

Rolls-Royce SMR Supplier Management System Requirements



Doc number: SMR0005223

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1 Introduction

- 1.1.1 Rolls-Royce Small Modular Reactor (SMR) is developing an affordable clean energy solution, by using proven Pressurised Water Reactor technology to deliver a fully integrated, compact, modular, factory-build nuclear power plant.
- 1.1.2 The Rolls-Royce SMR is special and unique with conformance to quality requirements critical to ensuring a safe and viable solution is achieved. The supplier must understand the consequences of their work and its applicability both to the Rolls-Royce SMR design and the achievement of a safe and reliable source of Nuclear Energy.
- 1.1.3 Rolls-Royce SMR is primarily responsible for the safety and quality of design, development, manufacture, build and commission of the Rolls-Royce SMR. The correct storage and digital integration of records is therefore paramount to Rolls-Royce SMR. To support the successful delivery of the Rolls-Royce SMR and demonstrate compliance to nuclear regulatory requirements, Rolls-Royce SMR has summarised the minimum requirements in this document related to any items, activities and services provided by its supply chain.

2 Purpose

- 2.1.1 To ensure the compliance of works produced by Rolls-Royce SMR suppliers and sub-tier suppliers, this document has been developed to flow down the core Rolls-Royce SMR quality and business requirements to all tiers of the supply chain. Rolls-Royce SMR requires its suppliers to implement, manage, and maintain adequate quality assurance management systems appropriate and consistent to the quality and safety significance of the Works being completed.
- 2.1.2 This document sets the minimum requirements, defined in a graded approach, for Rolls-Royce SMR Suppliers it does not supersede or replace any additional requirements defined in other contractual documents.
- 2.1.3 The quality assurance requirements in this document draw from but do not replace or negate the need for adherence to the requirements, if specified contractually, of:
 - BS EN ISO 9001:2015 Quality Management Systems Requirements [1]
 - Alignment to UK nuclear regulatory expectations TAG-77 [11]
 - NQA-1 quality assurance requirements [3]
 - Sub-section of ASME BPVC III Subsection NCA-4000 [5]
 - Best practise as defined in IAEA GSR Part 2 [2]
 - ISO 14001:2015 Environmental management systems [6]
 - ISO 45001:2018 Occupational health and safety management systems [7]
- 2.1.4 It is a minimum requirement that all Suppliers to Rolls-Royce SMR must operate a Quality Management System certified and compliant to ISO 9001:2015, unless agreed and approved otherwise in writing from Rolls-Royce SMR, such written approval must be secured prior to award and commencement of the Works.

3 Scope

- 3.1.1 This document applies to all suppliers and their Sub-tier suppliers permanent and temporary works, it covers the full product lifecycle and associated services. Works typically include but are not limited to, the following activities:
- Design
 - Development
 - Procurement
 - Manufacture
 - Verification
 - Packing
 - Handling
 - Transportation
 - Services
- 3.1.2 Additional requirements specific to civil construction, site installation, commissioning and decommissioning are subject to future review based on development of the Rolls-Royce SMR programme maturity.

4 Document Structure

- 4.1.1 Below is a summary of the document layout and its planned application.
- 4.1.2 Sections 5 and 6 define the applicable requirements based on the safety classification and type of work being completed.
- 4.1.3 Section 6.3, table 2 defines which requirements (detailed in sections 7 to 17) are applicable to the suppliers.
- 4.1.4 Section 18 specifies the requirements regarding change control and Section 19 specifies the Deviation, Non-conformance, and Concession requirements.
- 4.1.5 Section 20 details Abbreviations, Terms and Definitions
- 4.1.6 Section 21 Contains the document references

5 Graded Approach

5.1 Graded Approach to Quality Assurance

- 5.1.1 Rolls-Royce SMR has determined the safety classification for the Rolls-Royce SMR design Systems, Structures and Components ('SSC'), based on the categorisation or importance of safety functions and the associated consequences of any loss of those safety functions.
- 5.1.2 The level of safety classifications is determined by the Rolls-Royce SMR design team and listed as followed:
- Very High Reliability (VHR)
 - High Reliability (HR)
 - Safety Class 1
 - Safety Class 2
 - Safety Class 3
 - Non-safety classification
- 5.1.3 In conjunction with the safety classification listed above and SSC design codes requirements, consideration of the IAEA Safety Standards GSR Part 2 Leadership and Management of Safety [2] shall be applied. IAEA Safety Standards GSR Part 2 is informed by the IAEA guidance on Nuclear Management Systems in IAEA GS-G-3.5 [4].
- 5.1.4 The graded approach to quality assurance is derived from risk based and risk informed principles.

- 5.1.5 The management of the graded approach is achieved by:
 - a) Management of system requirements cascaded from Rolls-Royce SMR to the Supplier and sub-tier suppliers.
 - b) Specific quality assurance arrangement and supplier management requirements associated to the scope of works stated in the Rolls-Royce SMR contracts.
 - c) Surveillance levels determined by Rolls-Royce SMR based on design and manufacturing requirements, complexity and risk associated with their scope of works.
 - d) Surveillance level and surveillance plans specific to each contract will be notified to the suppliers. Refer to Section 9 of this document for further details.

5.2 Conformance Activities for FOAK

- 5.2.1 Supplier and Sub-tier suppliers delivering First-Of-A-Kind (FOAK) safety classification works shall carry out a process assessment to determine and identify conformance activities.
- 5.2.2 Activities shall be identified as Conformance Activities (CAs) and shall apply where the following criteria are met:

Any incorrect or inadequate execution of the related activity has the potential to impact nuclear safety;
and
subsequent planned activities will not supersede or rectify any potential errors or exposes a latent error.

- 5.2.3 Any CAs will be subject to additional technical controls as set out in controlling procedures. The supplier or sub-tier supplier shall gain Rolls-Royce SMR acceptance or approval prior to the work commencement.
- 5.2.4 Further guidance on CA can be supplied if required and when requested.

5.3 Managing Conformance Activities

- 5.3.1 The methodology applied to identify Supplier’s and sub-tier supplier’s Conformance Activities (CAs), and management of CAs and additional quality assurance arrangements to control the CAs, shall be described in the supplier’s Quality Assurance Plan (“QAP”). The QAP shall be submitted to Rolls-Royce SMR for approval. The supplier may seek guidance from Rolls-Royce SMR in determining the appropriate approach to fulfil this task or activity.
- 5.3.2 Each identified CA shall be described within a register and submitted to Rolls-Royce SMR for their written approval. CAs assessment records are also subject to Rolls-Royce SMR review upon request.
- 5.3.3 No works shall commence until the CAs register and controlling methods are accepted in writing by Rolls-Royce SMR, or it is agreed that there are no CAs associated with the scope of work.
- 5.3.4 The Supplier and sub-tier Suppliers shall provide training which includes awareness session to all personnel involved in executing, checking, and managing the CAs.
- 5.3.5 The Supplier and sub-tier Suppliers shall ensure all relevant records to demonstrate the traceability, control, and management of CAs are maintained, and such records shall be made available to Rolls-Royce SMR upon request.

6 Requirements Applicability

6.1 Types of Works Supplier undertaking

6.1.1 Table 1 below defines the supplier Type of Works (TOW) categories. This category in conjunction with the safety classification status defines the quality assurance requirements applicable to the supplier.

Table 1 Type of Works (TOW)

TOW	Description	Codes
Design and Development	Supplier is contracted to conduct design only work.	A
Make to print	Product produced to a Purchase Order and the technical requirement is cascaded from Rolls-Royce SMR to the organisation for manufacturing.	B
Design and make	Product produced to a Purchase Order and the generation of the Technical Requirement is the responsibility of the Supplier to produce. Technical Requirement shall be accepted prior to manufacture.	C
Raw material	Raw material manufactured to an agreed technical standard.	D
Stockist / Distributor	Stockist/Distributor of a raw material or product produced to an agreed technical standard and/or Purchase Order, including Commercial of the Shelf (COTS) items.	E
Service provider	A Third Party that provides a service in line with a Purchase Order for example a Third-Party Inspection Service, resource agencies.	F
	Requirement applies to all type of works listed above.	ALL

6.1.2 Supplier shall review table 1 to identify and cascade applicable requirements from table 2 based on the contracted scope of works to any sub-tier suppliers.

6.2 Notes to the Section 6.3 Requirements Applicability Table

6.2.1 Table 2 below defines the applicable quality requirements for the supplier based on safety classification implications and the suppliers TOW as defined in Table 1.

6.2.2 Two categories of requirements listed in the section 6.3 tables are originated from:

- a) Direct reference of ISO9001:2015 clauses.
- b) Rolls-Royce SMR supplemental requirements, as detailed in the section 5 to 19 of this document.

6.2.3 Two colour codes are applied to identify the following:

- a) Requirements high-lighted in **Yellow** apply to both safety classification and non-safety classification works.
- b) Requirements high-lighted in **Blue** apply to safety classification works only.

6.2.4 Note to table 2: 'Req. ID' is shorts for Requirement ID.

6.2.5 To align with the Rolls-Royce SMR supplier assessment audit programme and assist the lead auditors to recognise the relevant clauses without searching for information, requirement ID was assigned following the logic of ISO9001 standard clause's structure and extended Rolls-Royce SMR supplemental requirements.

6.3 Table 2: Requirements applicability table by Safety Classification and TOW

Req. ID	Management System Requirements		TOW
6.3.4.1	ISO9001:2015 Clause 4.1	Understanding the Organisation and its Context	ALL
6.3.4.2	ISO9001:2015 Clause 4.2	Understanding the Needs and Expectations of Interested Parties	ALL
6.3.4.3	ISO9001:2015 Clause 4.3	Determining the Scope of the Quality Management System	ALL
6.3.4.4	ISO9001:2015 Clause 4.4	Quality Management System and its Processes	ALL
6.3.4.5	Ensure suppliers' QMS addresses Rolls-Royce SMR and applicable statutory and regulatory requirements.		ALL
6.3.4.6	Identify a designated person, group or function with the authority who are not responsible for performing the work, or verifying the QMS, safety, quality, and performances of the product.		ALL
6.3.4.7	Comply with the Health, Safety and Environmental, Sustainability and other requirements specified in Section 11.1, 11.2, 11.3, 11.4 and 11.5.		ALL
6.3.5.1	ISO9001:2015 Clause 5.1	Leadership and Commitment	ALL
6.3.5.1.1	ISO9001:2015 Clause 5.1.1	General	ALL
6.3.5.1.2	ISO9001:2015 Clause 5.1.2	Customer focus	ALL
6.3.5.2	ISO9001:2015 Clause 5.2	Policy	ALL
6.3.5.2.1	ISO9001:2015 Clause 5.2.1	Establishing quality policy	ALL
6.3.5.2.2	ISO9001:2015 Clause 5.2.2	Communicating the quality policy	ALL
6.3.5.2.3	Senior management shall establish, implements, and maintains a nuclear safety and quality policy that: <ul style="list-style-type: none"> a) Is appropriate to the purpose and context of the organisation and supports its strategic direction. b) Provides a framework for setting nuclear safety and quality objectives. c) Includes a commitment to satisfy applicable requirements and continual improvement of the QMS. d) Ensure nuclear safety is not compromised by other priorities. 		ALL
6.3.5.3	ISO9001:2015 5.3	Organisational roles, responsibilities, and authorities	ALL
6.3.5.3.1	Assign an individual who is responsible for reporting on the performance of their QMS directly to Senior Management.		ALL
6.3.5.3.2	Ensure the designated person, group or function shall have enough independence from cost and schedule when opposed to safety function considerations. These verification functions shall be responsible for following: <ul style="list-style-type: none"> a) Identifying safety and quality problems. b) Ensure they have the authority to stop the producing of design and manufacturing works when issues arise, until such issues have fully resolved. c) Initiating, recommending, or providing solutions to safety and quality problems through designated channels. d) Verifying implementation of solutions. 		ALL
6.3.5.3.3	Assign an individual to implement the Safety Culture throughout the organisation in accordance with the requirements set out in Section 11.6.		ALL

Req. ID	Management System Requirements		TOW
6.3.6	ISO9001:2015 Clause 6	Planning	ALL
6.3.6.1	ISO9001:2015 Clause 6.1	Actions to Address Risks and Opportunities	ALL
6.3.6.1.1	When requested, suppliers shall establish Business Continuity Plans (BCP) that identify, analyse, evaluate and or mitigate risks related to Organisational Business Continuity according to the requirements specified in Section 11.9.		A, B, C, D
6.3.6.2	ISO9001:2015 Clause 6.2	Quality objectives and planning to achieve them	All
6.3.6.3	ISO9001:2015 Clause 6.3	Planning of Changes	All
6.3.6.3.1	Establish a documented process for change control and management.		A, B, C, D
6.3.6.3.2	Ensure senior management review, govern, and validate the change management related to QMS.		A, B, C, D
6.3.7.2	ISO9001:2015 Clause 7.1	Resources	ALL
6.3.7.1.1	ISO9001:2015 Clause 7.1.1	General	ALL
6.3.7.1.2	ISO9001:2015 Clause 7.1.2	People	ALL
6.3.7.1.3	ISO9001:2015 Clause 7.1.3	Infrastructure	ALL
6.3.7.1.3.1	Supplier and sub-tier suppliers shall comply with the applicable security measures as set out in the Section 11.7.		ALL
6.3.7.1.3.2	Supplier and sub-tier suppliers shall comply with the applicable Export Control requirements as set out in Section 11.8.		ALL
6.3.7.1.4	ISO9001:2015 Clause 7.1.4	Environment for the Operation of Processes	ALL
6.3.7.1.4.1	<ul style="list-style-type: none"> a) Maintain the workplace in a state of order and cleanliness. Inspection, calibration, storage, and repair areas appropriate with the code, product and production process required. b) Maintain a documented maintenance procedure for all equipment. c) Identify key equipment and provide resources and capacity for machine / equipment and tooling maintenance. Develop and execute an effective maintenance system. 		B, C, D, E
6.3.7.1.5	ISO9001:2015 Clause 7.1.5	Monitoring and Measuring Resources	ALL
6.3.7.1.5.1	ISO9001:2015 Clause 7.1.5.1	General	ALL
6.3.7.1.5.1.1	Instrument Calibration and Material Testing, including source material testing, must be conducted by an organisation accredited to ISO/IEC 17025; the scope of accreditation must match the scope of work being completed.		ALL
6.3.7.1.5.1.2	For other testing works, unless otherwise agreed with Rolls-Royce SMR, the organisation completing the testing shall accredited to ISO/IEC 17025, the scope of accreditation must match the scope of work being completed.		ALL
6.3.7.1.5.1.2	Supplier and sub-tier supplier shall control and manage the monitoring and measuring equipment in accordance with the requirements specified in Section 17.6.		A, B, C, D
6.3.7.1.5.2	ISO9001:2015 Clause 7.1.5.2	Measurement Traceability	ALL
6.3.7.1.5.3	Provide stamps or signatures register applied for production activities, detail the stamp holders' name, role, authorisation levels and scope.		A, B, C, D, E
6.3.7.1.6	ISO9001:2015 Clause 7.1.6	Organizational knowledge	ALL
6.3.7.2	ISO9001:2015 Clause 7.2	Competence	ALL
6.3.7.2.1	Establish and implement a competency framework to ensure the competency of all personnel, especially the personnel delivering works under Rolls-Royce SMR contract that performing activities impact safety and quality of the product and associate services. In accordance with the requirements set out in Section 12.		ALL

