There is no attempt to define what work still needs to be completed for the E3S case (particularly during GDA). This applies to justifications of both the design or E3S claims. It is therefore unclear how complete the current case is, nor the scope of what evidence still needs to be produced and documented. I do acknowledge that the RP has subsequently developed and agreed submission plans for Step 3, which may form part of the answer.
* There appears to still be work needed to align and integrate the E3S case development with the wider engineering and design activities (such as requirements management and gated definition reviews). Whilst this has improved, some E3S aspects are still separated and have not yet been given sufficient prominence in the RP’s overall arrangements to influence the design, in particular regarding which requirements are needed for the E3S case and what evidence will justify these are met.
* There remains some ambiguity over ownership and the “controlling mind” for the E3S case. No information was provided regarding training or roll out of the arrangements to all of those within the RP who contribute.

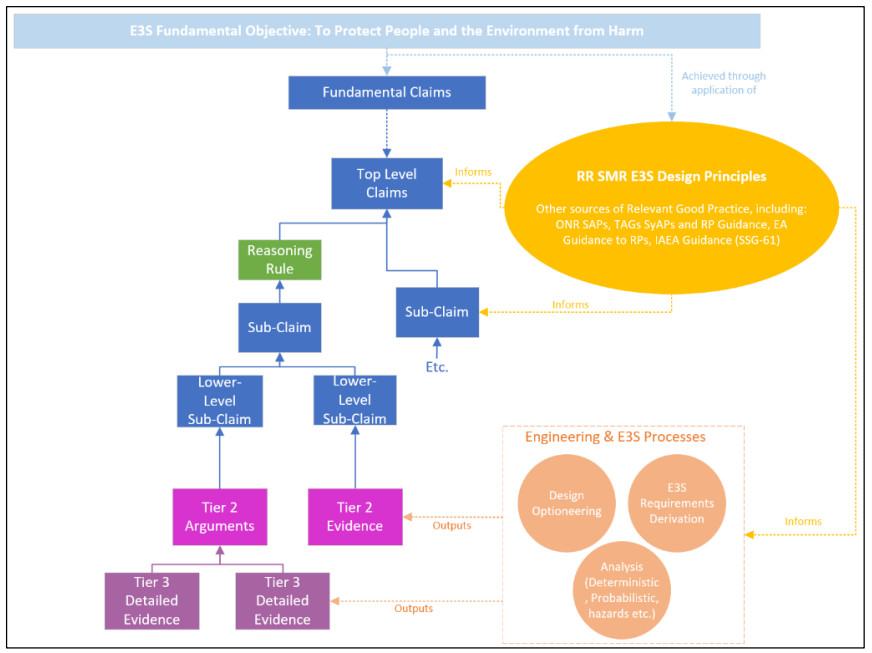
1. I am content these shortfalls can be resolved. They represent gaps in the documented arrangements, but do not systematically undermine the content of the E3S case assessed during Step 2. I will follow up on these during Step 3, as part of the work to resolve the RO.

#### Implementation of arrangements

1. The arrangements described previously need to be adequately implemented in order to deliver the E3S case. To test these arrangements, a regulatory intervention (ref. [46]) was undertaken in March 2024 as a joint review by ONR and the Environment Agency, seeking evidence to:

* Demonstrate that those arrangements will facilitate the RP in producing a generic E3S case during GDA that has the characteristics described within ONR guidance for safety cases, NS-TAST-GD-051 (ref. [19]).
* Gain assurance that the RP has implemented those arrangements and that they are embedded throughout its organisation.

1. The E3S health check conducted in February 2024 (ref. [43]) provides an indication of the progress over Step 2. This showed, in general, an improvement for the majority of topics. The theme of visibility of the full scope of work, particularly for those topics that rely on maturing of the design, remained. CAE and requirements are two key aspects where there is still work to do by the RP to demonstrate that these are being applied holistically, in particular regarding the ability to follow the “golden thread” for the justifications. These findings were factored into the planning of the intervention.
2. The intervention took place over two days and included a number of topic inspectors. It included discussions with a large number of RP staff from across its organisation, and access to the live versions of the RP’s digital tools being used as part of the development of the case. The main themes covered how the arrangements work in practice, how they have been implemented throughout the organisation and a sample of the information targeted towards demonstrating the approach to documenting the “golden thread”.
3. The main findings from the intervention are recorded within the Contact Record for the meeting (ref. [47]). These are described further below.
4. A useful aid is Figure 2, taken from the RP’s arrangements, which shows the flow of information and is referred to from my subsequent paragraphs. One of the key points to note is that this diagram shows the flow of information is always from the “bottom up” (i.e. the evidence is driving the claims), and also that the engineering (and requirement) is driving the E3S case. I acknowledge that this is just schematic and is not intended to reflect reality. However I do consider there to be some truth in this depiction and I would expect this flow to be more iterative and integral. I take comfort that there are indications that the RP is moving closer to this latter model.



