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| **Rolls-Royce SMR RO Resolution Plan** |

|  |  |
| --- | --- |
| RO unique Number: | RO-RRSMR-001 |
| RO Title: | Development of the generic E3S case |
| Lead technical topic: | Project |
| Related Technical topic(s) | ChemistryCivil EngineeringControl & InstrumentationConventional Fire SafetyConventional Health and SafetyElectrical EngineeringEnvironment External HazardsFault StudiesFuel and CoreHuman FactorsInternal HazardsManagement for Safety and Quality AssuranceMechanical EngineeringNuclear Liabilities RegulationProbabilistic Safety AnalysisRadiological ConsequencesRadiological ProtectionSafeguardsSecuritySevere Accident AnalysisStructural Integrity |

## Regulatory Observation Actions

***RO-RRSMR-001.A1 – E3S case strategy and forward plans***

In response to this Regulatory Observation Action, Rolls-Royce SMR Ltd should:

Document the on-going development of the E3S case in a defined development strategy that has a clear an unambiguous definition of the scope, content and development of the E3S case aligned to the various project milestones (design and GDA related) as it matures throughout GDA, with defined forward plans for aspects which require further development.

**Rolls Royce SMR Resolution Plan for RO-RRSMR-001.A1**

In response to this action, Rolls-Royce SMR will submit three overarching documents that will collectively describe the set of arrangements for how the generic E3S Case has been and is being further developed and managed to support the evolving design, for the remainder of GDA Step 2 and Step 3:

* Regulatory Affairs Functional Manual
* E3S Case Development and Management Arrangements
* E3S Requirements and Analysis Arrangements

The documents will encompass a suite of relevant information that has previously been shared with the regulators through GDA submissions during Step 1 and Step 2 to date. They will also incorporate information that has been shared through Regulatory engagements, including the Level 4 MSQA, project and topic meetings. A mapping of each of the three documents to relevant previous submissions is presented in Table 1, aligned to the regulatory expectations set out for RO-RRSMR-001.A1.

Additional information from ongoing work will also be incorporated into each document to provide further clarity and evidence for resolution of RO-RRSMR-001.A1; a description of the additional information to be incorporated is summarised below for each document.

The three documents will be submitted to the regulators in accordance with the plan in Schedule 1.

Regulatory Affairs Functional Manual

The ‘Regulatory Affairs Functional Manual’ provides the overarching organisational arrangements for the Regulatory Affairs function which performs the development, management, and oversight of the E3S Case. It will be an evolution of the E3S Management Manual, SMR0001328, which was previously submitted during GDA Step 1.

The updated manual will reflect the current organisational arrangements related to development and management of the E3S Case (amongst other activities), including roles, responsibilities, and interfaces for Regulatory Affairs (and combined E3S functions) and engineering. It will include further details of the arrangements to specify, control, and manage the supplied roles and services to fulfil the role of Intelligent Customer. It will also refer to the internal audit arrangements and project and quality metrics being applied to measure, review and control the progress and quality of E3S Case outputs.

E3S Case Development and Management Arrangements

The ‘E3S Case Development and Management Arrangements’ provides detail on how the overall E3S Case is being developed, managed, and assured as the design evolves. It will be an evolution of the ‘E3S Case Development Strategy’, SMR0000627, which was previously submitted during GDA Step 1.

The updated arrangements will include additional clarity on how Relevant Good Practice (RGP) has been used to develop the E3S design principles, and how this is reflected in the E3S case. It will also expand on how Claims, Arguments and Evidence (CAE) and E3S requirements are developed and presented in the E3S case to demonstrate the golden thread, including claims decomposition and alignment to the E3S design principles, and the digital tools being used to manage them.

The arrangements will document how the E3S case is being managed as a 'live' E3S case as it evolves with the maturing design, including capturing/tracking of actions and ongoing feedback, and interface with the Manage Change Process (C3.2.1-9, submitted in March 2023). It will also document how the Tier 1 chapters of the E3S case are planned, developed and endorsed, including governance and interfaces with existing processes such as the Gated Review (GR), technical checking, and Independent Peer Review (IPR).

Further information will be provided on the role of the E3S case route map (SMR0002155, submitted in June 2023) as a tool for development and management of the E3S case, and the ongoing work undertaken by the licensing and engineering teams to provide input and assurance of the route map – an updated snapshot of the live route map will be submitted to support the RO resolution, in accordance with Schedule 1.