Req. ID	Management System Requirements		TOW
6.3.7.3	ISO9001:2015 Clause 7.3	Awareness	ALL
6.3.7.3.1	Ensure the organisation conducts indoctrination and training to all employees regarding QMS and quality assurance arrangements established to ensure the conformity of product and service, in accordance with Section 12.1.		ALL
6.3.7.3.2	Ensure the organisation conducts Nuclear Safety Culture inductions for their personnel on the significance of activities they perform which impact on nuclear safety.		ALL
6.3.7.4	ISO9001:2015 Clause 7.4	Communication	ALL
6.3.7.4.1	Demonstrate and communicate Nuclear Safety Culture throughout the organisation that: <ul style="list-style-type: none"> a) Everyone is personally responsible for nuclear safety and exhibits individual and collective commitment to protection and safety at all levels of the organisation. b) Leaders and managers demonstrate alignment on a commitment to excellence and nuclear safety, and lead by example. c) A high level of trust is established in the organisation, fostered, in part, through timely and accurate communication. d) Decision-making reflects "safety first". e) Nuclear technology is recognised as special and unique. f) A questioning attitude is cultivated. Leadership encourages a questioning and learning attitude and discourages complacency regarding protection and safety. g) Organisational learning is embraced. Means are provided by which the organisation continually seeks to develop and strengthen its safety culture. h) Nuclear safety undergoes constant examination. 		ALL
6.3.7.4.2	Supplier shall apply a communication protocol to ensure relevant stakeholders including sub-tier suppliers are well informed of any changes related to Rolls-Royce SMR contract.		ALL
6.3.7.5	ISO9001:2015 Clause 7.5	Documented Information	ALL
6.3.7.6	Document management process shall incorporate the Rolls-Royce SMR records management requirements specified in the Section 13.		ALL
6.3.7.5.1	ISO9001:2015 Clause 7.5.1	Documented Information General	ALL
6.3.7.5.2	ISO9001:2015 Clause 7.5.2	Creating/ Updating	ALL
6.3.7.5.3	ISO9001:2015 Clause 7.5.3	Control of Documented Information	ALL
6.3.7.6	Maintain a process to manage approved signatories for all applicable documentation/products: <ul style="list-style-type: none"> a) Indicate their name, role, authorisation levels, delegation levels, authorized processes, and scope. b) Maintain an active signatory list that available during design and manufacturing activities. c) Maintain records of past signatories. 		ALL
6.3.7.7	Establish a process to manage and control the manufacturing documents such as work instructions, procedures, and drawings, refer to Section 17.4 for detail requirements.		B, C, D

Req. ID	Management System Requirements		TOW
6.3.8.1	ISO9001:2015 Clause 8.1	Operational Planning and Control	ALL
6.3.8.1.1	Supplier shall participate, plan, support and conduct the surveillance activities in accordance with the requirements set out in Section 9.		ALL
6.3.8.1.2	Supplier shall provide Quality Assurance Plan outline the established Quality assurance arrangement to support the delivery of Rolls-Royce SMR contract, refer to Section 15 for detail requirements.		ALL
6.3.8.1.3	Conduct operational process risk analysis, establish risk management plan prior to the commencement of work, in accordance with the requirements set out in Section 17.1		B, C, D
6.3.8.1.4	Conduct process assessment to identify conformance activities associated with the contract scope of works and establish the CAs management plan in accordance with the requirements set out in Section 5.2 and 5.3.		A, B, C, D
6.3.8.1.5	Ensure operational planning with processes implemented to prevent CFSI as set out in the Section 17.9.		B, C, D, E
6.3.8.1.5	Control and manage the COTS item used within Rolls-Royce SMR design in accordance with the requirements set out in Section 16.15.		A, B, C, D, E
6.3.8.2	ISO9001:2015 Clause 8.2	Requirement for products and services	ALL
6.3.8.2.1	ISO9001:2015 Clause 8.2.1	Customer communication	ALL
6.3.8.2.2	ISO9001:2015 Clause 8.2.2	Determining requirements for products and services	ALL
6.3.8.2.2.1	Based on technical requirements specified in Rolls-Royce SMR contract, suppliers shall ensure, where required, that their products are compliant with UKCA regulations and CE Marking directives and supplied with the legally defined product declarations for both UK and European Markets, instruction manual and associated technical information specified in the contract to Rolls-Royce SMR for acceptance which will allow the products to be incorporated into and support the conformity assessments of Rolls-Royce SMR systems/machines. Rolls-Royce SMR reserve the right to challenge the information provided by supplier.		A, B, C, E
6.3.8.2.3	ISO9001:2015 Clause 8.2.3	Review of the Requirements for products and service	ALL
6.3.8.2.4	ISO9001:2015 Clause 8.2.4	Changes to Requirements for products and services	ALL
6.3.8.2.4.1	Manage changes related to Rolls-Royce SMR contract via change management process, in accordance with the requirements set out in Section 18.1 and 18.2.		ALL
6.3.8.3	ISO9001:2015 Clause 8.3	Design and Development of Products and Services	A, C
6.3.8.3.1	ISO9001:2015 Clause 8.3.1	General	A, C
6.3.8.3.2	ISO9001:2015 Clause 8.3.2	Design and Development Planning	A, C
6.3.8.3.2.1	Establish the design and development management processes in accordance with requirements set out in Section 16, unless otherwise specified in the contract.		A, C
6.3.8.3.2.2	Based on Rolls-Royce SMR technical requirements, the suppliers shall ensure the regulatory, legislation, and other requirements are assessed and captured during design and development works, to assure the compliance to the associated safety requirements. Implement and integrate an appropriate safety programme with the product design and development programme as specified within Section 16.4, 16.5 and 16.6.		A, C
6.3.8.3.2.3	Establish design interface process in accordance with requirements set out in Section 16.11.		A, C
6.3.8.3.2.4	Apply suitable design method in accordance with the requirements set out in Section 16.9.		A, C
6.3.8.3.3	ISO9001:2015 Clause 8.3.3	Design and Development Inputs	A, C
6.3.8.3.3.1	Design inputs shall capture the design requirements set out in Rolls-Royce SMR technical specifications.		A, C
6.3.8.3.3.2	Supplier shall communicate any applicable statutory and regulatory requirements not stated by Rolls-Royce SMR.		A, C
6.3.8.3.3.3	Material selection during design and development work in accordance with the requirements set out in Section 16.14.		A, C

Req. ID	Management System Requirements	TOW
6.3.8.3.4	ISO9001:2015 Clause 8.3.4 Design and development controls	A, C
6.3.8.3.4.1	Manage the design risk in accordance with the requirements set out in Section 16.8.	A, C
6.3.8.3.4.2	Ensure computer program use for design and design analysis is verified prior for its application in accordance with the requirements set out in Section 16.10.	A, C
6.3.8.3.4.3	<ul style="list-style-type: none"> a) Optimise the design to mitigate the risk of obsolescence. b) Identify potential Component, material, tool, or process obsolescence during conceptual design. c) Assess and mitigate risks through modular design, use of standard Components/designs, and use of low-risk component materials. 	A, C
6.3.8.3.4.4	Maintain documented procedures to validate and verify the produce design, ensure design requirements are met in accordance with the requirements set out in the Section 16.7 design validation and verification strategy.	A, C
6.3.8.3.4.5	<ul style="list-style-type: none"> a) Perform technical checking (Section 16.2) of all outputs from their Design and Development process/processes. b) Perform technical checking prior to Technical Reviews (Section 16.3). 	A, C
6.3.8.3.5	ISO9001:2015 Clause 8.3.5 Design and development outputs	A, C
6.3.8.3.5.1	Submit design data to Rolls-Royce SMR in accordance with the requirements set out in the Section 16.13.	A, C
6.3.8.3.6	ISO9001:2015 Clause 8.3.6 Design and development changes	A, C
6.3.8.3.6.1	Manage and control the design and requirement changes in accordance with the requirements set out in Section 16.12.	A, C
6.3.8.4	ISO9001:2015 Clause 8.4 Control of Externally Provided Processes, Products and Services	ALL
6.3.8.4.1	ISO9001:2015 Clause 8.4.1 General	ALL
6.3.8.4.1.1	Provide a supply chain map detailing all levels of its sub-tiers supply contributing to the Works contracted by Rolls-Royce SMR, refers to requirements set out in the Section 7.	ALL
6.3.8.4.1.2	Rolls-Royce SMR reserves the right to carry out product verification activities on all its suppliers and their sub-tier suppliers throughout the duration and fulfilment of Rolls-Royce SMR contract at all locations where works are being undertaken, refers to requirements set out in the Section 8.	ALL
6.3.8.4.1.3	Supplier shall select, manage, and monitor the sub-tier suppliers through the following controls: <ul style="list-style-type: none"> a) Assess sub-tier suppliers' capability and quality assurance arrangements against Rolls-Royce SMR scope of works for suitability and effectiveness, prior to placing the purchase orders. b) Undertaking oversight and surveillance based upon surveillance levels defined. c) Evaluate root cause activities where non-conformances occur. 	ALL
6.3.8.4.1.4	Supplier shall measure suppliers' performance: <ul style="list-style-type: none"> a) Quality of the delivered product / service. b) Customer disruptions / customer returns. c) Delivery schedule and cost performance. d) Delivery and quality of contract deliverables. e) Technical Queries, earlier warning, changes, issues, non-conformance. f) Audit findings 	ALL
6.3.8.4.1.5	Conduct load and capacity reviews with key subcontractor / sub-tier Suppliers annually or following significant load increase.	B, C, D, E
6.3.8.4.1.6	Take appropriate containment and corrective action with insufficient performing sub-tier suppliers.	ALL

Req. ID	Management System Requirements	TOW
6.3.8.4.1.6	Enlist adequate and skilled resources to undertake the sub-tier supplier's management activities including the management of special processes.	ALL
6.3.8.4.1.7	Specify the supporting documents with the purchased product or service confirming compliance to specifications.	ALL
6.3.8.4.1.8	<ul style="list-style-type: none"> a) Approve the sub-tier suppliers by conducting audit and evaluation. E.g., for sub-tier suppliers contributing works to Rolls-Royce SMR contract, audit criteria should be the applicable requirements specified within this document, Rolls-Royce SMR technical and other requirements. b) Maintain supplier audit schedule, each supplier shall be re-audit and re-evaluated within a 3-year period, supplemented by annual review which focused on set scope and key processes against their contracted scope of work. c) Apply risk approach method to determine audit schedule and audit frequency. d) Supplier shall manage and track the audit findings. Only close off the audit findings based on sufficient evidence provided by the sub-tier suppliers demonstrating the implemented improvements. 	ALL
6.3.8.4.2	ISO9001:2015 Clause 8.4.2 Type and Extent of Control	ALL
6.3.8.4.3	ISO9001:2015 Clause 8.4.3 Information for External Providers	ALL
6.3.8.4.4	Supplier shall flow down the applicable requirements and information of the Rolls-Royce contract in their procurement specification to their sub-tier suppliers. Procurement specification shall include but not limited to technical, procurement and QA requirements (specified in this standard).	ALL
6.3.8.5	ISO9001:2015 Clause 8.5 Production and Service Provision	ALL
6.3.8.5. A	Apply ITPs to manage and control the product and service realisation activities in accordance with the requirements set out in Section 17.2, unless pre-agreed by Rolls-Royce SMR this is not required.	ALL
6.3.8.5. B	Manage Rolls-Royce SMR contract in accordance with the project/ contract management requirements set out in Section 14.	ALL
6.3.8.5. C	Identify the FOAK items and activities in accordance with the requirements set out in Section 17.3.	ALL
6.3.8.5.1	ISO9001:2015 Clause 8.5.1 Control of production and service provision	ALL
6.3.8.5.1.1	Methods such as Overall Equipment Effectiveness (OEE) should be used for equipment or processes that are a constraint to output, high value, or a risk to the guarantee of on-time delivery, quality, or cost from the process.	B, C, D
6.3.8.5.1.2	Special manufacturing processes related to Rolls-Royce SMR products and services are subject to validation and verification in accordance with the requirements set out in Section 17.5.	B, C, D
6.3.8.5.1.3	Establish a process to control of equipment, tools, and software Programs applied for manufacturing activities in accordance with the requirements set out in Section 17.7.	B, C, D
6.3.8.5.1.4	Establish FME processes when required, in accordance with the requirements set out in Section 17.10.	B, C, D, E
6.3.8.5.1.5	Manage the manufacturing related documentation in accordance with the requirements set out in Section 17.4.	B, C, D, E
6.3.8.5.2	ISO9001:2015 Clause 8.5.2 Identification and traceability	ALL
6.3.8.5.2.1	Establish a method to manage the identification and traceability from raw material to end products in accordance with the requirement set out in Section 17.8.	A, B, C, D