**Figure 2: Claim decomposition and Flow of Information** (ref. [27])

1. The RP has chosen to adopt a CAE approach to provide the narrative and structure for its E3S case. This is shown by the blue and purple boxes in Figure 2. This has matured over Step 2 and is key part of the work undertaken by the E3S team, who effectively own the E3S Case Route Map (ref. [24]). While there has been clear thought given to how this applies at the highest tier of the documentation, less evidence is available for how this may be used throughout the full depth of the case, nor how this may be adapted to topic specific differences and needs.
2. There is a clear demarcation in the RP’s organisation between the engineers and E3S team. In effect the engineers are represented by the “engineering and E3S processes” circles in the bottom right of Figure 2, and the E3S team are represented by the top half of the diagram. Yet successful delivery of the generic Rolls-Royce SMR design requires both the design and E3S case to be produced holistically. In many instances this is working well, but I have seen evidence that these teams are not working as effectively or as integrated as they need to fully achieve this objective which is to the detriment of the E3S case. This has clearly improved throughout the step, but the RP itself acknowledges that more work is needed in this regard. Part of this is procedural, but it does have a cultural element.
3. An important artifact of this approach is that the main influence that the E3S team currently have on the development of the design is via the E3S design principles (ref. [45]) to set requirements on the design and inform the CAE structure (shown by the yellow oval and arrows in Figure 2). The principles themselves were assessed during Step 1 and judged to be adequate. At that time it was noted that the mapping of the principles into requirements and the CAE structure remained ongoing but that this was important to ensure that all principles will be addressed by claims and supported by evidence. From our assessments during Step 2 it appears that this important enabling activity for development of the E3S case still remains ongoing, with no clear plan for when this will be completed. I consider this a gap that I would have expected to RP to have largely addressed during Step 2.
4. The design and engineering process used by Rolls-Royce SMR Limited draws upon its extensive experience from other industrial sectors, which brings obvious benefits. In particular the approach of establishing requirements for the design, and ensuring that the design achieves them through rigorous process and governance should lend itself to supporting the production of a sound E3S case. I consider it positive that the RP is bringing its experience of requirements management to develop the generic Rolls-Royce SMR design. However, the arrangements and their implementation in the RP mean that requirements which support the E3S case, or need to be demonstrated as part of that case, are not clearly distinguished amongst the totality. This does not mean that they won’t be achieved, rather it means that the documented case may be incomplete or conversely, overburdened and obscured.
5. The RP has invested heavily in digital tools to aid both its design work and E3S case development. The most relevant are Assurance and Safety Case Environment (ASCE®), Dynamic Object-Oriented Requirements System (DOORS®) and Teamcentre® software. Each offers different functionality, but they are intended to work together. The adoption of each of these is currently at different levels. I remain convinced that the digital platforms, if used and deployed to the RP’s own expectations, could be a powerful suite of tools to help coordinate, guide and produce the E3S case for GDA, and also for a future licensee’s benefit. I also consider that more development is needed to determine the appropriate role that each of these contribute to developing and documenting the case.
6. It is important to be clear that the digital tools themselves are not part of the RP’s generic E3S case. It is vital therefore that the E3S documentation is self-standing and is able to clearly demonstrate the “golden thread” from claim through to substantiating evidence. CAE is one aspect of providing this structure, but another is how the RP intends to detail and reference this within the various documents. I am not convinced that the RP has fully determined its own approach yet, and this has not yet been documented.
7. It is important that there are clear roles and responsibilities regarding all aspects of the delivery of the E3S case. I have not seen evidence of this for some important elements of the arrangement (such as the E3S Case Route Map or E3S requirements) and some roles within the RP. I consider this to be a clear shortfall against expectations for this stage of GDA.
8. Collectively, I am content that the RP is making good progress towards resolving the matters raised by the RO and there have been clear improvements throughout Step 2. I do judge that further work is required from the RP. In particular I consider that further details are required of:

* The future work to develop the E3S development arrangements. This includes how this is linked and informs relevant milestones (for GDA, E3S or design) to show it is produced/matured at the appropriate time, and further clarity over what the aspirations are regarding the end state for the E3S case expected for GDA, in terms of maturity and development.
* The intentions and supporting arrangement for the application of CAE throughout the E3S case. This should define the scope, application and approach across the case (e.g. decomposition of claims) and details how this is integrated with engineering activities and the digital tools (e.g. links to “E3S requirements”).
* The use of the digital tools as part of the E3S case development, covering ASCE, DOORS and Teamcentre software. This includes clarity on the content of these, access and control, and the approach for how this information will be documented within the E3S case, where necessary. This needs to provide clarity over how the “golden thread” will be demonstrated in the E3S case documents.
* Complete and defined roles and responsibilities for the development of a robust E3S case, including the use of supporting tools.
* Evidence to demonstrate that these arrangements are embedded throughout the organisation. For example, through training in the updated arrangements or appropriate linking with other engineering processes and guidance. I consider this to be particularly important to bridge the different teams within the RP’s organisation and fully embed development of the E3S case within engineering.

1. I am content that the RP can address these shortfalls in their arrangements and implementation as part of the work to resolve the RO. I am satisfied that they do not systematically undermine the content of the E3S case assessed during Step 2, and note that each of ONR’s technical topics have made their own judgements on the adequacy, maturity and alignment of design and E3S case for Step 2. As I consider these shortfalls will challenge the RP’s ability to deliver an adequate holistic case during GDA if not resolved, I will follow up on these during Step 3.
2. The RP’s own Nuclear Assurance function undertook a review of the responses to the RO, and their implementation (ref. [48]). This was submitted as part of the RO responses. This noted a number of positives in the RP’s responses, and acknowledges the improvements made. It does highlight further work is needed in some areas, with particular emphasis on “implementation and communication of the new arrangements to relevant stakeholders” (in particular the engineering function) and “progress with the DOORS tool to aid visibility of the golden thread”. Whilst out with the scope of the RO, it also notes some resource constraints may be a factor. I consider that these views are consistent with my own findings above.
3. I expect that the RP will undertake appropriate actions to respond to the findings of its own review and I will follow up on this during Step 3.

#### Summary

1. The Rolls-Royce SMR design originated as a design and engineering activity, and a significant focus of the RP remains to deliver this. It is my view that the E3S case started as a parallel task, and the RP has worked hard to better integrate this across its organisation. This has been partially successful to date and I expect to see further evidence of this to enable closure of the RO in due course.
2. The RP’s approach to development of the E3S case is ambitious, and if achieved would represent several areas of good practice. Earlier in GDA this approach resided within a small number of individuals within the E3S team, and was less prominent to others. The RP has made some good progress in documenting and developing arrangements for this, including the use of a number of digital tools, and rolling these out within the wider organisation. Despite this I judge that there remains work to do to fully document the enablers for the E3S case, to ensure consistency and clarity across all the purposes and topics. This is particularly true for the CAE approach, use of requirements and the DOORS tool to inform the case, and the intent for how the “golden thread” will be documented.
3. Overall, I am content that good progress has been made throughout Step 2, and some of the matters raised by the RO have been resolved. There does remain further work needed by the RP to fully resolve the RO. I will seek resolution of this as soon as possible, but am confident that the RP can achieve this in a timely manner during Step 3.
   * 1. Design control and change management
4. For any GDA, and perhaps more so for the Rolls-Royce SMR where the design continues to mature, there needs to be clarity over the physical design of the Nuclear Power Plant (NPP) at any point in time. This is to ensure that the E3S case is consistent with the design, and from a GDA perspective, so are our assessments. It is equally important that any changes to the design are appropriately controlled and their impact considered. The mechanisms to achieve this are specified in Guidance to Requesting Parties (ref. [10]) via setting of a Design Reference (DR) and adoption of change management arrangements. Further guidance is also provided related to the design reference and management of change under section 3.12 (management for safety and quality assurance) of the GDA technical guidance (ref. [20]).