The arrangements will also document the design maturity at each revision of the E3S case, relating to Reference Design (RD) baselines and expected SSC and analysis maturity. The E3S case development plan for each topic area will be summarised, covering broadly:

* Scope of the topic area in relation to the defined GDA Scope (as defined in SMR0002183, submitted in October 2022), and interfaces and dependencies across the E3S Case
* Summary of E3S procedures that inform the design and how their application will result in arguments and evidence to underpin the E3S case, with reference to the ‘E3S Requirements and Analysis Arrangements’
* Summary of what information will be submitted during GDA timescales, and the high-level claims it will underpin, with reference to the E3S case route map for detail
* Summary of the anticipated content and maturity of information during GDA timescales, with reference to the GDA scope & submission plan for the topic, submitted in January 2023\*
* Reference to the GDA schedule for detail of when the information is expected to be submitted during GDA timescales\*

*\*noting the GDA Step 3 scope and submission plans and schedule are still to be developed*

E3S Requirements and Analysis Arrangements

The ‘E3S Requirements and Analysis Arrangements’ provides the holistic description of how each E3S topic area is influencing the design development, for example (but not limited to), by defining requirements and providing feedback from analysis into the design as it matures.

The ‘E3S Requirements and Analysis Arrangements’ will provide an overview of, and reference to, the supporting procedures for each organisational topic area, describing how they are integrated into the engineering processes, including the design optioneering and Definition Review (DR) process for Structures, Systems and Component (SSC) design development.

Many of the supporting procedures have previously been submitted to the regulators, either through processes, methodologies, or strategies as listed in Table 1, noting some of the procedures are being updated to achieve a greater degree of standardisation.

Rolls-Royce SMR expect that the ‘E3S Requirements and Analysis Arrangements’ submission together with thee ‘E3S Case Development and Management Arrangements’ and ‘Regulatory Affairs Functional Manual’ will provide a sufficient level of evidence to support resolution of the RO. However, if the development of the ‘E3S Requirements and Analysis Arrangements’ identifies the need for a significant revision of a supporting procedure, or the need to develop an additional procedure that contains information pertinent to the resolution of the RO, then that procedure will also be submitted within a suitable timeframe (to be agreed with the regulators at the point it is identified).