Req. ID	Management System Requirements		TOW
6.3.8.5.3	ISO9001:2015 Clause 8.5.3	Property belonging to customers or external providers	ALL
6.3.8.5.3.1	<p>Supplier shall identify, verify, protect, and safeguard the demo, tooling, jigs, and fixtures owned by Rolls-Royce SMR and / or Rolls-Royce SMR customers (including shared ownership) in following manner:</p> <ul style="list-style-type: none"> a) Identified as Rolls-Royce SMR owned. b) Tooling register established. c) Used only for Rolls-Royce SMR applications. d) Audited annually and periodic preservation / condition checks for tooling held in storage. e) Modified only after written authorisation by Rolls-Royce SMR. f) Report any lost, damaged, unsuitable for use items. g) Disposed of only after written authorisation by Rolls-Royce SMR. h) Provide information on tooling (including photographic information) to Rolls-Royce SMR upon request. 		B, C, D, E,
6.3.8.5.4	ISO9001:2015 Clause 8.5.4	Preservation	All
6.3.8.5.4.1	<p>Preservation of product shall consider below when applicable, in accordance with Rolls-Royce SMR contract specification or referenced statutory and regulatory requirements, provisions for:</p> <ul style="list-style-type: none"> a) Limiting the access to the product to avoid undue intervention. b) Cleaning c) Implementation of FME if required, in accordance with the requirements set out in Section 17.10 		B, C, D, E
6.3.8.5.5	ISO9001:2015 Clause 8.5.5	Post-delivery activities	ALL
6.3.8.5.5.1	Supplier shall validate the transportation and packaging methods, then submit for Rolls-Royce SMR approval and acceptance prior to implementation. Unless already specified in the contract specification.		A, B, C, D, E
6.3.8.5.6	ISO9001:2015 Clause 8.5.6	Control of changes	ALL
6.3.8.5.6.1	Inform Rolls-Royce SMR in any changes related to manufacturing source and/or manufacturing methods, in accordance with the requirements set out in Section 18.2.		B, C, D
6.3.8.6	ISO9001:2015 Clause 8.6	Release of Products and Services	ALL
6.3.8.6.1	<ul style="list-style-type: none"> a) Place copy of the delivery documentation on the outside of the secondary packaging and a copy inside the secondary packaging. b) Submit the final documentation pack containing LTQR and Non-permanent Records to Rolls-Royce SMR for acceptance prior to arranging the shipment. c) Raise the shipping authorisation request prior to the shipment, and only release the shipment based on Rolls-Royce SMR acknowledgment and/or authorisation. 		B, C, D, E
6.3.8.7	ISO9001:2015 Clause 8.7	Control of nonconforming outputs	ALL
6.3.8.7.1	Where a supplier requests for a relaxation to Rolls-Royce SMR instruction, contract, and product requirements, deviation request shall be raised in advance of commencement of the works, in accordance with the requirements set out in Section 19.1		
6.3.8.7.2	<ul style="list-style-type: none"> a) Establish a method of detection and feedback of nonconformities and/or noncompliance. b) Take appropriate corrective action and perform problem solving activities to establish the root cause of the nonconformities. c) In accordance with the requirements set out in Section 19.2 d) Concession request shall be raised and approved by Rolls-Royce SMR in accordance with the requirements set out in Section 19.3 		ALL

Req. ID	Management System Requirements		TOW
6.3.9.1	ISO9001:2015 Clause 9.1	Monitoring, measurement, analysis, and evaluation	ALL
6.3.9.1.1	ISO9001:2015 Clause 9.1.1	General	ALL
6.3.9.1.2	ISO9001:2015 Clause 9.1.2	Customer satisfaction	ALL
6.3.9.1.2.1	Monitor Customer Satisfaction at all levels of the supply chain, evaluate product conformity with measures including delivery performance, customer related issues and how Nuclear Safety Culture is implemented within the organisation.		ALL
6.3.9.1.3	ISO9001:2015 Clause 9.1.3	Analysis and evaluation	ALL
6.3.9.2	ISO9001:2015 Clause 9.2	Internal Audit	ALL
6.3.9.2.1	<ul style="list-style-type: none"> a) Establish an annual internal audit to review the organisation's compliance to Rolls-Royce SMR requirements specified within this document. b) Ensure Auditor and Lead Auditors' competency, this includes the requirements of NQA-1 auditors when specified. 		ALL
6.3.9.3	ISO9001:2015 Clause 9.3	Management Review	ALL
6.3.9.3.1	ISO9001:2015 Clause 9.3.1	General	ALL
6.3.9.3.2	ISO9001:2015 Clause 9.3.2	Management review inputs	ALL
6.3.9.3.3	ISO9001:2015 Clause 9.3.3	Management review outputs	ALL
6.3.10.1	ISO9001:2015 Clause 10.1	General	ALL
6.3.10.2	ISO9001:2015 Clause 10.2	Non-conformity and Corrective actions	ALL
6.3.10.3	ISO9001:2015 Clause 10.3	Continual Improvement	ALL
6.3.10.4	<ul style="list-style-type: none"> a) Share industry experience and lessons learned (within the confines of negotiated non-disclosure agreements), regarding nuclear and industrial safety with other Nuclear Suppliers and sub-contractors to support continuous performance improvement. b) Use lessons learned and industry experience to improve quality, safety, and reliability effectively and efficiently. c) Structure methods for using lessons learned to provide applicable information to the right personnel in time to make effective decisions. d) Communicate lessons learned from internal errors or events to appropriate personnel in a timely manner to prevent any similar events, human performance errors, or problems resulting from weaknesses in processes, procedures, training, practices and system or component design. 		ALL

7 Rolls-Royce SMR Supply Chain Map

- 7.1.1 Rolls-Royce SMR will monitor the quality and performance of its supply chain where the level of surveillance shall be aligned to the Works performed by each supplier. To support the surveillance activities, the Supplier shall provide Rolls-Royce SMR with a supply chain map detailing all levels of its sub-tiers supply contributing to the Works contracted by Rolls-Royce SMR. The Supply Chain map shall detail all tiers of the supply chain including but not limited to all providers of sub-tier materials, substances, and services.
- 7.1.2 For each Sub-tier supplier, the supply chain map shall contain the following minimum content presented in a tabulated form:
- a) Legal entity and address
 - b) Name
 - c) Company registration number
 - d) Registered or head office address
 - e) Trading status
 - f) Registered VAT/ Tax number
 - g) Small and Medium Enterprises (Yes/No)
 - h) Name and address of production and/or service premises
 - i) Description of the contracted scope of works
 - j) The applicable safety classifications

8 Access for Rolls-Royce SMR and Others

- 8.1.1 Rolls-Royce SMR reserves the right to conduct audits, inspections, surveillance, and product verification activities on all its suppliers and their sub-tier suppliers throughout the duration and fulfilment of Rolls-Royce SMR contract at all locations where works are being undertaken.
- 8.1.2 The Rolls-Royce SMR's access rights detailed in this section extend to Rolls-Royce SMR customers and their customer representatives, the Regulators, Independent Third Parties Inspection Agency ('ITPIA') and Inspection Agency ('IA').
- 8.1.3 It is the responsibility of the supplier to secure Rolls-Royce SMR's access rights with its sub-tier suppliers.
- 8.1.4 Rolls-Royce SMR reserve the right to re-classify a suppliers approval status based upon ongoing reviews of their supplier's management system approval process, and all subsequent audit activities at all levels in the supply chain, if they are not ensuring that the requirements contained in this document and any other contractual document have been successfully implemented at all levels.
- 8.1.5 It is the responsibility of the supplier to notify Rolls-Royce SMR in advance of any audit, inspections, surveillance activities being undertaken, within a specified time frame, for Rolls-Royce SMR or representative to reserve the right of participation.
- 8.1.6 Access to all the supporting documentation, information, and records to demonstrate the compliance and conformity of Rolls-Royce SMR contracts.

9 Rolls-Royce SMR Surveillance of Supplier's Activities

9.1 Surveillance of supplier's activities

- 9.1.1 To ensure that safety, technical and quality assurance requirements are met, Rolls-Royce SMR will conduct surveillance and oversight of supplier's activities. Surveillance is managed by the Rolls-Royce SMR and includes where necessary Regulators and/or ITPIA oversight and endorsement.
- 9.1.2 Formal quality and process assessments and third-party audits may be utilised to confirm that the suppliers are meeting Rolls-Royce SMR quality assurance requirements.
- 9.1.3 A surveillance plan for each scope of work specified in the contract will be developed case by case based on Rolls-Royce SMR surveillance strategy, and risk informed from reviewing the safety classification, conformance activities, complexity of the design, manufacturing processes employed, supplier's risk levels and regulatory interest associated with each scope of works. Unless otherwise stated in the contract specifications.
- 9.1.4 Surveillance activities may include but are not limited to:
- Pre-contract kick off readiness review
 - Identify the Rolls-Royce SMR, Customer, Regulators, ITPIA, IA of their witness and hold points in relation to project gate review and milestones
 - SSC Verification plan, Qualification Plan, Compliance Plan
 - Detail Validation and Verification Testing
 - Surveillance of documents produced by suppliers during delivery of the Rolls-Royce SMR contract, including LTQR and Non-permanent records
 - Managing the Conformance Activities (CAs)
 - Identify the Rolls-Royce SMR, Customer, Regulators, ITPIA, IA of their witness and hold points in relation to Inspection and Test Plans ("ITPs") during manufacturing of an SSC
 - In-shop inspections, sampling
 - Supplier and Sub-tier supplier audits and site visits
 - Managing Non-conformance
 - Acceptance and Approval of the supplier's work
 - Release and authorisation of the supplier's work
 - Close off the surveillance and capture the lessons learned
- 9.1.5 To support Rolls-Royce SMR surveillance activities, the supplier shall determine and agree with Rolls-Royce SMR the management of sub-tier suppliers under their surveillance plan.
- 9.1.6 Products shall not be released for shipping and transportation without formal approval from Rolls-Royce SMR and/or it's delegated authorities. Where appropriate pre-approval for shipping can be agreed.
- 9.1.7 Further guidance can be provided if required and when requested.

9.2 Independent Third Parties Inspection Agency (ITPIA)

- 9.2.1 Rolls-Royce SMR will work collaboratively with the ITPIA and/or IA to manage activities undertaken by the suppliers and sub-tier suppliers, to ensure the technical and quality assurance requirements are met.
- 9.2.2 The surveillance plan will set out the level of ITPIA engagement with the suppliers for VHR and HR safety classification works.
- 9.2.3 Rolls-Royce SMR will appoint ITPIA to monitor and verify each suppliers' key activities to align with any hold, witness and review points defined in the supplier's Design Verification Plan, ITPs and/or other deliverables.
- 9.2.4 Suppliers and sub-tier suppliers shall implement a notification process, to ensure sufficient notice periods are given to Rolls-Royce SMR to participate in hold, witness, and review points in accordance with the contract and programme schedule, to minimize the impact on the manufacturing lead time and delivery schedules. A minimum notice period of 2 weeks is expected.

10 Rolls-Royce SMR Supplier Quality Assurance assessment programme

- 10.1.1 The quality assurance assessment scope for each supplier is based on defined safety classification, product design code and associated quality assurance requirements. The quality assurance assessment frequency defined in the assessment schedule is based on suppliers' risks, performance, complexity of the works, contract progress that are impacting safety, quality, cost, and schedule of Rolls-Royce SMR programme.
- 10.1.2 The primary reference for each supplier quality assurance assessment is this document.
- 10.1.3 Supplier shall develop a quality assurance assessment programme to manage their sub-tier suppliers, this includes auditing sub-tier suppliers against Rolls-Royce SMR contract scope of works and applicable requirements stated in this document, and other applicable quality assurance requirements to support the delivery of the safety classification works.
- 10.1.4 Supplier and sub-tier suppliers shall demonstrate the compliance to the quality assurance programme and quality assurance requirements based on applicable product design codes, effectiveness of this compliance is subject to Rolls-Royce SMR independent review during the quality assurance assessment.
- 10.1.5 Quality assurance assessments are carried out to evaluate the supplier's quality management system, manufacturing capability, planning and control of the works related to Rolls-Royce SMR contract.
- 10.1.6 Suppliers and sub-tier suppliers shall address Rolls-Royce SMR quality assurance assessment findings. Major and minor findings shall be investigated via the supplier's Non-conformance (NC) management process and closed out effectively and in a timely manner. Progress and status of these NC reports are subject for Rolls-Royce SMR review, effectiveness of improvement actions will be verified during the follow-up assessment.
- 10.1.7 Upon acceptance of suppliers' QAP, the supplier shall carry out an internal audit against the defined scope within the QAP to identify potential risks impacting the works, or opportunities for improvements. Progress and outcomes of such internal audits are subject to Rolls-Royce SMR review during the follow-up assessment.

11 Business Requirements

11.1 Health, Safety and Environmental Management System

- 11.1.1 Establish a documented Health, Safety and Environment (HS&E) Management System.
 - a) Provide evidence that the documented Health and Safety Management System meets a recognised standard. e.g., EN ISO 45001:2018.
 - b) Provide evidence that the documented Environmental Management System meets a recognised standard. e.g., EN ISO 14001:2015.
 - c) Provide Health, Safety and Environmental KPI's to Rolls-Royce SMR in including: accident frequency rate, number of major / significant incidents or near misses and any improvement notices and prohibition notices within the last 3 years. Incidents include, but are not limited to, loss of primary containment, uncontrolled discharges to land or water, uncontrolled emissions to air, spills, waste incidents, uncontrolled / unplanned disturbance in the form of noise, dust, light or other external impact, non-native species / biosecurity and ecological incidents, injuries, or deaths.
- 11.1.2 Produce a Health and Safety Plan.
- 11.1.3 Produce an Environmental Management Plan.
- 11.1.4 Comply with the relevant Health, Safety and Environment (HS&E) statutory, regulatory requirements, and any other HS&E requirements as specified in the contract documents. Including an accompanying Risk Registers / Risk Assessments / Method Statements as applicable.
- 11.1.5 Ensure that their personnel have the required safety training and are competent to undertake their required duties in a safe and efficient manner.
- 11.1.6 Ensure that supplier alerts Rolls-Royce SMR to any Nuclear, Health, Safety and Environment major incidents, breaches, or enforcement action (including but not limited to improvement notices and prohibition notices) as soon as possible. Any contact with the Health and Safety Executive, Environment Agency, or other enforcing authority regarding activities on supplier sites must be reported to Rolls-Royce SMR.

11.2 Control of Substances

- 11.2.1 Ensure that chemical constituting or contained in products supplied to Rolls-Royce SMR are not restricted or placed on watch lists under UK REACH. UK REACH is a regulation that applies to the majority of chemical substances that are manufactured in or imported into Great Britain (GB) (England, Scotland, Wales).
- 11.2.2 Provide sufficient information / data as to enable Rolls-Royce SMR to comply with its own obligations under any applicable legislation related to the use of chemicals, including that associated with hazardous materials in products.
- 11.2.3 Comply with the requirements to ensure continuity of supply when they have an obligation under any applicable legislation.

11.3 Sustainability

- 11.3.1 Supplier shall complete an Environmental, Social, and Governance (ESG) evaluation (e.g., EcoVadis) or equivalent when required and where needed develop a Specific, Measurable, Achievable, Relevant, and Time-Bound ('SMART') plan to improve this evaluation score within a reasonable time.