#### Design reference

1. The DR report should list all the documents that define the design of the NPP that the GDA submissions refer to. The DRP represents a fixed baseline for this at a point in time. Setting of a DRP is necessary to provide clarity over the design that is subject to assessment and also to invoke the RP’s change management process should changes to the design prove to be necessary. It is likely that multiple DRPs will be set during the course of a GDA.
2. During Step 1 ONR assessed the RP’s intentions for setting and controlling the DRP and were content with the approach detailed.
3. Requirement [2.16] of Guidance to Requesting Parties (ref. [33]) expects the RP to submit to ONR the first DRP during Step 2 and continue to update this as necessary. Rolls-Royce SMR Limited submitted its DR report, that defines the first DRP (DRP1), in December 2023 (ref. [30]).
4. The DR report details the purpose, approach and content of the DRP. It also summarises the change control process that will be employed. Placeholders are included to record relevant changes as they arise. There are links to other important GDA processes such as the maintenance of the master document submission list and GDA Scope. I am content with the structure of the DR report and its integration within the RP’s wider set of arrangements for GDA.
5. The approach taken by the RP to define the DR was to filter the relevant Master Records Index (MRI) produced as part of its engineering Definition Review process for artifacts related to the physical design of the NPP. The outcome from this filtering was subject to review and governance. This check include a cross comparison with the agreed GDA Scope (ref. [13]) to ensure consistency. This integrates the DR into the RP’s existing engineering process, which is beneficial given the structured approach to the design employed and avoids creation of a secondary process. I consider this approach to be a good practice adopted by the RP.
6. Given that the Rolls-Royce SMR design is maturing the original approach proposed by the RP during Step 1 would have seen only SSCs which had reached its internal Definition Review milestone of DR3 being included. The rationale for this was that, at this point, maturity was sufficient to define the design. However, a significant percentage of the SSCs are yet to formally reach the DR3 milestone, which would have meant less of the design would be fixed at DRP1. The DR3 milestone includes a number of detailed conditions that must be met for the milestone to be passed, but many of these are not E3S related and therefore of no impact on the design from a GDA perspective. I therefore agreed that the RP could include SSCs into the DRP which were of sufficient maturity, irrespective of whether the DR3 milestone had been achieved.
7. The DR report also includes a list of those SSCs which will be included in future updates of the DR. As described above, these are the SSCs which have yet to reach sufficient maturity to be included in the DRP but are within the GDA Scope. These are low in number, but there are some notable examples from an E3S perspective relating to core monitoring systems and some fuel handling equipment. This does not mean that there is no information available for assessment on these SSCs, rather that some important decisions have not yet been taken or finalised and it is therefore premature to baseline the design. I consider it reasonable that the RP has not included these yet, if they are considered too immature.
8. The bulk of the DR report is tables of referenced documents that provide details of the design. This is broken down by the Reference Designation System for Power Plants (RDS-PP) coding using by the RP. It includes a range of design, layout, engineering and analysis information which collectively defines the generic design.
9. To determine the adequacy of this list I sampled a range of SSCs included within the GDA Scope (ref. [13]) from across the plant, covering safety systems, electrical, Control and Instrumentation (C&I), civils, Heating, Ventilation and Air Conditioning (HVAC) and mechanical handling. For all of the SSCs I could readily identify references. For the majority I could identify from the references the design of the SSC. Hence I am content that these do define the DRP. However, for a number of areas and SSCs the references themselves identified multiple “options” for the design that were being progressed by the RP. These therefore do not represent a defined DR. In response to this challenge the RP updated the DR report to remove any such ambiguity (ref. [23]). I am content that this updated DR report does not represent a new DRP and it has clarified the design.
10. The DR report also indicates that further versions of the DRP will be set throughout Step 3. The content and date for these is subject to change, but the RP recognises the need to align these with other key design or E3S milestones. I am satisfied that agreement of these further updates is normal business.
11. Overall, I am therefore satisfied that DRP1 is adequate. The DR report is a suitable definition of the design and I consider it meets the requirements from Guidance to Requesting Parties (ref. [10]). I expect to maintain regulatory oversight of the developing DRP during Step 3, especially for any changes.

#### Change control

1. There are many reasons why changes to the DRP may be necessary during GDA, including normal design development, responding to ONR’s assessments or to adopt changes in relevant standards or guidance. To ensure control of the design the expectation is that the RP will implement a robust system similar to those implemented by licensees to satisfy nuclear site Licence Condition 20 (modification to design of plant under construction) (ref. [49]).
2. During Step 1 the RP proposed to develop a holistic change control process to cover all changes related to design, E3S and the DR. This was in response to my challenges regarding how E3S changes would be considered, and did require the RP to adopt its existing change management processes to reflect the E3S case. The intention was for this new process to be in place early in Step 2, to allow a period of implementation before setting the first DRP. This was achieved, but the RP’s adoption of the Teamcentre tool, which is used to manage design changes, required reworking of the process. At the time of writing all of these enablers are now in place, albeit there are some minor updates necessary to fully align all aspects. I am content this is normal business for the RP.
3. Change management is covered by the RP’s C3.2.1-9 process within its Integrated Management System (IMS). The associated guidance, SMR-GDN-071 (ref. [31]) provides more details of the process. The process and guidance are comprehensive and I am confident from these that the RP understands the need to have robust arrangements. The RP has clearly worked hard to adapt its existing process to be inclusive for E3S changes, which I am pleased to see. I am content that the arrangements implement the key aspects needed for GDA, namely:

* a categorisation process reflecting the potential E3S impact of the change;
* change control governance to oversee the categorisation of the proposed changes and the overall running of the process; and
* a method for alerting ONR to the more significant changes to the E3S case.