Table 1

| **Regulatory Expectations for RO-RRSMR-001.A1**  | **Overarching Document** | **Relevant Information Previously Shared**  | **Document Number** | **Date Shared** |
| --- | --- | --- | --- | --- |
| Information on the objectives, scope and purpose for the overall E3S case and how this will be cascaded into individual documents at all levels of the E3S hierarchyThe definition of the architecture of safety case documentation, demonstrating how the different levels and types of documentation, and the arguments and evidence contained therein, will be produced and linked together to cover the full scope, interactions and content of the E3S caseHow learning from previous safety case experience, and relevant national and international guidance, has been incorporated | E3S Case Development & Management Arrangements | E3S Case Chapter 1: Introduction  | SMR0004294 | Mar-23 |
| E3S001 E3S Case Technical Topic Level 4 Kick-off Meeting | SMR0007778 | Sep-23 |
| Rolls-Royce SMR GDA Scope Report  | SMR0002183 | Oct-22 |
| Project L3 Meeting: GDA Scope | SMR0001604 | Aug-22 |
| E3S Case Development Strategy Issue 1  | SMR0000627 | Aug-22 |
| Regulator Briefing: Requirements Management in DOORS  | SMR0004075 | Jan-23 |
| Project L4 Meeting: E3S Case Strategy | SMR0006531 | Jun-23 |
| E3S002 E3S Case Technical Topic Level 4 CAE Meeting | SMR0008032 | Sep-23 |
| How the E3S case maintains alignment with the developing design, including the arrangements for definition and control of the Design ReferenceThe means to ensure that the E3S case remains consistent with, and comprehensively addresses the agreed GDA ScopeHow the E3S case is used to inform and influence the design, and vice versaHow the development of the E3S case is linked to other key Rolls-Royce SMR engineering processes, such as requirements management and the gated definition reviewsThe integration of the overall strategy with any secondary strategies, such as those which may be produced at a topic, system or process level | E3S Case Development & Management Arrangements | Engineering Management Plan for RR SMR | SMR0000520 | Oct-22 |
| Engineer Safe, Secure, Safeguarded and Environmentally Sound Products Process | C3.2.2-3 | Aug-22 |
| Definition Review Process | C3.2.1-2 | Nov-22 |
| Conduct Design Optioneering (Live process) | C3.2.2-2  | Aug-22 |
| Decision Record Template  | TS-DD-02-SMR | Dec-22 |
| E3S Case Chapter 1: Introduction  | SMR0004294 | Mar-23 |
| Design Overview Report (Section 2) | SMR0000594 | Jun-22 |
| Rolls-Royce SMR Maturity Status of SSCs | SMR0007438 | Aug-23 |
| E3S001 E3S Case Technical Topic Level 4 Kick-off Meeting | SMR0007778 | Sep-23 |
| L4 Project & Technical Progress Meeting | SMR0008020 | Sep-23 |
| Project L4 Meeting: E3S Case Strategy | SMR0006531 | Jun-23 |
| Project L4 Meeting: Clarification of design decision making process and E3S interface | SMR0004209 | Jan-23 |
| E3S001 E3S Case Technical Topic Level 4 Kick-off Meeting | SMR0007778 | Sep-23 |
| How the development of the E3S case is linked to other key Rolls-Royce SMR engineering processes, such as requirements management and the gated definition reviewsThe integration of the overall strategy with any secondary strategies, such as those which may be produced at a topic, system or process level | E3S Requirements & Analysis Arrangements | Design for Conventional Safety Process | C3.2.2-4 | Nov-22 |
| Rolls-Royce SMR Deterministic Safety Case – Methodologies | SMR0000531 | Oct-22 |
| Rolls-Royce SMR Environment, Safety, Security and Safeguards Categorisation and Classification Method | SMR0006518 | Jul-23 |
| Identification of Environment Protection Functions and Environment Protection Measures | SMR0005548 | Jul-23 |
| Severe Accident Management Strategy | SMR0005258 | May-23 |
| PSA Development Strategy | SMR0004735 | Mar-23 |
| Vital Area Identification & Categorisation Methodology | SMR0006499 | Jun-23 |
| Cyber Security Risk Assessment & Methodology | SMR0006431 | Jun-23 |
| Categorisation for Theft Methodology | SMR0006854 | Jul-23 |
| Radiation Protection Guidelines for the RR SMR | SMR0001861 | Feb-23 |
| Hazard Identification Strategy | SMR0001228 | Jul-23 |
| Internal Hazards Strategy | SMR0005529 | Apr-23 |
| Site Fire Strategy | SMR0005825 | Jun-23 |
| SMR Construction (Design and Management) Strategy for Generic Design | SMR0006005 | May-23 |
| Combined External Hazards Methodology  | SMR0005917 | Jun-23 |
| Approach for the Demonstration of Optimisation through Application of BAT  | SMR0004683 | Mar-23 |
| The definition of what work still remains to be done, either in design or E3S case justifications, and the documentation of this into clear forward action plans | E3S Case Development & Management Arrangements | Rolls-Royce SMR GDA Scope Report  | SMR0002183 | Oct-22 |
| GDA Scope & Submission Plans for each topic area | Various | Jan-23 |
| L4 meetings for each topic area, discussing how gaps in Issue 1 of the E3S Case will be addressed through GDA and expected maturity  | Various | Various |
| Rolls-Royce SMR Maturity Status of SSCs | SMR0007438 | Aug-23 |
| E3S Case Route Map | SMR0002155 | Jun-23 |
| E3S001 E3S Case Technical Topic Level 4 Kick-off Meeting | SMR0007778 | Sep-23 |
| The integration of digital tools, used to aid the production of the case and design, into the strategy and development | E3S Case Development & Management Arrangements | E3S Case Development Strategy Issue 1 | SMR0000627 | Aug-22 |
| E3S001 E3S Case Technical Topic Level 4 Kick-off Meeting | SMR0007778 | Sep-23 |
| How progress will be measured, reviewed and controlled and how the success (in terms of adequacy, quality, suitability etc.) of the outputs will be measured | Regulatory Affairs Functional Manual | - | - | - |
| Clear identification and definition of technical, design and E3S interfaces, and a description of how they are being effectively managed | Regulatory Affairs Functional Manual | E3S Management Manual | SMR0001328 | Aug-22 |

***RO-RRSMR-001.A2 – E3S processes, governance and oversight***

In response to this Regulatory Observation Action, Rolls-Royce SMR Ltd should:

Demonstrate the adequacy of their organisational arrangements to support the development of the E3S case for GDA. This should include roles and responsibilities, relevent processes, governance and oversight of the case.