11.4 Environment

- 11.4.1 Suppliers shall as a minimum calculate and monitor their Scope 1 (Direct emissions) and 2 (Indirect emissions from the purchase of electricity and energy) greenhouse gas emissions, supported by a plan to actively reduce their greenhouse gas emissions and meet near and long-term targets required by our Code of Conduct, and contribute to Rolls-Royce SMR's net zero targets. Supplier shall be transparent about its greenhouse gas emissions and provide progress updates against their reduction plan upon request by Rolls-Royce SMR.
- 11.4.2 Supplier shall monitor and track its energy consumption and advancement of low carbon energy sources for their operations, industrial processes, facilities and logistics. Supplier shall be able to demonstrate continuous improvement through the identification and implementation of opportunities for energy efficiency and low carbon energy sources.
- 11.4.3 Supplier shall monitor and track water consumption generated by its operations, industrial processes and facilities and be able to demonstrate continuous improvement through the identification and implementation of opportunities to minimise water use.
- 11.4.4 Supplier shall monitor, track and take full accountability for the waste generated by its operations, industrial processes and facilities and be able to demonstrate continuous improvement through the identification and implementation of opportunities for waste minimisation and the incorporation of circular closed loop systems.
- 11.4.5 Supplier shall provide data on product packaging associated with primary, secondary and tertiary packaging and be able to demonstrate efforts to optimise the design and composition of their packaging. Minimising the packaging material that will become waste at Rolls-Royce SMR, in line with the waste hierarchy and circularity principles e.g., by utilising packaging that is reusable, biodegradable or made from non-complex materials than can be recycled locally.
- 11.4.6 Supplier shall understand the environmental impact of their products through a Life Cycle Assessment, Environmental Product Declaration or carbon analysis. Supplier shall provide data / relevant documentation when requested by Rolls-Royce SMR for the quantification and reporting of environmental impacts associated with the specific activities undertaken in the supply of goods and/or services for Rolls-Royce SMR. Such environmental indicators may include but are not limited to:
- Climate change/ carbon intensity
 - Water use
 - Minerals and metals
 - Land use
- 11.4.7 Produce improvements plans as requested by Rolls-Royce SMR to support compliance with any other environmental or sustainability requirement or expectation.
- 11.4.8 Provide details on any improvement plans or initiatives to improve environmental performance and define how those plans or initiatives will specifically address the impacts associated with the supply of goods and/or services to Rolls-Royce SMR.

11.5 Responsible Sourcing & Human Rights

- 11.5.1 Provide evidence that products and services supplied to Rolls-Royce SMR are made from materials, including constituent materials, which are sourced responsibly in accordance with the Organisation for Economic Co-operation and Development (OECD) guidelines and verified as being “conflict free”.
- 11.5.2 Flow down the requirement above to all its suppliers. The supplier must provide Rolls-Royce SMR with supporting data on their supply chain of minerals, when requested. In the event that the material “chain of custody” supplied is “indeterminable” or otherwise unknown, the supplier must commit to either attaining the appropriate certifications, or to the phase out of the material.
- 11.5.3 Produce a responsible consumption plan to demonstrate continual improvement in supply chain stewardship and the reduction of any threats associated with any activities involved in the supply of goods and/or services to Rolls-Royce SMR in accordance with achieving Rolls-Royce SMR own aspirations for responsible sourcing standards.
- 11.5.4 Complete a human rights self-assessment prior to selection and contract placement.
- 11.5.5 Ensure that supplier alerts Rolls-Royce SMR to any human rights breaches identified in supplier operations or those of its suppliers.
- 11.5.6 Provide details of any improvement plans or initiatives to improve the robust management of supply chain ethics or other threats emerging from the responsible sourcing of material, goods, and services associated with the supply of goods and/or services to Rolls-Royce SMR.
- 11.5.7 Suppliers shall not directly or indirectly procure minerals or materials that contribute to illegal deforestation, and all timber products shall be either FSC16, PEFC17 certified or equivalent, sourced from plantation or recycled timber, or licensed under the Forest Law Enforcement, Governance and Trade (FLEGT) system.
- 11.5.8 Steel and construction products should be accredited to BRE Standard BES 6001 or equivalent.

11.6 Safety Culture

- 11.6.1 Safety Culture is the core values and behaviours resulting from a collective commitment by leaders and individuals to emphasise safety over competing goals, ensuring the protection of people and the environment.
- 11.6.2 For further guidance of nuclear safety culture refer to the IAEA document INSAG 4. The principal IAEA publication on strengthening nuclear safety culture is International Nuclear Safety Advisory Group INSAG-15: which identifies the key principles for demonstrating and maintaining a strong nuclear safety culture.
- 11.6.3 The supplier should demonstrate that safety is the overriding priority and that there is collective commitment by leaders and individuals to emphasise safety over competing goals, ensuring the protection of people and the environment.
- 11.6.4 Ensure that leadership commitment to fostering the values and behaviours which identify the special nature of the nuclear sector and place an overriding emphasis on safety.
- 11.6.5 To ensure suppliers understand the importance of their works impact on safety, Rolls-Royce SMR require suppliers and sub-tier supplier to commit, develop and implement a strong safety culture which could be subject to approval assessments.

11.7 Security Arrangement & Information Management

- 11.7.1 Supplier shall comply with the Rolls-Royce SMR Supplier Cyber Security Standard [14] and ensure an Information Security governance process is in place.
- 11.7.2 Suppliers' security management system may be subject to formal review and acceptance by Rolls-Royce SMR to ensure compliance.

11.8 Export Control

- 11.8.1 Supplier shall ensure the export of documents, items, or services are in compliance with the sanction laws and regulations of export control applied in each country.
- 11.8.2 Refer to Rolls-Royce SMR Export Control policy and requirements as stated in the Purchase Order T&C.

11.9 Business Continuity

- 11.9.1 Supplier shall establish Business Continuity Plans (BCP) that identify, analyse, evaluate and/or mitigate risks related to Business Continuity, including but not limited to the following:
 - a) Product, facility, or individual's skill uniqueness
 - b) Access to alternative production facilities
 - c) Single points of failure (including sub-tier suppliers) or key processes
 - d) Remote backup of computer data
 - e) Access to alternative information technology systems
 - f) Action plans and timescales for business recovery
 - g) Contacts, process owners and procedures to follow in the event of emergency
 - h) A strategy control process to ensure periodic review of plans and their communication to all relevant personnel.
- 11.9.2 Perform a business risk assessment, the output of which will be used as part of the BCP that includes (but is not limited to) the following:
 - a) Risk identification – identify sources of risk, their cause and effects and their potential business impact
 - b) Risk analysis – consider the likelihood and level of impact of the identified risks
 - c) Risk evaluation – compare the level of risk found during the analysis process and prioritise risk treatment
 - d) Risk treatment – prepare contingency and / or mitigation plans to reduce risk levels
 - e) Monitor and review risk management activities to ensure controls are effective
- 11.9.3 Inform Rolls-Royce SMR Buyer immediately regarding the following:
 - a) Changes to third party or other party certification including lapse / withdrawal / major audit findings
 - b) Change of the nominated Quality representative
 - c) Significant change to the QMS
 - d) Change in ownership or discontinuation of business activities
 - e) Risks that could impact upon the continuity of the Suppliers business or operations
 - f) Risks with the supply of substances used in production or physical make-up of products, due to regulatory changes or otherwise.
- 11.9.4 Ensure that data related to the use of substances and mixtures that has been provided to the Suppliers by Rolls-Royce SMR is passed onto sub-tier suppliers when applicable.
- 11.9.5 Submit risk register and contingency plans to Rolls-Royce SMR upon request.

12 Competency

12.1 Job Indoctrination and Training

- 12.1.1 Suppliers shall have a training programme to ensure personnel performing or managing activities affecting quality shall receive or have received the appropriate indoctrination in their job, responsibilities and authority that includes general criteria, technical objectives, requirements of applicable codes and standards, regulatory commitments, company procedures, and quality assurance program requirements.
- 12.1.2 Create role profiles / accountabilities and provide on-the-job training for personnel performing work directly or indirectly affecting conformity to product or production process requirements, including any new or modified job, contract, or agency personnel.
- 12.1.3 Establish a documented procedure for identifying development and training needs, achievements, and review of competence of all personnel performing work directly or indirectly affecting conformity to product or production process requirements.
- 12.1.4 Indoctrination and training shall be commensurate with scope, complexity, importance of the activities, and the education, experience, and proficiency of the person.
- 12.1.5 Review education, experience, and proficiency of the person against the work they are performing.
- 12.1.6 Maintain records of indoctrination, training, and competence for a period that the employee remains within the supplier's employment, plus three (3) years.
- 12.1.7 Ensure indoctrination requirements are reviewed following any major changes to code, standards, legislation, and organisation to establish the need for indoctrination training updates.

12.2 Competence of Design and Development Personnel

- 12.2.1 For suppliers authorised by Rolls-Royce SMR to create product definitions using the design rules and standards, they shall:
 - a) Ensure design and development tasks are carried out by Suitably Qualified Experienced Personnel (SQEP) and ensure they understand the design implication aligned with the Rolls-Royce SMR design and safety classification requirements.
 - b) Ensure that verification activities are managed by an independent SQEP or group other than those who created the original design.

12.3 Competence of Inspection and Test personnel

- 12.3.1 Personnel conducting inspection and test activities, shall be trained commensurate with scope, complexity, importance of the activities. Review of their education, experience, and proficiency of the person against the scope of work shall be undertaken.
- 12.3.2 Ensure that the personnel nominated to perform Inspection and Test activities are competent, including their capability of using the monitoring and measuring equipment.
- 12.3.3 The acceptance of work shall be approved by authorised personnel who are independent from the personnel performed the task.
- 12.3.4 Ensure initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration.

- 12.3.5 Ensure job performance of Inspection and Test personnel shall be re-evaluated at periodic intervals not to exceed 3 years. Ensure any person who has not performed Inspection or Testing activities in the qualified area for a period of 1 year shall be re-evaluated.
- 12.3.6 Ensure re-evaluation be by evidence of continued satisfactory performance and/or redetermination of commensurate scope.
- 12.3.7 Ensure if during the re-evaluation or at any other time, it is determined by the responsible organisation that the capabilities of an individual are not in accordance with the qualification requirements specified for the job, that person shall be removed from that activity until such time as the required capability has been demonstrated.
- 12.3.8 Record of qualification for Inspection and Test personnel shall include the following:
- Employer's name
 - Identification of person being certified
 - Activities certified to perform
 - Signature of employer's designated Education

12.4 SQEP Register

- 12.4.1 Suitably Qualified and Experienced Personnel is an individual who has the necessary competence to perform the duties, which may affect safety, as defined as part of their role as demonstrated by their training and experience.
- 12.4.2 When requested, the supplier shall demonstrate the key personnels' competency by submitting a Suitably Qualified and Experienced Personnel (SQEP) register, listing all personnel performing works that impact safety and quality of the Rolls-Royce SMR products and services, submit this register to Rolls-Royce SMR for review along with the relevant evidence based on agreements once in place.
- 12.4.3 Typically, key personnel may include but are not limited to:
- Design engineers carrying out design activities supporting the safety case, or activities associated with safety functions of the Rolls-Royce SMR design.
 - Design engineers producing design definition that supporting the compliance to Rolls-Royce SMR specified design codes and standards.
 - Designers as defined in Construction Design and Management ('CDM') Regulations 2015 or personnel responsible for product compliance to any relevant legislation and regulation.
 - Welding engineer producing welding qualification specification and welding procedure.
 - Welders and Welding inspectors
 - QC personnel verifying products against acceptance
 - NDE personnel
 - Auditors & Lead Auditors
 - Technical and other SQEP reviewing and approving technical documents.
- 12.4.4 The relevant record of SQEP shall be submitted as part of contact deliverables when requested.

13 Control of Documented Information

13.1 Contract list of deliverables

- 13.1.1 Supplier shall manage a List of Deliverables (“LOD”) that lists all the contract deliverables in accordance with Rolls-Royce SMR contract specification.
- 13.1.2 The Supplier shall track and report the progress of contract deliverables against the project schedule to ensure on-time delivery. Rolls-Royce SMR should be notified of any changes to the deliverables and/or expected delivery dates
- 13.1.3 Any changes to the LOD shall be subject to change control process approval by Rolls-Royce SMR.
- 13.1.4 Based on the LOD, the supplier shall review the overall relevant records going to be produced during the duration of Rolls-Royce SMR contract and establish a plan to manage deliverables and associated records. This plan shall take into consideration how the records are going to be grouped into packages, and presented in an organised, structured, traceable, and logical manner, based on the Rolls-Royce SMR contractual delivery schedule. Further guidance can be provided if required and when requested.
- 13.1.5 All records shall be attributed as either Lifetime Quality Record (“LTQR”) or non-permanent records. Further guidance can be provided if required and when requested.
- 13.1.6 All contract deliverables and key supporting documents shall be written in English. Any translation of the technical information shall be verified by independent bilingual personnel with technical understanding in both languages.
- 13.1.7 The Supplier shall retain all compliance and conformity records produced within sub-tier suppliers related to Rolls-Royce SMR product and purchase orders. These records shall be included in the final documentation pack submitted to Rolls-Royce SMR for product acceptance.
- 13.1.8 All records shall include the protective marking, export control and security classification, with a statement specifying the sensitivity of the document as per Rolls-Royce SMR Marking of Business Sensitive Information Standard [13].
- 13.1.9 All records shall be correctly referenced and traceable to Rolls-Royce SMR product and purchase orders unambiguously. Marking and attributions may include but are not limited to: Rolls-Royce SMR PO or contract number, Rolls-Royce SMR unique identification, Rolls-Royce SMR placeholder document number, suppliers document numbers, document titles, document type, formats, revision status, planned delivery dates, author, reviewer and approver.
- 13.1.10 The supplier shall control any records related to Rolls-Royce SMR Purchase Orders / contracts in a manner that will allow the recovery of a readable version of any record (including digital records) within 24hrs of a Rolls-Royce SMR request.
- 13.1.11 Where features, acceptance and test data values are recorded, this shall be a digital format that allows it to be easily processed for data analyses.
- 13.1.12 Rolls-Royce SMR should have the option to review or approve all identified prerequisites deliverables such as drawings, procedures, and specifications prior to proceeding work stages commencing. Rolls-Royce SMR will specify in the technical procurement specification which deliverables shall require approval and/or which are for information only.