1. The incorporation of this process within Teamcentre is a strength in the RP’s approach and should offer benefits in producing updated DRP’s during GDA as well as monitoring the implementation of agreed changes.
2. During Step 2, given the timing for setting DRP1, there have not been any changes proposed, and therefore I have not been able to determine the adequacy of this process. However, I have been given confidence using examples proposed by the RP.
3. I will maintain oversight of the change control process during Step 3.

#### Summary

1. I am satisfied that the RP has met the requirements from Guidance to Requesting Parties (ref. [10]) regarding setting a DRP and establishing change management arrangements during Step 2. These represent a sound basis for controlling the design as part of Step 3 of the GDA. I expect to maintain oversight of the implementation of these processes, as the design continues to mature and changes are proposed by the RP.

### Approach and impacts of modularisation

1. One of the main drivers for development of the Rolls-Royce SMR design is to “minimise the build schedule” and a key enabler to this is the RP’s build certainty philosophy. This is described more fully in (ref. [50]). Application of this philosophy leads to six objectives which in turn have led to the development of the modularisation approach adopted in the design. This is a key commercial aspect of the RP’s offering, aimed at providing confidence in the build schedule and costs. One of the main objectives for my assessment during Step 2 was to determine if this approach impacts any safety, security or safeguards aspects of the design or E3S case.
2. It is important to note that the RP has stated that modularisation is therefore not an aim in its own right. It is an enabler and tool to deliver the RP’s underpinning philosophy around build certainty. I agree with this characterisation of its approach.

#### Approach to modularisation

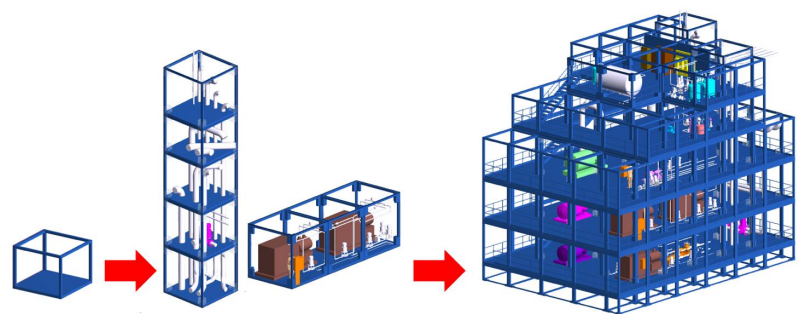
1. Before describing modularisation it is worth explaining the construction approach for the Rolls-Royce SMR design as the two are intrinsically linked. The intention is to construct the plant using volume manufacturing processes as opposed to “stick built” (i.e. on site) which is conventionally used for such large infrastructure projects. Some parts of the design will still need to be built in situ, but the RP is aiming to maximise what can be done off site. In essence components and systems will be manufactured in dedicated factories, before being transported to site and assembled. Transportation via roads puts restrictions on the size of what can be sent via this route. The RP claims that such an approach offers a range of advantages, over the commercial benefits, such as opportunities for improved quality control and benefits of standardisation.
2. Application of modularisation within this framework leads to four specific methods for modularisation. The response to Regulatory Query (RQ) RQ-01222 (ref. [51]) confirmed that each of these methods will be used in the design and provided further details for their application. These are:

* The Modular Kit of Parts (MKoP). These are used mainly within the Reactor Island to house the Mechanical, Electrical and Plumbing (MEP) systems and consist of standard structural frames and standardised barriers and fittings for those frames.
* The Civil Kit of Parts (CKoP). Several areas of the civil design use standardised materials, components and methods. These include some areas of the RI (for example the hazards shield and seismic isolation) and structures which support the essential service water system and back-up generation.
* Original Equipment Manufacturer (OEM) modules or skids. These are typically Commercial Of The Shelf (COTS) products sourced direct from the manufacturer. They are largely restricted to areas of the conventional plant and could include, for example Turbine Island or cooling water equipment.
* Bespoke modularised structures of assemblies. These are non-standardised structures which are outside the boundaries for the MKoP or CKoP, and cannot be delivered by OEM equipment. For example steam generator supports would be bespoke, but would be the same for all SGs and across all Roll-Royce SMR plants.

1. My assessment during Step 2 has therefore concentrated on the overall approach to modularisation, including development of the associated E3S case, and the MKoP method.
2. I have excluded the CKoP method from my own assessment because this is entirely covered within the civil engineering topic within both the RP and ONR. The application and justification for the CKoP is normal business for civil engineering and the relevant assessment of these is described within the Step 2 assessment report (ref [52]).
3. I am content that the OEM or bespoke methods are either of lower E3S significance or where they are more significant would be within the scope of those relevant topics to sample as they consider necessary.

#### Modular Kit of Parts

1. The “head” document for the MKoP is the strategy report (ref. [32]). In addition to summarising how the RP’s modularisation concept has developed, this document provides additional information that is not available elsewhere in the E3S case. This includes the interactions between the MKoP and the layout design process, the E3S impacts of modularisation and the RGP considered by the RP. I consider several of these important aspects in more detail in subsequent sections below.
2. The design of the MKoP is described in the design definition documents for the MKoP frame (ref. [33]) and barriers (ref. [34]) respectively. The former details the design aspects of the primary structures (frames) for the modules. There are three standard frames defined. The standard frame (Type A) is the basic core building block of the modularisation concept. It is intended to consist of separate corner elements and structural beams and columns, manufactured from steel and of a welded construction. The frame corners are intended to provide integrated features to allow frames to be connected by bolted joints (horizontally and vertically). Type B and C frames differ in size and are intended to be used for larger equipment or in exceptional circumstances. Other frame variants may be needed to meet the plant layout needs (for example, triangular or high strength variants), but these are not yet defined.
3. The frames tesselate on a standard grid to form larger clusters. Clusters are combined to form the various blocks within the reactor island. Such assemblies are illustrated in Figure 3. The blocks are surrounded by concrete walls and anchored at the base.