**Rolls-Royce SMR Resolution Plan for RO-RRSMR-001.A2**

The three overarching documents described for resolution of RO-RRSMR-001.A1 will also document the arrangements relevant to RO-RRSMR-001.A2. The three documents will describe and refer to many of the submissions and processes that have been shared with the regulators during GDA Step 1 and Step 2 to date through the MSQA topic area. A mapping of each of the three documents to relevant previous submissions is presented in Table 2, aligned to the regulatory expectations set out for RO-RRSMR-001.A2. Additional information from ongoing work will also be incorporated, as summarised in the description for each document above.

To demonstrate the adequacy of the arrangements, the Rolls-Royce SMR Nuclear Assurance team will perform an internal inspection of the deployment of the arrangements, to form an independent view on whether the revised suite of arrangements are suitable and sufficient to enable production of fit-for-purpose E3S Case Tier 1 chapters at Issue 2 and beyond. The inspection will also sample the deployment and implementation of the arrangements across Rolls-Royce SMR personnel using them, to provide assurance to the Head of Regulatory Affairs that the ownership and accountabilities required by the arrangements is embedded. A report on the findings of the independent internal inspection will be issued to the Head of Regulatory Affairs, this report will also be submitted to the regulators for information in accordance with the plan in Schedule 1.

During GDA Step 2, the licensing and technical leads for each topic area have been working closely with the E3S case manager and authors to increase understanding of the arrangements for E3S informed design and their relation to the E3S Case development arrangements. This has included input and assurance of the E3S Case Route Map and associated claims, arguments, evidence (CAE), to confirm the information represents an appropriate decomposition of the E3S design principles related to their topic, and that the initial arguments/evidence presented shows an appropriate trajectory towards a final, fully evidenced E3S Case as far as their topic is concerned. An updated snapshot of the live route map will be submitted to support the RO resolution, in accordance with Schedule 1. Training on application of Best Available Techniques (BAT) in the design has been developed as a formal training module on the Rolls-Royce SMR Integrated Management System (IMS), and has been delivered to E3S and engineering teams. Similar topic-specific training has been developed for Radiation Protection ALARP in the design, which is planned to be delivered to E3S and engineering teams towards the end of 2023 and through 2024. Internal briefings have also been delivered to E3S case authors on the use of digital tools adopted to manage the E3S case as the design evolves.

Following submission of the arrangements, an internal briefing session will be held with each topic area, including technical leads, licensing leads, and other personnel involved in development of the E3S Case for that topic, to ensure ownership, accountabilities and responsibilities set out out in the arrangements are fully understood. This will be undertaken in line with the plan in Schedule 1.

During GDA Step 2, Level 4 topic meetings have been held across topic areas to brief regulators on the development of the E3S Case and how ‘gaps’ in Issue 1 of the E3S Case will be addressed through Step 2 and Step 3, including use of the E3S Case Route Map and Scope and Submission Plans to document the forward plan and trajectory of evidence. Briefings will continue to be held internally and to the regulators in Level 4 topic meetings for topic areas as necessary, in accordance with the plan in Schedule 1.

RR SMR will then facilitate a regulator intervention to assess the adequacy of the implementation of the arrangements on the in-flight revison of the Tier 1 chapters of the E3S Case at Issue 2, in accordance with the plan in Schedule 1.