13.2 Documentations

13.2.1 Suppliers shall ensure their retention period labelling for Documents and Records are aligned with Table 2 unless otherwise stated in the contract specifications:

Table 2 Retention Requirements

Category	Retention Period	Requirements
A	Minimum of 10 years following withdrawal from Rolls-Royce SMR Plant decommissioned	Category A indicates the record is retained for statutory or regulatory requirements including LTQR. The minimum retention period for a Category A record relating to the lifetime of Rolls-Royce SMR power plant is ten years after the power plant is decommissioned.
B	6 years	Category B indicates the record is be retained for business requirements. The retention period for Category B records is six years however this may be adjusted based on the business requirement.

13.2.2 All documentation supplied must be delivered both in its requested state and as a digital copy, where digital copies are both traceable, searchable, and correctly indexed for ease of integration into the Rolls-Royce SMR’s digital solution.

13.2.3 Document Storage and Archiving

- a) Any paper copies of documents relevant to the Rolls-Royce SMR deliverable must also be also available digitally.
- b) Suppliers shall establish and maintain progressive records of all manufacturing processes. All records of manufacturing processes should be signed and / or stamped, and dated, or signed and dated digitally, by a person designated by the Suppliers as being responsible.
- c) Ensure records are classified as ‘A’ for retention purposes unless otherwise stated in the Product Definition.
- d) Ensure that storage, usage, and disposal of records are performed in a manner appropriate to their security classification to prevent unauthorised or fraudulent use.
- e) Suppliers are not expected unless otherwise agreed to keep records for the full retention period, however they are required to ensure that Rolls-Royce SMR has securely retained any records before deleting them from their record storage system.
- f) It is expected that once confirmed that Rolls-Royce SMR has retained the relevant records, that the supplier should keep Rolls-Royce SMR product data for no longer than the minimum required for completion of Rolls-Royce SMR contractual requirements.

13.2.4 Possible Examples of LTQR are given below:

- a) Design Reports
- b) Design Change Request
- c) Deviation list, Non-conformance reports, Concession request
- d) Conformance activities assessment and register
- e) Index of items contained
- f) Certificate of Conformance
- g) Complete Quality control plan or Shop Floor Traveller
- h) Certified Material Test Reports (CMTR) and documentation providing traceability
- i) Examination and test results, weld data sheets, and test coupon reports
- j) Heat treatment records
- k) Welding data package and procedure data sheets, Filler metals qualification, Weld repair
- l) Examination, test procedures and instructions
- m) Technical control procedures applied for Witness and Hold Points

- n) Manufacturing procedures or instructions
 - o) Calibration procedure and certificates
 - p) Overpressure Protection Report
 - q) As-built drawings
 - r) Records of any post-tensioning sequence, procedure, and loads
- 13.2.5 Rolls-Royce SMR contract specification related to product requirements are managed via supplier's document control system to ensure tracking of the application and correct revisions. E.g., technical and quality assurance specifications, definition drawings, etc.
- 13.2.6 Any hand-written amendments to records are annotated by striking through the error (leaving the original information readable) and then signing and dating (in ink) the handwritten change. Any handwritten amendments should be incorporated into the digital record as soon as practical.

14 Project Management of Rolls-Royce SMR Contracts

14.1 General

- 14.1.1 The following sections outline project management requirements associated with supplier managing Rolls-Royce SMR contracts.

14.2 Project Manager

- 14.2.1 Supplier shall assign a SQEP Project Manager to manage Rolls-Royce SMR contract.
- 14.2.2 Suppliers Project Manager shall define a project organization structure identifying stakeholders, SQEP, and responsible personnel to support the Rolls-Royce SMR contract. These roles and responsibilities shall be described in the supplier's QAP.
- 14.2.3 Ensure cross-function project team members understand their responsibility to comply with the requirements in this document.
- 14.2.4 Establish clear communication protocols within supplier's organisation and with Rolls-Royce SMR team.
- 14.2.5 Any comments and feedback made by Rolls-Royce SMR team shall be recorded to endure they are traceable to the related works and documents.
- 14.2.6 Set and maintain a project baseline, project goals and objectives that aligned with the Rolls-Royce SMR contract delivery requirements.
- 14.2.7 Ensure all SQEP and stakeholders are engaged, and their inputs are considered during the planning stage. Inclusive of technical, design, manufacturing, production planning, quality assurance and quality control, cost controller, resource availability and other functions which will support successful contractual delivery of Rolls-Royce SMR works.
- 14.2.8 Align suppliers project gate review and milestones with the Rolls-Royce SMR contract milestone requirements.
- 14.2.9 Ensure project gate readiness review are embedded within project schedule.
- 14.2.10 A Suppliers Project Manager shall ensure the full implementation of changes related to Rolls-Royce SMR contracts within their organisation.
- 14.2.11 Ensure technical query (TQ), early warnings are promptly responded and resolved.
- 14.2.12 Manage the project schedule and ensure the on-time delivery.
- 14.2.13 Work to ensure contract deliverables are right first time.

14.3 Project Planning and Control (Schedule)

- 14.3.1 Suppliers shall establish a project baseline and delivery schedule based on Rolls-Royce SMR contractual requirements, utilizing suppliers' operational experience, good practice, and lessons learnt from previous projects.
- 14.3.2 Submit a level one to level four project delivery schedule to Rolls-Royce SMR during the planning phase prior to work commencement.
- 14.3.3 Monitor, update and report the progress of the project delivery schedule in accordance with the defined reporting period specified by Rolls-Royce SMR project team.
- 14.3.4 The Project delivery schedule shall include sub-tier suppliers' activities and identify the critical path.
- 14.3.5 Any Project delivery schedule shall take into consideration the time required for reviewing and approving contract deliverables, as well as cooperating with the project gate review, technical review, data package or documentation submission, whilst incorporating sub-tier suppliers' schedules.
- 14.3.6 Manufacturing suppliers must ensure project delivery schedules indicate and take account of activities such as equipment set up, production schedule conflicts, long lead item and equipment delivery, manufacturing and QC control activities, product transportation, requests for shipping release authorisation.
- 14.3.7 Proactively identify any roadblocks in delivery of the works and report to Rolls-Royce SMR promptly to develop the appropriate resolution.
- 14.3.8 Ensure lessons learnt and continuous improvements are implemented throughout the lifetime of the project.

14.4 Project Risks

- 14.4.1 Establish a risk management process to outline how risks will be controlled during the management of Rolls-Royce SMR contracts. The risk management process should be described within the supplier's QAP.
- 14.4.2 Produce a Risk Management Plan against Rolls-Royce SMR contract requirements and submit to Rolls-Royce SMR project team. The plan shall include a risk analysis and assessment report covering cost, performance, and successful delivery of Rolls-Royce SMR contract.
- 14.4.3 Monitor, maintain and report on the Risk Management Plan to Rolls-Royce SMR project team regularly.
- 14.4.4 Monitor the project progress against latest approved project delivery schedule and identify potential delays.
- 14.4.5 Communicate any issues or high-risk items related to technical Requirements to the Rolls-Royce SMR design and development team at the earliest possible opportunity.

14.5 Project Progress Meeting

- 14.5.1 The supplier shall regularly communicate project progress and report the progress of the project to Rolls-Royce SMR, communications shall cover issues, risks, changes, queries, and non-conformance. The duration and frequency of progress meetings should be agreed prior to commencement of works and should be proportional to the work being completed. Where required additional meetings can be initiated by Rolls-Royce SMR or suppliers, a proactive approach should be promoted.
- 14.5.2 Ensure meeting minutes are accurate, appropriate, and timely, with clear recording and identification of actions, decisions, progression and contract delivery assurance.

14.6 Production Planning & Capacity

- 14.6.1 Manufacturing suppliers shall coordinate inclusion of production planning into the project schedule.
- 14.6.2 Production planning shall take into consideration of below but not limited to resource and equipment planning, procuring, order processing, operation, production schedule, material requirements, control of sub-tier suppliers' activities, control of production activities, training, qualification of key personnels.
- 14.6.3 Establish a process to plan and manage production capacity that minimum includes:
 - a) Availability of resources for labour and equipment
 - b) The impact of new product introduction / product introduction on available capacity
- 14.6.4 Resolve discrepancies between the available capacity and the demands of Rolls-Royce SMR.
- 14.6.5 Monitor the effectiveness of labour, equipment, and processes to ensure planning assumptions are accurate and enable feedback into the planning process.
- 14.6.6 Communicate the production schedule information with the sub-tier suppliers.
- 14.6.7 Review and feedback to the contract schedule requirements issued by Rolls-Royce SMR project team.

14.7 Other types of Project Review Meetings

- 14.7.1 To manage the Rolls-Royce SMR schedule and track the progress of each contract, Rolls-Royce SMR will hold periodic meetings with the supplier aligned with the defined milestones (gate review, technical review, hold and witness points, etc). These meetings should be held for every contract applies with safety classification work, although the time spent, and detail can be commensurate based on the contract and type of works applied.
- 14.7.2 These meetings are general conducted during below phases of the contract-

14.7.3 Contract Kick Off Review:

- a) Contract kick off meeting shall be hold with the suppliers and sub-tier suppliers when required, to ensure that at every level of the supply chain the contractual requirements have been understood by all parties.
- b) Ensure at every level of the supply chain that Rolls-Royce SMR's expectations and requirements have been specified in the contractual requirement. Clarify that all activities important for safety are controlled shall be carried out in accordance with the contractual requirements.
- c) Ensure the Purchase Order has been correctly interpreted by the Supplier specially the technical and quality requirements.
- d) Describe the role and responsibility of all stakeholders, includes the point of contact responsible for nuclear safety culture and managing the surveillance activities.
- e) Describe the relevant QA arrangements.
- f) Describe the record and deliverables requirements.
- g) Describe the additional inspections and verifications activities required for managing Conformance Activities.
- h) Describe the management of delivery schedules and action trackers.
- i) Where required by the contract, appoint ITPIA/ IA to support the surveillance activities.

14.7.4 Readiness Review:

- a) Prior to the work commence (e.g., prior to suppliers and sub-tier suppliers start the design and manufacturing works), readiness review meeting shall be held to ensure the effective planning are established, contract deliverables are defined, and pre-requisitions are approved and/or accepted before initiating any works.
- b) Rolls-Royce SMR will review and check suppliers' readiness as part of the surveillance plan; this includes the assessment to relevant processes and procedures.
- c) List of deliverables ("LOD") outlining the compliance trail to contract specification shall be accepted by Rolls-Royce SMR. Ensure LTQR and non-permanent records are attributed within the LOD.
- d) Identify the key deliverables that shall be reviewed and approved by Rolls-Royce SMR SQEP in preparation for the work commence.
- e) Ensure suppliers' project schedule considered all activities associated with executing Rolls-Royce SMR contracts, including the submission of contract deliverables and operational planning.
- f) Ensure all activities listed in readiness review action plan are either completed or accepted by Rolls-Royce SMR before any works commence unless agreed by Rolls-Royce SMR that open actions going to be managed otherwise.

14.7.5 Contract Progress Review:

- a) Rolls-Royce SMR project team will work with the suppliers to control, monitor, and record the contract progression, including contract related technical and other queries, issues, changes, non-conformity, deviations, concessions, risks, and opportunities.
- b) Milestones review meetings shall be arranged to assess the pass/fail criteria aligned with Rolls-Royce SMR requirements.
- c) Supplier shall submit a monthly progress report to provide executive summary of the works completed during the period, against the overall project schedule to reflect the planned, actual, and forecast.
- d) Report the contract related key performance indicators ("KPI"), including sub-tier suppliers' KPI.
- e) Report the occupational Health, Safety and Environmental statistics when requested.

14.7.6 Surveillance Plan Kick Off Meeting:

- a) Rolls-Royce SMR will engage and manage all delegations working with suppliers collaboratively to ensure surveillance plan are defined and clearly communicated between all stakeholders during the surveillance plan kick off meeting.

14.7.7 For required Definition Review, Gate Review, and Technical Reviews, please refer to Section 16 for definitions.

14.8 Other types of Readiness or Kick Off Meetings

14.8.1 When other types of readiness review, kick off or gate review meetings are required to support the wider communication and delivery of Rolls-Royce SMR contracts, this will be arranged on a case-by-case basis, which can be initiated broadly from Suppliers, or Rolls-Royce SMR Design, Technical, Manufacturing, Supply Chain or QA teams.

14.9 Project Close-off Meetings

14.9.1 Close-off meeting shall be held when, unless otherwise pre-agreed:

- a) Concluding the activities listed in the surveillance plan.
- b) To confirm completion of a purchase orders works
- c) To confirm the end of supplier's contracted period

14.9.2 Lessons learnt shall be captured during project close-off meetings, relevant lessons shall be formally captured by suppliers' and Rolls-Royce SMR to drives the continuous improvement.

15 Supplier's Quality Assurance Plan

- 15.1.1 Suppliers executing safety classification work shall produce and submit a QAP to Rolls-Royce SMR for review and acceptance. Any exception to this requirement must be pre-approved by Rolls-Royce SMR quality and project teams.
- 15.1.2 The QAP shall outline the quality assurance arrangements the supplier will apply to support the successful delivery of Rolls-Royce SMR contract.
- 15.1.3 ISO 10005 standard [15] provides further guidance on quality (assurance) plans. Rolls-Royce SMR guidance can be provided as required and when requested.
- 15.1.4 QAP shall contain the following content:
 - a) The scope of the contract
 - b) Indicate the Safety Classification applies to the contract scope of works
 - c) Roles and Responsibility of project team members
 - d) Organisation chart
 - e) QAP inputs
 - f) Quality objectives
 - g) Management responsibilities
 - h) Control of contract deliverables and QA records (including LTQR)
 - i) Management of documents and data
 - j) Resources and competency
 - k) Communications method and protocol
 - l) Design and development controls
 - m) Purchasing activities and supply chain management
 - n) Manufacturing control and management
 - o) Non-conformance management
 - p) Risk mitigation
 - q) CFSI prevention
 - r) COTS strategy
 - s) Internal Audits and Supplier audits
 - t) Deviation management
 - u) Other sectors specified within this document to be described within QAP
- 15.1.5 **Notes:** QAP can also be referred to as design QAP, manufacturing QAP, project QAP or contract QAP depending on the type of work being undertaking.