**Figure 3: Assembly of Modular Kit of Parts (MKoP) frames to clusters and blocks** (ref. [53])

1. Within and attached to the frames are barriers and fittings, which are described in the barriers design definition report (ref. [34]). This includes walls, floors and ceilings as well as means of achieving openings and penetrations through them. The barriers will therefore have important safety claims made against them, to provide protection and mitigation for internal and external hazards, and to enable SSCs to function correctly.
2. Collectively these documents provide valuable information on the MKoP. They explain how the various elements interact with each other, and provide clarity on the application of the MKoP within the design. The RP has progressed its approach and design for modularisation significantly during Step 2. However, the MKoP design is still maturing. There are detailed aspects of the design where the RP still needs to make decisions, before substantiation and analysis can be undertaken. This means there remains a large amount of development needed to reach the level of design and substantiation needed for GDA. I consider the current position for some of the most relevant aspects in subsequent sections.

#### Relationship to layout

1. The use of modularisation, in particular adoption of the MKoP frames to form the various blocks, directly impacts on plant layout. Combined with maturing the design, during Step 2 the RP has worked to develop and justify its plant layout and embed the processes and arrangements it needs to do so.
2. The RP submitted a suite of reports, aligned to the DRP, to provide detailed layout information for the reactor island. This consists of the reactor island architectural and layout summary report (ref. [35]) and the five more detailed layout reports for specific areas of the reactor island (refs [36], [37], [38], [39] and [40]). I have not assessed the adequacy of the layout documented within these reports in detail for my assessment, which is considered by other topics in ONR. I have specifically considered how the layout interacts with modularisation, and the associated E3S case.
3. The summary report (ref. [35]) and MKoP strategy (ref. [32]) describes the RP’s layout design process including the decision making and governance processes. There has clearly been much effort put into both the process and the organisational arrangements to deliver this. It integrates and builds on the RP’s overarching engineering processes, including for definition reviews and requirements management. The RP cites a range of inputs, across all purposes, that together will directly or indirectly impose requirements on the layout, including for example the RP’s E3S principles, internal hazards strategy and EIMT strategy (amongst many others). I am satisfied that this provides evidence of a holistic approach to develop the layout and the rationale for design decisions. I am satisfied that this demonstrates clear logic, and considers relevant factors across all purposes. The interaction and feedback, to the MKoP and modularisation more generally, is prominent.
4. I am satisfied the RP is adequately considering how its layout process will allow it to demonstrate how SAPs ELO.1 (facilitate access) and ELO.4 (minimise the effects of incidents) (ref. [7]) can be achieved by the design.
5. During Step 2 the layout of the reactor island was updated to optimise the arrangement of key systems and improve the resilience to hazards. The main changes were to explicitly segregate the different blocks and safety trains, considering operational factors. The civil walls and structures, as opposed to the MKoP barriers, are used as the principle hazard barriers (although the MKoP barriers may provide local shielding). This layout is an improvement on the previous iteration in this regard, and demonstrates the validity of both the RP’s design processes and the maturing thinking underpinning the MKoP.
6. From a modularisation perspective, the layout documents provide a useful basis to contextualise the approach, and use of the MKoP. I am satisfied there is a suitable link between layout and modularisation for the design. I do consider that this process would benefit from being formally documented as part of the RP’s design arrangements, and I will follow this up in Step 3.

#### E3S case

1. Version 1 of the tier 1 E3S chapters, from March 2023, had no meaningful information on modularisation. Version 2 was produced to summarise the tier 2 and 3 information submitted during Step 2. The main chapter which includes modularisation (the MKoP in particular) is Chapter 14 regarding plant construction and commissioning (ref. [4]). The main claim made is that “modularisation approach minimises risks during manufacture, assembly, installation and commissioning”. This is a broad claim and the E3S Case Route Map (ref. [24]) is cited as providing the link to the underpinning arguments and evidence. This improvement in the visibility of the E3S case for modularisation is welcomed.
2. However, Chapter 14 contains little in the way of arguments or evidence to support the claim made. In my opinion it is not yet an accurate summary of the extant E3S case regarding modularisation of the generic design. The E3S Case Route Map includes additional sub-claims and “reasoning rules” that are not representative of either the chapter, or the detailed tier 2 and 3 reports submitted during step 2. The “golden thread” that should provide the link from claims, through arguments, to evidence is therefore unclear and incomplete.
3. The tier 2 and 3 submissions themselves (refs [32], [33] and [34]) are much more useful and substantial as E3S case documents. As described earlier they are still a work in progress, reflecting the design maturity. They are, as currently presented, very useful engineering and design documents, but this does mean that they contain lots of information which may not be relevant as part of an E3S case. They are also not structured or presented to align with the E3S claims or requirements. I consider this a presentational matter, rather than a flaw in the underpinning case itself, which can be resolved.
4. The strategy report includes a section which describes what the RP considers to be RGP (ref. [32]). Reference is made to the design documents for more detailed consideration. This is a useful high level summary of benchmarking. It considers both nuclear and non-nuclear applications. This demonstrates that there is clearly a significant source of Operating Experience (OPEX) for the RP to draw upon. Importantly, it also shows that the concept of modularisation is not novel, rather it is the extent and specific application for the Rolls-Royce SMR design that is different. I am satisfied that the RP has started to include such considerations as part of its E3S case, which I judge to be important. The RP have explored a number of concepts and approaches from an effectiveness viewpoint but have not developed a specific statement of good practices. I would expect this to be strengthened as part of the matured case, including highlighting specific aspects that the RP consider to be RGP and demonstrating its design fulfils them.
5. The frames and barriers design definition documents (refs [33] and [34]) acknowledges that there is currently a low maturity of E3S requirements for the MKoP. The reports do include some preliminary information on what some of those requirements may be, albeit incomplete. The RP expects these to mature alongside the design, which I consider reasonable. The RP’s standard engineering and requirements approach will be used for the MKoP elements, which provides confidence that substantiation evidence will be produced in a consistent manner to other parts of the E3S case and design.
6. Overall, I acknowledge the large improvements made by the RP during Step 2 to document the modularisation aspects of the E3S case. However, there are improvements needed to the presentation and alignment across all tiers of the case to produce an adequate justification during GDA, and meet my expectations against SAP SC.2 (safety case characteristics) (ref. [7]). I would expect this to focus on the substantiation and justification for the design adopted, consider all purposes, and to provide a demonstration that risk are indeed reduced to ALARP. I will continue to engage with the RP on this during Step 3, as the design and evidence matures.