Table 2

| **Regulatory Expectations for RO-RRSMR-001.A2**  | **Overarching Document** | **Relevant Information Previously Shared** | **Document Number** | **Date Shared** |
| --- | --- | --- | --- | --- |
| Organisational arrangements, roles and associated responsibilities and authorities related with the development of the E3S case | Regulatory Affairs Functional Manual | E3S Management Manual | SMR0001328 | Aug-22 |
| Organisational Capability Report | SMR0004127  | Feb-23 |
| Arrangements for how the E3S Case is being managed as it evolves alongside the design, by individuals with authority and influence  | E3S Case Development & Management Arrangements | Manage Change Process | C3.2.1-9 | Mar-23 |
| Change Management Guidance | SMR-GDN-071 | Mar-23 |
| Identifying, recording and tracking GDA and Licensing Assumptions and Commitments | SMR0002119 | Oct-22 |
| E3S Case Route Map | SMR0002154 | Jun-22 |
| Arrangements to ensure that suitably qualified and experienced E3S Case professionals are used to provide advice on and support development of the E3S Case at all levels within the RPAny training undertaken / planned to authors or other individuals who have a role in producing the E3S case | Regulatory Affairs Functional Manual | Organisational Capability Report | SMR0004127  | Feb-23 |
| Identify and Manage Core Capability | S1.1.5-1 | Apr-23 |
| Develop Competence Framework Process | S1.1.4-1 | Oct-22 |
| Assess Competence Process | S1.3.1-1 | Oct-22 |
| Undertake training and evaluation Process | S1.3.2-1 | Oct-22 |
| Arrangements which provide governance of the E3S case outputs, including how they are planned and undertaken to ensure they deliver appropriate E3S outcomes | E3S Case Development & Management Arrangements | Engineering Management Plan for RR SMR | SMR0000520 | Oct-22 |
| E3S Management Manual | SMR0001328 | Aug-22 |
| E3S Document Categorisation Guidance | SMR0001175 | Aug-22 |
| Manage engineering activity | C3.2.1-1 | Jun-23 |
| Develop Integrated Assurance Programme | S2.3.1-1 | Jan-23 |
| Conduct Assurance Activity | S2.3.2-1 | Jan-23 |
| Any independent or peer review activities and processes that may be employed | Regulatory Affairs Functional Manual | IPR Batch 1 Position Report | SMR0004844 | Mar-23 |
| How E3S processes are linked to associated engineering activities, including the defined gated review process | E3S Case Development & Management Arrangements | Engineering Management Plan for RR SMR | SMR0000520 | Oct-22 |
| Engineer Safe, Secure, Safeguarded and Environmentally Sound Products Process | C3.2.2-3 | Aug-22 |
| Definition Review Process | C3.2.1-2 | Nov-22 |
| Conduct Design Optioneering (Live process) | C3.2.2-2  | Aug-22 |
| Decision Record Template  | TS-DD-02-SMR | Aug-22 |
| E3S Case Chapter 1: Introduction  | SMR0004294 | Mar-23 |
| Design Overview Report (Section 2) | SMR0000594 | Jun-22 |
| Rolls-Royce SMR Maturity Status of SSCs | SMR0007438 | Aug-23 |
| E3S001 E3S Case Technical Topic Level 4 Kick-off Meeting | SMR0007778 | Sep-23 |
| L4 Project & Technical Progress Meeting | SMR0008020 | Sep-23 |
| Project L4 Meeting: E3S Case Strategy | SMR0006531 | Jun-23 |
| Project L4 Meeting: Clarification of design decision making process and E3S interface | SMR0004209 | Jan-23 |
| E3S001 E3S Case Technical Topic Level 4 Kick-off Meeting | SMR0007778 | Sep-23 |
| How any third-party inputs for the E3S case will be specified, controlled, managed and integrated | Regulatory Affairs Functional Manual | Evaluate Capability of the Supplier | S4.3.1-1 | Mar-23 |
| Supplier Approval and Surveillance Procedure | S4.3.2-1 | Mar-23 |
| Monitor and Evaluate Supplier Performance | S4.7.1 | Mar-23 |

## Schedule 1

###  Schedule 1, timeline of RO from issue to closure.

## Impacted Submissions

### Table 3 lists the submissions on the Master Document Submission List (MDSL) that will be impacted through resolution of this RO, and how they will be impacted, e.g., through new submissions.

Table 3

|  |  |
| --- | --- |
| **Existing MDSL Submission** | **Impact** |
| E3S Management Manual (SMR0001328) | Replaced with new document: Regulatory Affairs Functional Manual |
| E3S Case Development Strategy (SMR0000627) | Replaced with new document: E3S Case Development and Management Arrangements |

## References/Attached Documents (if applicable)

### None.

## Record of Change

|  |  |  |
| --- | --- | --- |
| **Date** | **Revision Number** | **Reason for Change** |
| 13/10/2023 | 1 | First issue of RO Resolution Plan |

## Approvals

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Author: | Sign | Print  | Role | Date  |
|  |  | E3S Case Manager | See Digital Signature |
| Reviewer | **Sign** | **Print**  | **Role** | **Date**  |
|  |  | Head of Regulatory Affairs  | See Digital Signature |
|  | **Sign** | **Print**  | **Role** | **Date**  |
| Approver |  |  | Safety & Regulatory Affairs Director | See Digital Signature |