16 Provision of the Rolls-Royce SMR Products and Services

16.1 Definition Review (DR) Processes

- 16.1.1 For design, development, manufacturing, and verification activities, suppliers shall follow the Rolls-Royce SMR Definition Review (DR) processes, unless specified otherwise in the contract.
- 16.1.2 The DR process is a nine-step detailed gated review process to review and sentence the maturity of the definition at system, sub-system, and component level. The DR process is used as the key technical control process for an individual SSC delivered in line with the specified requirements, DR process also provides technical governance for the development of Rolls-Royce SMR SSC throughout the design lifecycle.
- 16.1.3 DR stages overview:
- DR0- Launch
 - DR1- Concept
 - DR2- Material Confirmation
 - DR3- Final Concept
 - DR4 -Early Manufacturing Release
 - DR5- Manufacturing Release
 - DR6- Finished Parts
 - DR7- Construction/Assembly Review
 - DR8- Handover Readiness Review
- 16.1.4 The review of DR stages is staged in line with product maturity development. A detailed description of each DR stage can be provided if required and when requested.
- 16.1.5 For each contract appropriate DR gates shall be agreed, the minimum mandated gates for each contract are: DR0, DR1, DR3, DR5, DR6, DR8.
- 16.1.6 Collaboratively, Rolls-Royce SMR cross-function project team and Supplier's project team shall embed the relevant DR processes within the contract delivery programme and manage them accordingly.
- 16.1.7 Supplier shall provide input and support to the development of the technical requirements when required.
- 16.1.8 Each DR stage is subjected for peer review and assessing against a pass/ fail criteria.
- 16.1.9 Each gate review is structured around a detailed checklist covering a broad range of areas from: Scope and requirements, Interfaces, Governance, Resource, Cost and Schedule, Quality Assurance, Engineering methods, Tools, Capability, Capacity, Product definition (technical maturity), Configuration Management, Design for X, Verification, Manufacturing and assembly, Quality Control, Supply Chain management, Information Management, IP and Export Control, Risks and Opportunities, Lessons Learned.

16.2 Gated Review, Technical checking and approval

- 16.2.1 Gated Review (GR) process is used to provide governance for a small scope of work or a standalone technical element of work. The GR process is structured around multi-stakeholder reviews and endorsement. The Supplier shall support the GR process when requested.
- 16.2.2 Supplier shall apply an appropriately SQEP technical checking and approval process to release technical information that is produced as part of engineering design activities. This process should ensure that work produced meets the safety and technical requirements and regulations.
- 16.2.3 Technical checking and approval activities include but are not limited to: calculations; analyses; data sheets; drawings; technical reports and specifications.
- 16.2.4 Ensure technical checking is performed by suitably independent SQEP.

16.3 Technical Review

- 16.3.1 Technical Reviews, checking and approvals associated with a DR gate, must be completed in advance of the DR gate meeting, to provide evidence of appropriate independent validation and endorsement of technical activity have been completed.
- 16.3.2 Supplier shall plan and agree with Rolls-Royce SMR regarding the applicability of each Technical Review to the scope of its Product's Design and Development programme throughout the Product's lifecycle.
- 16.3.3 Supplier shall define and agree with Rolls-Royce SMR the roles, accountabilities, responsibilities, deliverables, ownership, attendees, functional checklists, and agenda for each Technical Review process aligned to the standard Rolls-Royce SMR technical review process or to a specific process as stated in the project contract.
- 16.3.4 Supplier shall provide Rolls-Royce SMR with all Technical Review material one week in advance prior to the review, recognising that the complexity of the topic might require a different interval, as agreed within the programme plan.

16.4 Product Safety, Reliability, and Integrity

- 16.4.1 Plan, implement, and control the processes needed to assure product safety, reliability, and integrity, as appropriate to the organisation or product.
- 16.4.2 Ensure that processes include but are not limited to:
 - a) Hazard identification, including reactive and proactive methods.
 - b) Analysis, assessment, and control of safety, reliability and integrity, risks associated with identified hazards.
 - c) Identification and management of changes that may impact product safety, reliability and/or integrity.
 - d) Assessment of the effectiveness of safety management processes.
 - e) Ensure training on product safety responsibilities to relevant personnel.
 - f) Ensure communication of product safety information, including safety-critical information, safety events, and changes to safety procedures, as applicable.
 - g) Ensure reporting of safety events to Rolls-Royce SMR, authorities, and type certificate holder in accordance with Rolls-Royce SMR and regulatory requirements.
 - h) Retain documented information determined as being necessary for the effectiveness of product safety, reliability and/or integrity management in line with regulatory requirements.
- 16.4.3 Maintain mechanisms for the identification and resolution of all Product safety concerns. Where Product safety concerns have been identified, they shall be formally reported to Rolls-Royce SMR at the earliest possible opportunity.
- 16.4.4 Report all findings relating to the Product's safe and reliable operation, identified at any stage in the Product's lifecycle to the Rolls-Royce SMR Buyer within 24 hours of their discovery. The communication shall be titled **"NOTIFICATION OF POTENTIALLY UNSAFE CONDITION"**.
- 16.4.5 Findings relating to safety, reliability and/or integrity concerns will be welcomed by Rolls-Royce SMR. However, as the type certificate holder/Technical Approval Authority for the Product, Rolls-Royce SMR will make the final judgment on whether there is an actual risk to safe and reliable operation, where legislation permits.
- 16.4.6 Note: Where Rolls-Royce SMR considers that a risk to the Product's safe and reliable operation exists, the Supplier shall initiate customer protection measures and work collaboratively with Rolls-Royce SMR to implement necessary corrective actions to eliminate the risk.

- 16.4.7 Maintain records of all hazards identified during the Product's development and in-service lifecycle, together with details of the investigation carried out, corrective actions, verification, and their approval.
- 16.4.8 Provide all necessary information and assistance to Rolls-Royce SMR, and/or to any third parties identified by Rolls-Royce SMR, to investigate Product Safety, Reliability, and/or Integrity concerns related to or affecting the supplier's Product.
- 16.4.9 Implement any actions in relation to its Product's design, manufacture, repair, maintenance, or inspection that are considered necessary, by either the Supplier or Rolls-Royce SMR, to resolve any Product safety, Reliability, and/or Integrity concerns.

16.5 Design for Safety

- 16.5.1 Product system safety assessment shall be carried out using recognised techniques (e.g., FMECA, FTA) to identify the causes and effects of failures. The assessment shall be recorded in formal documentation which is reported and agreed with Rolls-Royce SMR. Key assumptions shall be recorded. Should any failure modes be identified which have an impact on safety, but which are not covered by the specified safety requirements, then these shall be formally reported to Rolls-Royce SMR.
- 16.5.2 Ensure the product is designed such that all the safety requirements are satisfied. Verification shall be provided for each safety requirement. Should the Supplier encounter difficulties in satisfying any safety requirement, this shall be raised with Rolls-Royce SMR at the earliest opportunity so that the implications can be considered, and a solution determined.
- 16.5.3 Apply the As Low as Reasonably Practicable (ALARP) principle in developing the Product and in satisfying the safety requirements. The Supplier shall demonstrate to Rolls-Royce SMR how the ALARP principle has been applied as part of the safety assessment.
- 16.5.4 Ensure at any events at any time that question the safety assessment or verification shall be investigated and addressed.
- 16.5.5 Ensure the safety controls needed to deliver Product safety throughout its life cycle shall be identified and reported and agreed as part of the safety documentation.

16.6 Construction Design Management (CDM)

- 16.6.1 The Supplier appointed to carry out design work must have and show evidence they have, appropriately SQEP resource, the organisational capability, and processes to meet Designer responsibilities under UK Construction (Design and Manufacture) 2015 (CDM) Regulations.
- 16.6.2 It is the Supplier responsibility to inform Rolls-Royce SMR if the supplier is unable to meet their responsibilities under CDM regulations.
- 16.6.3 Rolls-Royce SMR has the right to audit the Suppliers processes and procedures to make the determination of the Suppliers suitability to meet CDM regulations.
- 16.6.4 If the Supplier determined to be unable to meet their responsibilities under CDM regulations, then the supplier must provide an action plan with deliverable dates to meet CDM regulations.
- 16.6.5 The Supplier must take all reasonable steps to provide adequate design, installation, maintenance, and associated Designer Risk Assessment(s) so that the Client, Principal Designer, Principal Contractor, other Designers and Contractors to comply with their duties under the CDM Regulations.
- 16.6.6 CDM regulations and this section 16.6 apply both to the supplier and any of their Sub-tier suppliers regardless of whether they are UK based or not.

16.7 Design Validation and Verification Strategy

- 16.7.1 For suppliers authorised by Rolls-Royce SMR to create product definitions using the design rules and standards, suppliers shall provide a verification strategy detailing how compliance with Rolls-Royce SMR design requirements is going to be demonstrated.
- 16.7.2 The verification strategy and supporting information should be completed in accordance with the 'Rolls-Royce SMR Vendor Verification Strategy Guidance' document [Ref 12].
- 16.7.3 Submit verification strategies for Rolls-Royce SMR review and approval 2 months prior to the relevant design technical review gates (DR1, DR3 etc.), or as agreed within the relevant technical work package plan.
- 16.7.4 Conduct verification and validation activities in accordance with an approved verification strategy (verification activities including method, exit criteria and when they are required by are determined by the verification strategy).
- 16.7.5 Agree the format and content for design compliance checking and verification reporting with Rolls-Royce SMR.
- 16.7.6 Where testing is used for verification or validation purposes, the test shall be defined and recorded to enable audit and reproducibility. These requirements include (but are not limited to) the following:
 - a) Calibration
 - b) Test facility configuration control
 - c) Verification planning
 - d) Verification procedures/methods
 - e) Verification inspection and data acquisition
 - f) Verification witness and hold points
 - g) Verification evidence and documentation
- 16.7.7 Where analysis is used for verification purposes, the following shall be defined and recorded to enable audit and reproducibility:
 - a) Verification plan including the approach, method, test cases and acceptance criteria.
 - b) The type and versions of tools, software, and software platforms used.
 - c) Tool/software verification and validation plans and results".
 - d) Source data used where relevant (e.g., materials data for stress analysis).
 - e) The definition/configuration of the Product analysed.
 - f) The results of the analysis.
 - g) Pass/fail conclusions where applicable.
- 16.7.8 Each design verification plan shall identify the Conformance Activities associated with the design works.

16.8 Design Risk Management

- 16.8.1 Demonstrate a satisfactory approach to design risk management for the product to an established industry standard (such as DFMEA, HAZID, HAZOP etc), as documented in Rolls-Royce SMR specifications. This shall be agreed on a case-by-case basis by Rolls-Royce SMR and specified in the Statement of Work ("SoW").
- 16.8.2 Maintain appropriate mechanisms for Design risk assessment and mitigation associated with (but not limited to) technology, complexity, obsolescence, materials, environment, application, physical and functional tolerance stack-up associated with the assembly, counterfeit, service and manufacturing requirements, resource availability, information dependencies, supply chain availability, competence, HS&E.
- 16.8.3 Obsolescence may be associated with (but not limited to) non-availability of standard parts, technological advancement, change in Legislation/standards, change in manufacturing processes, compatibility issues, sub-tier suppliers ceasing trade, production, or support.

16.9 Design Methods

- 16.9.1 Make appropriate use of design methodologies and techniques throughout their Design and Development process, at system and component levels.
- 16.9.2 These shall include but not limited to:
- All agreed Design and Engineering disciplines, such as, but not limited to: Stress, Thermal analysis, Computational Fluid Dynamics
 - Design for Quality/Variation (Robust Design)
 - Design for Manufacture, Assembly, Aftermarket (Service) and Cost
 - Design for Reliability and Safety
 - Design for the prevention of foreign objects and contamination being trapped during manufacture, maintenance, or repair in such features as, but not limited to apertures, orifices, sharp bends, and corners.

16.10 Design Software

- 16.10.1 All software and computerised models used to develop the design and design analysis shall be subject to verification, validation, and formal configuration management.
- 16.10.2 The supplier shall be responsible for working with Rolls-Royce SMR to maintain software version compatibility. Where a software version change must be implemented the timetable should be agreed between all parties to ensure compatibility is maintained.
- 16.10.3 Each computer program used for design analysis shall be accepted for use and controlled by defined method prior to use, or the computer program's results shall be independently verified with the design analysis for each application.
- 16.10.4 The acceptance of controlled computer programs used for design analysis, and verification methods applied to the results of unproven programs, shall meet the following requirements.
- The computer program, or the verification method applied to the computer program results, shall be shown to produce correct solutions for the applied mathematical model within defined limits for each parameter employed.
 - The applied mathematical model shall be shown to produce a valid solution to the physical problem associated with the particular application.
- 16.10.5 Configuration management includes controls related to configuration identification, configuration change control, configuration status control and configuration audits.
- 16.10.6 Retain all the design software validation and verification records and submit to Rolls-Royce SMR for acceptance when required.
- 16.10.7 Individuals shall demonstrate their SQEP for using this software.

16.11 Design Interfaces

- 16.11.1 During the design and development planning phases take into consideration the design interfaces where appropriate.
- 16.11.2 Provide systems evaluation to understand any interfaces, interactions, or changes in behaviour of the products and components.

16.12 Design and Requirements Change Control

- 16.12.1 Ensure changes in requirements or the addition of new requirements during a design project (e.g., as an outcome of developing the detail of the concept solution, trading requirements between contracts, or from gate reviews) shall be incorporated in the Technical Requirements at appropriate design stages.
- 16.12.2 Change Control is applicable to design changes that affect the fit, form or function of existing designs i.e., design changes following a configuration freeze. Suppliers shall:
- After the baseline configuration is established, ensure any change to any document that defines the configuration of an item is considered under change control.
 - Ensure design changes are authorised in the change control process by their Rolls-Royce SMR Technical Authority before implementation including verification and validation as appropriate.
 - Ensure that configuration management related to design changes are controlled and traceable.

16.13 Design Data

- 16.13.1 Rolls-Royce SMR uses a systems engineering approach to design, the suppliers design deliverables should be compatible with this approach.
- 16.13.2 Provide a Design Technical Data Package to Rolls-Royce SMR.
- 16.13.3 Agree with Rolls-Royce SMR the Design Technical Data Package content prior to commencement to the task.
- 16.13.4 Ensure the Design Technical Data Package includes all the design data items based on the scope of supply. The documentation listing shall be agreed with Rolls-Royce SMR prior to work commencement.
- 16.13.5 Submit the initial Design Technical Data Package upon completion or at the next Technical Review in accordance with planned and agreed arrangements.
- 16.13.6 Submit an updated Design Technical Data Package at subsequent technical reviews or applicable changes, in accordance with planned and agreed arrangements.
- 16.13.7 Update the configuration of the product following Rolls-Royce SMR acceptance of the Design Technical Data Package

16.14 Material Selection

- 16.14.1 Designers must show that the hierarchy of control has been applied to the selection of materials and chemical substances that can be found in their design.
- 16.14.2 Certify and warrant that products and services supplied to Rolls-Royce SMR are made from materials, including constituent materials, which are sourced responsibly in accordance with the OECD guidelines and verified as being 'conflict free'.
- 16.14.3 Flow down the requirements above to all its suppliers. The Supplier must provide Rolls-Royce SMR with supporting data on their supply chain of minerals, when requested. If the material "chain of custody" supplied is "indeterminable" or otherwise unknown, the supplier must commit to either attaining the appropriate certifications, or to the phase out of the material in the Rolls-Royce SMR applications.
- 16.14.4 Above should be captured and reflected within the design register.

