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**Title**

**Quality Assurance Topic Report**

**Executive Summary**

This Quality Assurance Topic Report is produced for the Rolls-Royce SMR (RR SMR) Pre-Application activity under United States (US) Nuclear Regulatory Commission (NRC) Docket Number 99902143. This document is based on the United Kingdom (UK) Environment, Safety, Security, Safeguards (E3S) Case Chapter 17 (Management of Safety and Quality Assurance), Version 3 at UK Generic Design Assessment (GDA) Design Reference Point 4. It covers certain aspects of Quality Assurance (QA) required to be demonstrated in a future Preliminary Safety Analysis Report (PSAR) under 10CFR50 Appendix B.

This Topic Report presents the organizational and Quality Assurance (QA) arrangements for development of the RR SMR generic design in the UK by Rolls-Royce SMR Ltd. Deployment of the RR SMR in the United States of America (USA) will be undertaken by a different organization, although organizational arrangements for this company are expected to be similar to those presented in this document. Any differences in organizational or QA arrangements between the two entities will be highlighted and reported at the appropriate future licensing stages. In any event, this document describes the arrangements in place for the initial design of the RR SMR. This document demonstrates that suitable, appropriate, and established arrangements are in place in relation to the management of Environment, Safety, security and Safeguards (E3S) and QA which enable appropriate standards in support of E3S and quality to be applied throughout all phases of the RR SMR lifecycle.

The arrangements, including the Integrated Management System (IMS) documents, policies, manuals, procedures and supporting systems have been developed, deployed and evaluated in line with the delivery of the design and E3S Case. The E3S Case is the base document from which the Safety Reports for the RR SMR will be produced in the USA.

The IMS is certified to the following International Organization for Standardization (ISO) standards:

- ISO 9001:2015 Quality Management Systems (in 2023),
- ISO 19443:2022 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) (in 2024),
- ISO 14001:2015 Environmental Management System (in 2024),
- ISO 45001:2018 Occupational Health and Safety Management Systems (in 2024),
- ISO 27001:2022 Information Security Management Systems (in 2024).

The arrangements continue to evolve and improve, through building in learning from experience, operating experience, results and feedback from performance measures, assurance activities, internal and external evaluation, assessments and reviews. Changes to arrangements are managed through appropriate change control governance arrangements. The arrangements described in this Topic Report have been sampled and assessed by the UK Regulators, the Office for Nuclear Regulation (ONR), Environment Agency (EA) and Natural Resources Wales (NRW) through the UK Generic Design Assessment (GDA) program.

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# 1 Introduction

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## 1.1 Introduction

- 1.1.1 This Topic Report demonstrates that suitable and established arrangements are in place in relation to the management of Environment, Safety, Security and Safeguards (E3S) and Quality Assurance (QA), which ensures appropriate standards in support of E3S, and quality are applied throughout all phases of the UK generic 50 Hz Rolls-Royce SMR (RR SMR) design lifecycle.
- 1.1.2 This Topic Report has been written to support the Pre-application engagement of RR SMR with the US NRC. As such, this Topic Report does not, and is not intended to, contain all the information that will be provided by RR SMR in a future Preliminary Safety Analysis Report (PSAR) for a Combined Construction Operating Licence (COL), manufacturing process or Early Site Permit (ESP). This document and the supporting documents within the references are intended to describe the QA arrangements in place that RR SMR have used in the development of the generic RR SMR design are suitable and sufficient. For the 60 Hz design, this document will be updated and together with the references, are intended to provide confidence to US NRC Inspectors that the RR SMR will meet the requirements of 10 CFR 50 Appendix B and associated rulemaking and guidance for the requisite future licensing steps.
- 1.1.3 This Topic Report and the supporting references are intended to provide confidence in the following areas required by 10CFR50 Appendix B for the generic 50 Hz design:
- Design Control (3),
  - Procurement Document Control (4),
  - Instructions, Procedures and drawings (5),
  - Document Control (6),
  - Corrective Action (16).
- 1.1.4 The E3S Case is the principal licensing document in the UK, composed of three levels. Level 1 is structured according to IAEA SSG-61, Structure and Format of Safety Analysis Reports [1] and US Regulatory Guide 1.70 [2]. It is comprised of 33 principal chapters, with supporting information and evidence provided in levels 2 and 3. This Topic Report is produced from Chapter 17 of the UK E3S Case [3]. The UK E3S Case will serve as the basis for future licensing of the RR SMR in the USA through a PSAR through to a Final Safety Analysis Report (FSAR).