#### Impacts of modularisation

1. Use of the MKoP is such an integral part of the generic Rolls-Royce SMR design that there are inevitable impacts on the design or E3S case from its adoption. I am satisfied that most of these are likely to be similar to any new build project, and many are not likely to have a significant impact on the E3S case. An important focus of my assessment was therefore to identify those which are novel or significant in terms of the E3S case, with the objective of establishing that the RP recognises these and has plans in place to address them.
2. The RP describe what it considers to be the potential impacts in the strategy report (ref. [50]). This recognises that the use of the MKoP will be consistent with the RP’s own design principles, and will help other SSCs to achieve compliance. Given the maturity, this cannot yet be demonstrated, but I consider it positive that the RP commits to do so specifically for the MKoP components. This report also considers the benefits and compromises from use if the MKoP approach, across all lifecycle stages and considering physical, organisation and procedural impacts. The RP commits to review and substantiate this analysis as the design of the MKoP system progresses. It represents a good framework for further development and I consider it useful that the RP is considering impacts in this wider context applicable to its endeavours. Whilst valid, many of the impacts identified are outside of the GDA Scope (for example, factory commissioning) or are not strongly E3S related.
3. I do recognise the potential benefits highlighted by the RP, including standardisation and the ability to design to facilitate EIMT at the outset. If these can be proven they will contribute significantly to the E3S case.
4. Based on my own assessment of the RP’s submissions (refs [32], [33] and [34]), and cognisant of the RP’s view on potential impacts, I have identified the following areas which I judge to be the most relevant from a design and E3S case perspective:

* The novelty of some aspects of the MKoP may challenge application of relevant codes and standards (as per SAP ECS.3 (ref. [7])). This may be important for those aspects which are being used in a novel way, or where there are multiple demands. The RP has started to identify some of the key codes and standards it will use, and these are common industry standards, but the details of how they will be applied and what departures are not yet clear.
* The RP’s intention is to use standardised designs for the frames, barriers and fittings (wherever possible) which will be designed to meet bounding requirements. This means that once substantiated, the RP intends to use the standard MKoP elements throughout the plant. This has obvious efficiencies, but does require a suitable bounding case to be identified, justified and demonstrated, and will mean that some elements are “over engineered” for their application. This is demonstrated by the assumption that the frames will perform a category A safety function, and therefore be class 1 structures.
* Whilst segregation between divisions of safety systems is claimed to be achieved by the layout, with the civil structures providing the principle barrier, segregation within individual clusters or blocks will be realised using the MKoP internal barriers. This may require the barriers to provide protection to bounding cases for multiple hazards.
* The MKoP frames and barriers provide the main structures inside the reactor island which contains all of the plant SSCs. The structural performance and analysis of these will therefore be key to underpinning their adequacy. This includes under internal or external hazard loading conditions, such as for fire withstand or during a seismic event. The RP has undertaken some initial analysis of the MKoP frames, which shows that the concept is feasible. I have not assessed this analysis, but take comfort that the RP recognises this work is needed and has confidence that a case can be made.
* The SSCs inside the MKoP frames will also need to be able to meet the seismic requirements placed on them. Whilst the demonstration of this should be normal business for the RP as part of its engineering activities, whether the MKoP changes any of these requirements or what is required for their substantiation is unclear.
* The use of a modular systems implies that there will need to be arrangements and processes to manage the interfaces and connections between individual frames, clusters or blocks. This includes all of the SSCs that span across these, including fluid systems, HVAC, electrical and C&I systems. This also includes how the alignment and tolerance between SSCs will be achieved and how this interfaces with the civil structures. The RP has not yet specified how this will be achieved.
* There will be the need to undertake EIMT of the MKoP frames and barriers during their lifetime (as per SAP EMT.1 (ref. [7])), and to consider their ageing and degradation (as per SAP EAD.1 (ref. [7])). As with other aspects of the Rolls-Royce SMR design, and given the maturing design, what is needed and how this can be achieved is still to be defined. One of the more significant benefits of the MKoP highlighted by the RP is the incorporating of provisions to facilitate EMIT of the SSCs contained within the frames (for example, by inclusion of mechanical handling devices). Conversely, the frames themselves may present challenges regarding access, space and proximity for EMIT activities. Demonstration that EMIT can be safely undertaken is normal business, but how this interacts with the MKoP will be important to clarify.

1. I would also note that there are two aspects where the RP is making key claims on the MKoP approach, which are not entirely within the GDA Scope. These relate to factory commissioning and the importance of this being maintained before installation on site, and the transport loads experienced by the modules. These may both directly impact on the safety of the future operating plant. I will seek further clarity on the extent to which these will be considered by the RP during GDA.
2. I am satisfied that there is no reason to suggest that the aspects described above cannot be addressed by the RP. There is clear evidence of the RP considering the main hazards and requirements that need to be demonstrated, but there is little detail of what will be done. I will seek further evidence and justifications for these as the design matures.