16.15 Application of COTS item in Rolls-Royce SMR Design

16.15.1 The table 4 indicates the definition of COTS items and their application in Rolls-Royce SMR products based on a risk-based approach.

Table 3 COTS Item definition

Items	Definition	Safety Classification	Approach
COTS items	Bulk items which have been selected to use within Rolls-Royce SMR products and supplied with a certificate of conformity to a manufacturer’s technical specification, product code, and has not been specifically designed or manufactured for Rolls-Royce SMR design application.	YES	See requirements specified in Section 16.15.2, 16.15.3, 16.15.4
		NO	See requirements specified in Section 16.5.5

16.15.2 Where COTS items are proposed for use in designs with safety classification implications, the supplier shall conduct a suitability assessment for its application, this assessment is subject to approval by Rolls-Royce SMR.

16.15.3 COTS items shall be validated through stages of specified test and inspection when required. Stages such as: independent verification, performance test, functional, material tests, or other specified methods as stated in the contract technical specification. Demonstration records of compliance shall be submitted to Rolls-Royce SMR as part of the contract deliverables.

16.15.4 COTS suppliers shall apply a graded approach methodology and be managed as part of a surveillance programme.

16.15.5 For non-safety classification COTS items, suppliers and sub-tier suppliers shall provide conformity certificates or other applicable Quality Assurance Records to prove conformance to the technical specification and regulatory requirements, this includes COTS item that are:

- a) Procured to a recognised industry standards, specification, and product code
- b) Procured by using a Bill of Material (BoM) including batch requirements
- c) Demonstration of manufacturers’ specification meets Rolls-Royce SMR requirements
- d) Can be accepted by having a certificate of conformity or equivalent LTQR demonstrating its conformity

17 Manufacturing and Product Verification Activities

17.1 Process Risk Analysis and Risk Management

- 17.1.1 For suppliers authorised by Rolls-Royce SMR to create and apply product definitions for manufacture or design to manufacture type of works, suppliers and sub-tier supplier shall conduct process risk analysis or risk assessment for the product to evaluate and identify potential failures related to operational processes (analytical tool such as PFMEA, etc).
- 17.1.2 The analysis method shall be agreed on a case-by-case basis by Rolls-Royce SMR unless specified in the Statement of Work (SoW).
- 17.1.3 Engage Rolls-Royce SMR and the supplier's cross-function team to accomplish a process risk analysis that includes but is not limited to the following elements:
- a) Process identification
 - b) Process works elements
 - c) Potential process failure mode
 - d) Severity (S) – The seriousness of a failure mode
 - e) Occurrence (O) – The likelihood that a given failure mode will happen.
 - f) Detection / Prevention (D) – The likelihood that the failure mode will be prevented / detected
 - g) Risk Priority Number (RPN) = Severity (S) x Occurrence (O) x Detection (D)
 - h) Standard scoring criteria
- 17.1.4 Develop a process risk analysis or risk assessment for the production processes identified in the process flow diagram in advance of producing the product.
- 17.1.5 Ensure the risk analysis or risk assessment records are documented.
- 17.1.6 Determine the risk priority related to the impact on the product, process associated with Rolls-Royce SMR contract scope of works.
- 17.1.7 Take appropriate corrective action for high level risks (e.g., high RPN) to reduce or eliminate the chance of the potential failure occurring.
- 17.1.8 Review / update and recalculate risk levels (e.g., RPN) for the risk analysis or risk assessment when changes are made to product definition, process operating conditions or when non-conformances have been identified.
- 17.1.9 Provide feedback to Rolls-Royce SMR along the Purchase Order cascade when appropriate risk mitigation cannot be provided.

17.2 Inspection and Test Plans (ITP)

- 17.2.1 ITPs are the primary document for controlling work arrangements and realisation of products and services. ITPs also provide a method to engage Rolls-Royce SMR and Rolls-Royce governance SMR representatives with the suppliers during surveillance and verification works.
- 17.2.2 Supplier and sub-tier suppliers shall use ITPs during the delivery of their works, including but not limited to the following activities: supplying, manufacturing, verification, qualification, installation, testing and commissioning of the SSC.
- 17.2.3 Suppliers undertaking manufacturing works related to safety classification items, shall produce ITPs specified for the Rolls-Royce SMR contract, setting out the specific quality practices, resources, sequence of activities and pass/fail criteria, relevant to the realisation of the works defined in Rolls-Royce SMR contract, and submit to Rolls-Royce SMR for acceptance or approval.
- 17.2.4 No works shall commence until acceptance or approval of the ITPs.

- 17.2.5 ITPs shall include activities related to manufacturing, assembly, testing, transportation, installation, and qualification, and indicate the release of any material, concession, rework, calibration register, equipment validation and other activities.
- 17.2.6 ITPs shall highlight Conformance Activities.
- 17.2.7 All prerequisite deliverables identified with the procedures and specifications referenced with the ITPs shall be reviewed, accepted, and/or approved prior to the work commencement.
- 17.2.8 Any documentations produced during the manufacturing process to support the ITPs shall be submitted as part of the ITPs records to Rolls-Royce SMR.
- 17.2.9 ITPs shall co-ordinate the supplier and sub-tier supplier's interactions with Rolls-Royce SMR, the regulator, ITPIA or IA and other third parties through the identified witness, review, and hold points.
- 17.2.10 Notes:
 - a) ITPs also known as Quality Control Plan.
 - b) Further guidance can be provided if required and when requested.

17.3 First-Of-A-Kind (FOAK)

- 17.3.1 The supplier shall identify all the FOAK items and activities associated with Rolls-Royce SMR contract during management of the manufacturing works. Identified FOAK items and activities inform the risks associated with each scope of work and the suppliers, enable Rolls-Royce SMR to develop the supplier surveillance plan accordingly.
- 17.3.2 FOAK item and activity shall include the activities undertaken by the sub-tier suppliers.
- 17.3.3 Surveillance from Rolls-Royce SMR to the supplier, and surveillance from the supplier to their sub-tier suppliers, FOAK items and activity shall be targeted and identified with 'reinforced' surveillance based on risk informed from various factors highlighted within the surveillance strategy.
- 17.3.4 When a risk exists on a FOAK item and activity to be delivered by a supplier or sub-tier supplier, it must be captured through the risk analysis and addressed with the appropriate mitigation actions, details shall be defined in the associated Rolls-Royce SMR surveillance plan risk analysis section.
- 17.3.5 Supplier's and sub-tier supplier's deliverables shall attribute the 'FOAK' document, management of FOAK deliverables shall be described within the QAP.
- 17.3.6 Rolls-Royce SMR shall accommodate the surveillance levels for Nth of a Kind (NOAK) items and activities, based on lessons learnt captured through the management of the FOAK items and activities, and development of Rolls-Royce SMR programme maturity.
- 17.3.7 Note: Nth of a Kind (NOAK) defined as "identical plant supplied and built by the same vendors and contractors as the FOAK plant with only the site-specific scope adopted for the NOAK plant site needs".

17.4 Manufacturing Documents

- 17.4.1 Prepare documented Work Instructions, Procedures and Drawings for personnel undertakes the operational processes.
- 17.4.2 Ensure that the Work Instructions, Procedures and Drawings include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished.
- 17.4.3 Described requirements to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results.
- 17.4.4 Deliver trainings or brief sessions to operation personnel to ensure their correct understanding of the information stated within the Work Instructions, Procedures and Drawings.

17.5 Validation Control of Special Processes

- 17.5.1 Rolls-Royce SMR will identify together with the suppliers of all the prerequisite manufacturing procedures related to special processes as contract deliverables for acceptance or approval prior to kick off the manufacturing works.
- 17.5.2 Ensure prerequisite manufacturing procedures reference and contain the correct and applicable standards codes and/or regulatory requirements, as well as the acceptance criteria for the special process.
- 17.5.3 The suppliers shall establish a documented procedure for approval and validation of special processes.
- 17.5.4 The suppliers shall ensure that documentation related to special processes are controlled and verified via document control processes by a quality function, such as those used in welding, heat treating, and non-destructive examination, documents include working instructions, process and procedures, drawings, checklists, travellers, equipment used for special processes their qualification, verification, and maintenance records.
- 17.5.5 In case of the special processes are not defined by existing codes and standards, or where quality requirements specified exceed those of existing codes or standards, these additional requirements related to qualifications of personnel, procedures, or equipment shall be described in a specific document, submit this document for acceptance or approval when requested by Rolls-Royce SMR.
- 17.5.6 Ensure only suitably qualified and experienced personnel are assigned to perform the task and process validation associated to the special processes.
- 17.5.7 Demonstrate how individuals are competent to carry out the inspection and test activities in accordance with applicable standards, relevant procedures shall also describe how their performance are monitored, as well as management of the timescales for the re-evaluation and qualification.
- 17.5.8 Maintain qualification records for personnel, process procedures, materials, and documentation, and equipment according to the requirements of applicable codes and standards.
- 17.5.9 Personnel validating the special processes shall be independent to those who performed the operation and production activities.

17.6 Monitoring and Measuring Resources

- 17.6.1 Implement a management process for all the measurement, testing and inspection equipment, describe the calibration, validation, and verification processes related to the equipment.
- 17.6.2 Ensure that equipment used for the final verification of the product is independent to those used for product measurement during production activities or will be re-calibrated / verified prior to use where independence cannot be achieved.
- 17.6.3 Maintain a register of the measurement, testing and inspection equipment, includes but not limited to following information: equipment type, name, description, measurement range, location, and the calibration or verification method, frequency, records, and acceptance criteria.
- 17.6.4 Attached a register listing the measurement, testing and inspection equipment used for Rolls-Royce SMR contract. Attach this register to the related ITPs as an appendix.
- 17.6.5 All inspection record shall reference the unique identification of the measuring equipment when applied for monitoring, inspection, and testing activities.
- 17.6.6 Validate the measurement, testing and inspection equipment associated with Rolls-Royce SMR contract, by performing Measurement System Analysis (MSA) or statistical studies related to a representative range of tolerances and features (including tightest tolerance measured) to analyse the variation present in the results of each type of monitoring /measuring and test equipment system. The participants in the study shall be representative of those using the measurement system on a day-to-day basis.
- 17.6.7 Record the results of statistical studies in a study report, describe study methodologies, criteria, and conclusions.
- 17.6.8 Perform a review of measurement capability when tolerances, personnel or environmental conditions have changed.
- 17.6.9 Personnel verifying the automated measurement system inspection programmes is independent from the original programme setter.
- 17.6.10 Programmes shall be independent; equipment does not need to be.

17.7 Control of Manufacturing Equipment, Tools, and Software Programs

- 17.7.1 Establish a system for the management of pre-production and production tooling, jigs and fixtures that includes but not limited to the following:
 - a) Unique tool identification
 - b) Validation of tool prior to release for production
 - c) Protection from damage and deterioration during storage
 - d) Maintained as fit for purpose
 - e) Storage and retrieval
 - f) Tool set-up
 - g) Tool life control / tool-change programmes
 - h) Tool design modification documentation, including engineering change level
 - i) Tool modification and revision
- 17.7.2 Ensure that they have an established process for the control of software programmes for machine-tools and coordinate measuring machines (e.g., CMM's).
- 17.7.3 Tools such as 5S (Five-S) and visual management may be used for workplace organisation improvement.

17.8 Identification and Traceability

- 17.8.1 Control the unique and serialised identification of the product when specified in the Rolls-Royce SMR technical specifications. When unspecified, ensure a proposal was acknowledge or accepted prior for implementation.
- 17.8.2 Establish measures for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures shall ensure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures shall be designed to prevent the use of incorrect or defective material, parts, and components.
- 17.8.3 Ensure an internal review was conducted to verify the serialisation requirements are implemented prior to manufacturing work commence.
- 17.8.4 Identify physical items from raw material to finish product by suitable means throughout production activities including a process for the control of splitting raw material to ensure traceability is maintained.
- 17.8.5 Describe this traceability method within the supplier's QAP when required.
- 17.8.6 Maintain the traceability for all products during production, including product quantities, split orders, nonconforming product.
- 17.8.7 Establish a method to differentiate between an unfinished / incomplete product during subcontract / sub-tier supplier processing activities and a finished / completed product.

17.9 Prevention of Counterfeit, Fraudulent or Suspect Items (CFSI)

- 17.9.1 The supplier and the sub-tier suppliers are responsible for prevention and mitigation of CFSI by implementing a risk-based approach process to identify, mitigate, and control the CFSI products and materials throughout its supply chain, ensure CFSIs are not provided as part of the end item of the delivery under Rolls-Royce SMR Purchase Orders.
- 17.9.2 Supplier shall detail the policy and objectives associated with CFSI prevention, process related to mitigation and risk management, within their QAP.
- 17.9.3 CFSI process shall describes the management of identification, segregation, and documentation for identified CFSI.
- 17.9.4 Risk-based approach process shall apply set of inspections and tests proven to detect CFSI and consider the following but not limited to:
 - a) Altered manufacturer's name, logo, serial number, manufacturing date.
 - b) Items differing in configuration, dimensions, fit, finish, colour, or other attributes from that expected.
 - c) Markings on items or documentation are missing, unusual, altered, or inconsistent with that expected.
 - d) Markings or documentation from country other than that of sub-tier suppliers.
 - e) Items, sold as new, exhibit evidence of prior use.
 - f) Performance inconsistent with specifications or certification or test data furnished.
 - g) Documentation that appears altered, incomplete or lacks expected traceability
- 17.9.5 Develop CFIS awareness training within the organization and sub-tier suppliers.
- 17.9.6 Ensure suspected or identified CFSI related to the products or materials are notify to Rolls-Royce SMR point of contacts and buyers immediately and initiate the investigation together with all relevant stakeholders.
- 17.9.7 The Supplier's procurement documents to the sub-tier suppliers shall contain conditions that prohibit delivery of CFSIs, or misrepresentation of the item, sub-tier suppliers shall be aware of their accountability for providing the correct items and the consequences for supplying CFSIs.