## 1.2 Scope

- 1.2.1 This Topic Report covers the generic arrangements for:

- Processes and systems in place and established, to ensure environment, safety (both nuclear and conventional health and safety), security, safeguards, and QA requirements,
- Quality management of the design and E3S Case production,
- Control of the design and E3S Case.

1.2.2 Rolls-Royce SMR Limited are certified to the following International Organization for Standardization (ISO) standards:

- ISO 9001:2015 Quality Management Systems,
- ISO 19443:2022 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),
- ISO 45001:2018 Occupational Health and Safety Management Systems,
- ISO 14001:2015 Environmental Management System,
- ISO 27001:2022 Information Security Management Systems,
- ISO 19650 - 2: 2018 Building Information Modelling (BIM).

### **1.3 Applicable Codes, Standards, Best Practice and Recognised Guidance**

The Rolls-Royce SMR Limited management arrangements were developed to ensure compliance with relevant codes, standards, best practices, and recognized guidance, to ensure adequate arrangements for management of E3S and QA, noting this list is not exhaustive:

- ISO 9001:2015 - Quality Management Systems,
- 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),
- ISO 45001:2018 - Occupational Health and Safety Management Systems,
- ISO 14001:2015 - Environmental Management Systems,
- ISO 27001: 2022 - Information Security Management Systems,
- ISO 19650 - 2: 2018 Building Information Modelling (BIM),
- International Atomic Energy Agency (IAEA) GSR Part 2: Leadership and Management for Safety [4],



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- American Society of Mechanical Engineers (ASME) ASME NQA-1: Quality Assurance Arrangements for Nuclear Facilities [5],
- Environment Register based internally within Rolls – Royce SMR Smart Reporting System,
- Management and leadership for the environment: generic developed principles – GOV.UK ([www.gov.uk](http://www.gov.uk)) [6],
- Radioactive Substance Regulation (RSR): Objective and Principles and RSR Generic Developed Principles [7],
- Office for Nuclear Regulation (ONR) Safety Assessment Principles (SAPs) [8] and Technical Assessment Guides [9].

## 2 General Characteristics of the Management System

### 2.1 Business Vision

Rolls-Royce SMR Limited has a vision statement ‘To provide clean, affordable energy for all’ which is supported by a number of strategic priorities, enabling programs, functions, values and behaviors. The Rolls-Royce SMR Limited values and behaviors support the embedding of behavioral expectations into a sustainable Rolls-Royce SMR Limited culture (SMaRt Culture) for everyone (see Figure 17.1 1). Our values and behaviors underpin who we are as an organization. They act as a guide to enable us to build upon our strong culture that also supports a healthy nuclear safety culture. Through displaying behaviors which align with our values, we can positively bring them to life and ensure they act as a guiderail to drive us forward and ensure we make the right decisions individually, and as a team.