#### Independent review

1. As part of my assessment of modularisation during Step 2 I commissioned an independent review by a TSC. The purpose of this review was to provide advice to the Regulators on aspects of the RP’s approach to modularisation that may be of regulatory significance and merit further scrutiny during Step 3. At the time of writing, this review remains ongoing. However, the initial summary (ref. [54]) is consistent with my assessment. I will factor the final outputs into assessment during Step 3.

#### Summary

1. I expect modularisation to continue to be an area of focus for the RP into step 3. Based on my assessment to date I consider:

* The degree to which the RP is applying modularisation, and the specifics of its application, are novel, not the concept in itself. Modularisation has been applied for many years outside the nuclear industry and at varying levels within the nuclear industry. A wealth of relevant OPEX exists for the RP to draw upon.
* The ambitious application of modularisation proposed by the RP will likely create challenges. Largely I would expect these to be similar to those seen in other new build projects. I am therefore content that these are normal business as part of design development and am confident that the RP should be able to resolve these satisfactorily.
* There remains a large amount of substantiation work to underpin the use of the MKoP. This includes matters relating to structural performance, seismic withstand, hazard barrier justification, management of interfaces and connections, and EIMT. Given this is integral to many areas of the E3S case the RP will need to ensure it has appropriate control and oversight, and close working practices embedded. The RP recognises this, has plans in place to do so and has provided reassurances that this can be achieved.
* Improvements will be necessary to the E3S case for modularisation, to justify the relevant impacts, and to focus on the E3S implications including the overall justification and ALARP demonstration. I have seen progress on this during Step 2, and have confidence this will continue.

1. Overall, based on my assessment to date, I judge that the RP should be able to demonstrate that modularisation of the generic design will be compatible with maintaining adequate safety, security and safeguards. The RP has also highlighted a number of potential benefits in its approach from an E3S case perspective which, if they can be substantiated, would provide strong justifications for the adoption of modularisation.

### Approach to demonstrating risks are reduced to ALARP

1. Requirement [2.4] of Guidance to Requesting Parties (Ref. [10]) expects the RP to submit to ONR a demonstration that the proposed design is likely to reduce safety risks to ALARP. Similarly, requirement [2.11] c. expects the RP to submit methodologies and approaches which form part of this demonstration; in this case how the RP will provide a convincing demonstration that relevant risks are reduced to ALARP and that there are no further reasonably practicable improvements that can be made.
2. The important context for the assessment undertaken during Step 2 is that the judgement is not whether risks have indeed been demonstrated to be reduced to ALARP, rather that the RP has adopted methodologies and approaches which will allow them to do so in due course as the design matures and evidence is substantiated. The judgement on whether the RP has demonstrated that the generic design reduces risks ALARP will be taken at the end of Step 3.
3. Chapter 24 of the E3S case (ref. [5]) provides the tier 1 summary of how the RP considers it has reduced risks to ALARP based on the extant E3S case information available at that time. It is high-level, given it is a summary and many of the references are to other chapter of the E3S case. It does however, contain information on the approach adopted by the RP to include considerations of ALARP within its design processes and E3S case development.
4. The main claim made within chapter 24 is that the “design permits construction, commissioning, operation, maintenance and decommissioning with risks and exposures reduced to ALARP”. I am content that the claim does cover both nuclear and conventional safety without this being mentioned explicitly.
5. The principal reference to chapter 24, and cited within the E3S Case Route Map (ref. [24]), is the ALARP summary report (ref. [26]). This report is based upon the RP’s internal Reference Design seven (RD7) design milestone and is therefore consistent with the design reference presented in DRP1 (ref. [23]).
6. The RP recognises that this summary report represents a view on achieving an ALARP design at that point in time. It is therefore limited in both the claims it can make in terms of the demonstration of ALARP and the supporting evidence that can be cited. This is primarily a function of design and E3S case maturity. This report itself concludes that the generic design is capable of reducing risks to ALARP, but that further work is required to demonstrate this. The RP commits to update it alongside the design and E3S case, with the intention that it will ultimately summarise the full demonstration that risks are reduced to ALARP. As a submission for assessment during Step 2, and as a future intention for GDA, I consider this approach reasonable.

#### Approach to demonstrating that risks are reduced to ALARP

1. The RP’s approach to demonstrating risk are ALARP is described in both chapter 24 (ref. [5]) and the ALARP Summary Report (ref. [59]). The described methodology is based on the RP’s optioneering and decision making processes, which form part of its integrated management system. The main attributes are consideration of RGP and OPEX, design optioneering, risk assessment, and implementation of improvements. This means that, at the SSC level, the RP claims that the design is aligned to RGP and OPEX, designed to codes and standards according to their safety classification, and alternative options were considered and selected based on assessment against relevant E3S criteria. This approach is also included within the RP’s E3S Requirements and Analysis Arrangements (ref. [28]).
2. The approach is thorough and addresses the main features I would expect for ALARP, as described in the ALARP TAG, NS-TAST-GD-005 (ref. [18]). As processes these are satisfactory. These cover both new and ongoing design work and include the requirement to consider options (or collection of options) to identify what is reasonably practicable, that give the best safety benefit, and make this consideration transparent. I am therefore content that the RP’s methodology gives it the opportunity to demonstrate why its decisions represent the ALARP option.
3. Importantly the RP recognises that ALARP is not a discrete piece of work, and it needs to be applied throughout the design and embedded throughout the E3S case. As a UK based organisation, the RP is already familiar with the ALARP principle, and it is demonstrably a key factor in its design approach.
4. The RP also recognises the iterative nature of the design and analysis, identifying that deterministic, probabilistic, hazards, human factors, radiation protection and conventional safety analysis all have a role. This includes the analysis influencing the design and demonstrating that relevant targets and objectives are met. At DRP1 the maturity and scope of each of these analyses differ. There remains a possibility that the design will need to change as the analysis updates. The likelihood and significance of this reduces as the design matures. The RP’s current view is that they have confidence that the current analysis is sufficient to show that the safety functions can be delivered by the design, and therefore significant design changes are considered unlikely. I consider this possibility cannot be excluded, but it is positive that the RP acknowledges this and has prioritised its work to minimise this outcome.
5. I would note that, to date, identification and consideration of RGP and OPEX, is limited in the submissions made during Step 2. As a key part of the RP’s ALARP process I would expect this to improve as the E3S case matures. This will form an important part of ONR’s judgements of whether risks associated with the design are reduced to ALARP.