17.10 Foreign Material Exclusion (FME)

- 17.10.1 Established FME process to prevent the introduction of foreign objects into an operational area that may result in damage or system interruptions to assets, harm to people, harm to the environment, loss of quality or economic loss.
- 17.10.2 Supplier and sub-tier suppliers shall develop a FME program based on detailed assessment of the work environment and associated hazards. FME program should consider below fundamentals, listed as follow:
- a) Defining the FME zone or area where exclusion is a concern
 - b) Assessing hazardous materials and chemicals used in the FME zone and tier effects on people and equipment
 - c) The impact of the cleanliness of tools and equipment used in the FME zone
 - d) Workplace culture and its effect on employee attitude and buy-in to the FME program
 - e) Inspection of equipment used in the FME program
 - f) Prevention methods
 - g) Making sure items are easily visible and retrievable
 - h) A program to track items in and out of the FME zone
 - i) Implementation of FME Program
- 17.10.3 Ensure that non-metallic are controlled in line with the requirements identified in the procurement specification.
- 17.10.4 Ensure that any non-metallic items that are used to prevent ingress of dirt or contaminants into an assembly or component with internal features e.g., plugs, blanks, caps etc. comply with cleanliness and non-metallic requirements in the product definition.
- 17.10.5 Establish a register to monitor the approval expiry and shelf life of non-metallic material to prevent incorrect use.

18 Change Control and Management

18.1 Change Request

- 18.1.1 Any proposed changes to an existing contract, shall be managed via Rolls-Royce SMR's change control and management processes, whether either those changes are initiated by Rolls-Royce SMR or by a Supplier.
- 18.1.2 For change initiated by the suppliers, the supplier shall raise a change and submit to Rolls-Royce SMR Buyers via its project or supply chain team to kick off the change process. Rolls-Royce SMR shall review all change requests on a case-by-case basis and issue the appropriate authorisation where such change is approved.
- 18.1.3 The supplier and sub-tier supplier shall ensure any records supporting the change request, including change review, scope of change, change impact assessment, are captured as supporting evidence, and submitted together with the change request to Rolls-Royce SMR for review and assessment in accordance with the Rolls-Royce SMR change process.
- 18.1.4 Any cost and schedule impact associated with proposed changes, shall be managed by the commercial, procurement or project teams and between Rolls-Royce SMR and the Suppliers representatives, these types of changes are managed outside the scope of this document.
- 18.1.5 Where significant changes made within supplier's organisation, supplier shall notify Rolls-Royce SMR in formal writing.
- 18.1.6 Supplier shall consult with Rolls-Royce SMR, prior to raising any change request that impacts on the Rolls-Royce SMR design.
- 18.1.7 Change related to contract specification that are initiated and issued by Rolls-Royce SMR, shall follow a change control process, these documentations shall be managed through the supplier's document change control system, or change management process for further implementation.

18.2 Manufacturing Source and Method Changes

- 18.2.1 Under circumstances that a supplier intends to transfer works to a different location, or deviate from the approved or agreed manufacturing methods, the supplier shall notify Rolls-Royce SMR prior to this work commencing.
- 18.2.2 The Supplier shall establish a documented procedure within their QMS for the control of manufacturing source and methods change to plan, control, and verify the conformity to specified requirements during the temporary or permanent transfer of work, and submit a plan to Rolls-Royce SMR for acceptance.
- 18.2.3 The procedure shall contain (but not be limited to):
 - a) Formal notification to all stakeholders and Rolls-Royce SMR before any change commences.
 - b) Risk assessment and mitigation.
 - c) Transfer plan.
 - d) Demonstration of capacity at the in-loading area to protect Rolls-Royce SMR delivery.
 - e) Demonstration that generation of buffer stocks are built into load and capacity plans to protect Rolls-Royce SMR delivery.
- 18.2.4 The above should be described in a formal project plan with all evidence and documents associated with this plan submitted to their Rolls-Royce SMR Supply Chain contact for review. This change request is subject to Rolls-Royce SMR's formal change control process. Suppliers should ensure that no change takes place until the approval to proceed is received from Rolls-Royce SMR.
- 18.2.5 Ensure delivery performance is protected prior to any work transfer.
- 18.2.6 Demonstrate that any export control risks associated with the work transfer have been properly assessed and any changes to or requirement for new export authorisations have been planned for.

19 Management of Deviation, Non-Conformance, and Concession

19.1 Deviation Request

- 19.1.1 A deviation request is where a supplier requests for a relaxation to Rolls-Royce SMR instruction, contract, and product requirements in advance of commencement of the works, for example:
- When supplier believe that the contract specification and requirements are not applicable.
 - When the suppliers are unable to comply to certain clauses and/or requirements.
- 19.1.2 Then, Suppliers shall submit the deviation request with defined scope to Rolls-Royce SMR for review and acceptance.

19.2 Non-Conformance

- 19.2.1 A non-conformance is where the works produced by the supplier and/or sub-tier suppliers, fail to meet either the Rolls-Royce SMR instruction, contractual requirements, product and technical specifications, or purchase order conditions.
- 19.2.2 When suppliers and sub-tier suppliers are addressing a non-conforming output related to Rolls-Royce SMR products and services, the supplier shall report these findings in a Non-conformance (NC) report to the Rolls-Royce SMR point of contract. Suppliers and sub-tier suppliers' own NC report format can be used, unless otherwise specified by Rolls-Royce SMR.
- 19.2.3 Any non-conformance that impacts safety, reliability and integrity of the Rolls-Royce SMR products and services are considered as major issues. All major issues shall be contained within suppliers and sub-tier suppliers' premises immediately and reported to Rolls-Royce SMR within 24Hrs of issues being identified.
- 19.2.4 NC reports shall identify the affected areas such as: work in progress, stores stock, shipping area, in transit, sub-tier / subcontract activities, similar products. When any effected products have been delivered to the Rolls-Royce SMR supplier shall immediately notify their point of contact and Buyers and continually pursue a response until the notification has been received by Rolls-Royce SMR.
- 19.2.5 Repair, rework, or salvage shall be communicated with Rolls-Royce SMR in advance, and shall be conducted in accordance with controls specified within the process specifications on the product definition or to an agreed rework procedure authorised by Rolls-Royce SMR.
- 19.2.6 Suppliers shall indicate all applicable open/ closed NC reports associated with each delivery within the final documentation pack submitted to Rolls-Royce SMR.
- 19.2.7 Associated documents, records and evidence related to the nonconforming outputs shall be maintained by the supplier and made available when requested.

19.3 Concession Approval

- 19.3.1 After a supplier submits to Rolls-Royce SMR a non-conformance, a concession request can be made by the supplier, acceptance is not guaranteed.
- 19.3.2 Concession requests shall include sufficient information to make an informed decision that accounts for the consequences of the non-conformance, as a minimum a concession request should include: impact, detail of the deviation from technical or quality requirements, associated PO, part number, related services, associated records, and related deliverables.

19.4 Guidance

- 19.4.1 Further guidance regarding Deviation, Non-conformance and Concession can be supplied if required and when requested.

20 Abbreviation, Terms and Definitions

20.1 Abbreviation and Definition

Abbreviation	Definition
ALARP	As Low as Reasonably Practicable
ASME	American Society of Mechanical Engineers
BPVC	Boiler and Pressure Vessel Code
CAs	Conformance Activities
CDM	Construction Design Management
CFSI	Counterfeit, Fraudulent or Suspect Items
DFMEA	Design Failure Mode and Effects Analysis
E3S	Environment, Safety, Security and Safeguards
FOAK	First-of-a-Kind
FME	Foreign Material Exclusion
FMECA	Failure Mode, Effects and Criticality Analysis
FTA	Fault Tree Analysis
HAZID	Hazard Identification
HAZOP	Hazard and Operability
HR	High Reliability
IAEA	International Atomic Energy Agency
ITNS	Important To Nuclear Safety
ITPs	Inspection and Test Plans
ITPIA	Independent Third-Party Inspection Agency
IA	Inspection Agency
IAEA	International Atomic Energy Agency
LOD	List of Deliverables
LTQR	Lifetime Quality Record
NC	Non-Conformance
NCR	Non-Conformance Report
NDE	Non-Destructive Examination
ONR	Office of Nuclear Regulation
PFMEA	Process Failure Mode and Effect Analysis
Rolls-Royce SMR	Rolls-Royce Small Modular Reactor (Organisation)
RR SMR	Rolls-Royce Small Modular Reactors (Design)
QAP	Quality Assurance Plan
QMS	Quality Management System
SMART	Specific, Measurable, Achievable, Relevant, and Time-Bound
SMSR	Supplier Management System Requirements (This document)
SQEP	Suitably Qualified and Experienced Personnel
SSC	Systems, Structures and Components
T&C	Terms and Conditions
UKCA	United Kingdom Conformity Assessed
VHR	Very High Reliability
W/H points	Witness and Hold points

20.2 Terms and Definition

Terms	Definition
Activity	The work of an individual, group, or organisation to achieve an aim.
Commercial off-the shelf items (COTS)	Products which are supplied with a certificate of conformity or quality assurance records to a manufacturer's technical specification or product catalogue code and that have not been specifically designed or manufactured for the Rolls-Royce SMR design.
Configuration	Interrelated functional and physical characteristics of a product defined in the product configuration information
Configuration Management	Coordinated activities to direct and control configuration. Configuration management generally relates to technical and organisational activities that establish and maintain control of a product and throughout the life cycle of the product
Contract	Legal agreement between the Rolls-Royce SMR and the supplier as defined in the Purchase order
Contract specification	A statement of needs or requirements that prepared for a specific contract and consisted of an assembly of appropriate standard and specifications supplemented by detailed descriptions of the goods or services to be supplied.
Counterfeit items	Items intentionally manufactured or altered to imitate a legitimate product without legal right to do so.
Fraudulent items	Items intentionally misrepresented to be something they are not, including items provided with incorrect identification or falsified/ inaccurate certification. Fraudulent items also include items sold by entities that have acquired the legal right to manufacture a specified quantity of an item but produce a larger quantity than authorised and sell the excess as legitimate inventory
Inspection and Test Plans	Also known as Quality Control Plan. Inspection and Test Plans sets out the specific quality practices, resources, sequence of activities and pass/fail criteria, relevant to the realisation of the works. It also indicates concession, rework, calibration register, equipment validation and other aspects. It is used for formalising and co-ordinating the interactions of various organisations: Rolls-Royce SMR, the regulator, ITPIA or IA ad other third parties through the identification of W/H points
Inspection Agency	The IA will act as a third party to perform inspection and verification activities specified by the Rolls-Royce SMR, Rolls-Royce SMR Delegation, Suppliers, or Sub-tier suppliers when required by construction code or regulatory requirements.

Terms	Definition
Independent Third-Party Inspection Agency	<p>The ITPIA will act independently on behalf of the Rolls-Royce SMR to carry out inspection and other duties as required by for example the ASME Construction Code for items designated as Very High Integrity or High Integrity.</p> <p>All references in the ASME BPVC to the Inspector, Authorised Inspection Agency or Authorised Nuclear Inspector shall be read as referring to the ITPIA.</p>
Nuclear Safety	<p>The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards</p>
Nuclear Safety Culture	<p>The assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, protection and nuclear safety issues receive the attention warranted by their significance</p>
Quality Assurance Plan	<p>QAP describes the quality assurance arrangement established by the supplier and its sub-tier suppliers to support the delivery of the works</p>
Quality Escape	<p>An undeclared non-conformity that has been delivered to RR-SMR</p>
Safety Classification	<p>Safety classification is defined for the SSC in the contractual documents, also known as safety class.</p>
Supplier	<p>Any organisation or individual person that provides a product or service for Rolls-Royce SMR under a legally binding contract, partnership or otherwise.</p>
Sub-tier suppliers	<p>As defined in the contract with the supplier. Includes any suppliers or consultants in its supply chain contributing works to support the Rolls-Royce SMR contract.</p>
Suspect items	<p>An item about which there is an indication by visual inspection, testing or other preliminary information that it may not conform to acceptable standards, specifications and/or technical requirements and there is a suspicion that the item may be counterfeit, fraudulent or non-conforming. Generally additional investigation is required to determine whether the suspect item is acceptable, non-conforming, counterfeit, or fraudulent</p>
Works	<p>As defined in the contract</p>

21 Reference Standards and Specifications

No.	Reference	Title
[1]	BS EN ISO9001:2015	ISO Standard: Quality Management System Requirement
[2]	IAEA GSR-Part 2	Leadership and management for safety
[3]	ASME Nuclear Quality Assurance (NQA)-1	Quality Assurance Requirements for Nuclear Facility Applications
[4]	IAEA Safety Guide GS-G-3.5	The Management System for Nuclear Installations
[5]	ASME BPVC III Subsection NCA-4000	Quality Assurance Requirements
[6]	BS EN ISO 14001:2015	ISO Standard: Environmental management systems
[7]	BS EN ISO 45001:2018	ISO Standard: Occupational health and safety management systems
[8]	BS EN ISO 17025	General requirements for the competence of testing and calibration laboratories
[9]	ISO/ IEC 17020	Conformity assessment – Requirements for the operation of various types of bodies performing inspection
[10]	ISO 19443:2018	Quality management systems – Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)
[11]	NS-TAST-GD-077	ONR technical assessment guides (TAG 77)- Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services
[12]	SMR0003526	Rolls-Royce SMR Vendor Verification Strategy Guidance
[13]	Rolls-Royce SMR IMS Standard: SMR-STD-003	Rolls-Royce SMR Marking Business Sensitive Information
[14]	Rolls-Royce SMR IMS Standard: SMR-STD-042	Rolls-Royce SMR Supplier Minimum Cyber Security Standard
[15]	ISO 10005:2018	ISO Standard: Quality management – Guidelines for quality plans



22 Change History

Revision	Date	Description of Change	Author
02	03/10/2023	Re-written based on revision 01. New sections added, listed as follow: 4, 5.2, 5.3,6, 7, 8, 9, 10, 12.4, 14, 16.1, 16.2, 16.6, 16.15, 17.2, 17.3, 17.10, 18, 19. Other section reviewed and revised with relevant SQEP.	BeiBei Tong

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Supply Chain Approval

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Engineering Approval

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Document update policy

This document may be updated periodically based on development of the Rolls-Royce SMR programme maturity.