#### Integration with other purposes

1. It is important that the ALARP process also consider the impacts on other drivers such as Secure by Design (SbD) or the use of Best Available Techniques (BAT). For the E3S informed approach adopted by the RP this should drive a combined ALARP, BAT, SbD and safeguards by design approach to ensure all E3S aspects are considered and any potential conflicts are managed through the design process. I am satisfied that the RP’s approach to ALARP ensures that other relevant purposes are considered. I would expect to consider examples where such conflicts exist, and how these have been resolved, during Step 3.

#### Current position on whether risks are reduced to ALARP

1. The RP had already taken key and fundamental design choices before entering GDA. It is claimed these have safety benefits. The ALARP summary report (ref. [26]) provides a narrative and justification for how significant design choices were made, what factors were taken into consideration, and how the final position is consistent with the ALARP principle. I have not formed a regulatory view on the outcome of these decisions, but they clearly demonstrate the successful application of the RP’s ALARP process to the design.
2. I note that the ALARP summary report, almost universally, does not indicate the detriments associated with the chosen options. It is rare to have such optioneering without having to balance benefits and detriments, and the RP’s process does require this balancing to be considered and documented in the lower level tier 3 decision files. I would expect the ALARP summary report to include evidence to show how important detriments are being resolved as part of the design and E3S case. I consider this to be a consequence of the report being a summary. I will follow up on this in Step 3.
3. The RP concludes that the generic design is capable of reducing risks to ALARP, but that the RP needs to complete further work to demonstrate this. Based on evidence to date, I agree with this conclusion. The RP has committed to further updates alongside the design and E3S case, with the intention that it will ultimately summarise the full demonstration that risks are indeed reduced to ALARP. I am satisfied with this position for Step 2.

#### Summary

1. The key duty in Great Britain (GB) health and safety legislation is for dutyholders to demonstrate that risks have been reduced to ALARP. This is also part of the RP’s own fundamental objectives for what the E3S case will demonstrate for its design. My assessment have given me confidence in the RP’s approach to address this duty. I am satisfied that the RP intends to present evidence in the E3S case that will allow ONR to make a judgement on whether it has demonstrated that the design reduces risk to ALARP during GDA.

# Conclusions

* 1. Conclusions

1. This report presents the Step 2 project assessment for the GDA of the Rolls-Royce SMR design. The focus of my assessment in this step was towards the fundamental adequacy of the design and safety, security and safeguards case. I have assessed the tier 1 E3S chapters and relevant supporting documentation provided by Rolls-Royce SMR Limited to form my judgements. I targeted my assessment, in accordance with my assessment plan (ref. [11]), at the content of most relevance against the expectations of ONR’s SAPs, TAGs and other guidance which ONR regards as relevant good practice.
2. Based upon my assessment, I have concluded the following:

* The RP’s approach to development of the E3S case is ambitious, and if achieved would represent several areas of good practice. The RP has made some good progress in documenting and developing arrangements for this, including the use of a number of digital tools, and rolling these out within the wider organisation. Despite this I judge that there remains work to do to fully document the enablers for the E3S case, to ensure consistency and clarity across all the purposes and topics. This is particularly true for the CAE approach, use of requirements and the DOORS tool to inform the case, and the intent for how the “golden thread” will be documented. There does remain further work needed by the RP to fully resolve RO-RRSMR-001, but I am confident that the RP can achieve this in a timely manner during Step 3.
* I am satisfied that the RP has met requirement [2.16] from guidance to requesting parties regarding setting a DRP and establishing change management arrangements during Step 2. These represent a sound basis for controlling the design as part of Step 3 of the GDA. I expect to maintain oversight of the implementation of these processes, as the design continues to mature and changes are proposed by the RP.
* I judge that the RP should be able to demonstrate that modularisation of the generic design will be compatible with maintaining adequate safety, security and safeguards. The RP has also highlighted a number of potential benefits in its approach from an E3S case perspective which, if they can be substantiated, would provide strong justifications for the adoption of modularisation. There remains a large amount of substantiation work to underpin the use of the MKoP. This includes matters relating to structural performance, seismic withstand, hazard barrier justification, management of interfaces and connections, and EIMT. Improvements will be necessary to the E3S case for modularisation, to justify the relevant impacts, and to focus on the E3S implications including the overall justification and ALARP demonstration.
* The key duty in GB health and safety legislation is for dutyholders to demonstrate that risks have been reduced to ALARP. This is also part of the RP’s own fundamental objectives for what the E3S case will demonstrate for its design . My assessment have given me confidence in the RP’s approach to address this duty. I am satisfied that the RP intends to present evidence in the E3S case that will allow ONR to make a judgement on whether it has demonstrated that the design reduces risk to ALARP during GDA.

1. Overall, based on my assessment to date, and subject to the provision and assessment of suitable and sufficient supporting evidence, I have not identified any fundamental shortfalls that could prevent ONR permissioning the construction of a power station based on the generic Rolls-Royce SMR design.
   1. Recommendations
2. My recommendations are as follows:

* Recommendation 1: ONR should consider the outcomes from my assessment as part of the decision to progress to Step 3 of GDA for the generic Rolls-Royce SMR design.

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# Appendix 1 – Relevant SAPs considered during the assessment

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| SAP No. | SAP Title |
| SC.1 | Safety case production process |
| SC.2 | Safety case process outputs |
| SC.4 | Safety case characteristics |
| SC.7 | Safety case maintenance |
| SC.8 | Safety case ownership |
| ECS.3 | Codes and standards |
| EMT.1 | Identification of requirements |
| EAD.1 | Safe working life |
| ELO.1 | Access |
| ELO.4 | Minimisation of the effects of incidents |