Figure 2-1: Rolls-Royce SMR Values and Behaviors

### 2.2 Rolls-Royce SMR Limited Policies

2.2.1 Rolls-Royce SMR Limited has developed and deployed a strategic set of mandated policies.

- 2.2.2 Rolls-Royce SMR Limited policies define why the policy topic is important and the appropriate organization's values, code of conduct, leadership commitment, intent, and supporting principles and expectations we place on all our people in order to maintain consistent standards across the organization when carrying out particular activities in our day-to-day work.
- 2.2.3 All the policies are mandatory and are understood and followed by everyone at Rolls-Royce SMR Limited. These are deployed through staff inductions, initial and annual refresher mandatory training, staff objectives and appraisals, communications, staff awareness and coaching sessions.
- 2.2.4 The Rolls-Royce SMR Limited policies continue to develop and are reviewed to capture and reflect the business values, leadership commitments, and nuclear industry and stakeholder expectations, using Relevant Good Practice (RGP) that's appropriate for the Rolls-Royce SMR Limited business.
- 2.2.5 The development and deployment of these policies is integrated and part of the Integrated Management System (IMS) development, deployment, and continuous improvement program. Policies are controlled documents that reside within the Integrated Management System and are managed, governed and change controlled accordingly. Each has a Policy Owner (Executive Leadership Team), supported by a Policy Owner Delegate (if appropriate) and Policy Lead.
- 2.2.6 The Health, Safety and Environment Policy [10] sets out the business commitment to take care of the environment as well as the safety, health and wellbeing of our colleagues and those who work with Rolls-Royce SMR Limited. The policy defines key responsibilities for implementation including accountability, high standards and compliance. The policy sets out that Rolls-Royce SMR Limited expect the highest standards of behavior to protect their own and others, health and safety, and the environment in which Rolls-Royce SMR Limited operates.
- 2.2.7 The Quality Policy [11] sets out the importance of robust quality that is delivered through processes, to ensure that products and services, including those of suppliers, conform to specification. The policy defines key responsibilities including the importance of understanding individual roles and responsibilities in relation to quality and to participate in the deployment and implementation of the policies, processes, and quality programs. It highlights the need to identify areas for improvement and learning opportunities to drive towards best practice and business excellence. This is supported by the identification of risks and encouragement of challenge in the processes.
- 2.2.8 The Nuclear Safety Culture Policy [12] highlights the importance of a nuclear safety culture to support the creation of an environment where concerns can be raised, continuous improvement promoted, problems identified and resolved and working processes are planned and controlled.
- 2.2.9 The Sustainability Policy [13] highlights the importance of being a sustainable business for the purposes of safeguarding the environment and resources, supporting people and the communities in which Rolls-Royce SMR Limited operate and future generations, whilst

delivering value for investors and customers. It sets out the aim to develop a long-standing sustainable business through alignment with the United Nations Sustainable Development Goals [14], embedding sustainability in decision making throughout the organization, measuring ongoing and continuous improvement and ensuring that the approach is applied to future business development.

- 2.2.10 The Product Safety Policy [15] highlights the importance of eliminating, as far as reasonably practicable, the risk of delivering an unsafe nuclear power station in order to protect the wellbeing of the communities and environment in which our products operate. This encompasses all aspects of the design, manufacture, assembly and commissioning and, to the extent within our control the operation, maintenance and decommissioning. It sets out responsibilities and commitments to safety with key principles including Leadership accountability, robust product safety standards, safety awareness and competence, safe conforming products and the Identification and evaluate safety issues.
- 2.2.11 The Speak Up Policy [16] highlights the importance of having an environment where employees and stakeholders feel able to speak up when they have concerns without fear of retaliation. It is vital that all employees and stakeholders are able to speak up when they have questions or suspect any breaches of the Rolls-Royce SMR Limited policies or unethical behavior. It provides the commitment that all matters raised will be appropriately investigated.
- 2.2.12 The Security Policy [17] highlights the importance of maintaining security of our business, people, customers, and partners. It provides the key objectives and commitment to safeguarding our assets, through clearly defined requirements, objectives and enabling program, promoting a security risk-aware culture, staff and supply chain roles, responsibilities, awareness and training, responding to incidents and driving continuous improvement.
- 2.2.13 The Compliance Culture Policy [18] highlights the commitment to conducting business in a responsible, ethical and compliant manner. It highlights the importance of the company values and behaviors, the consequences of a breach, and that a compliance culture is fundamental to our success part of how we work. Rolls-Royce SMR Limited is subject to a range of UK and international laws and regulations governing topics including Ethics & Compliance, Data Privacy, Export Control and Sanctions Compliance, Corporate Governance and Intellectual Property that set out expected standards of conduct. The policy set out the principles to support a compliance culture in meeting these standards, and to speak up and ask, if unsure.
- 2.2.14 The Enterprise Risk Management Policy [19] highlights the importance embedding risk management into its culture and into the behavior of all people involved in the management, operation, development, and delivery of its objectives. The policy identifies key objectives, supporting principles, responsibilities for staff at all levels of the organization.
- 2.2.15 Through these policies, Rolls-Royce SMR Limited has committed to engaging, communicating clearly and openly with all stakeholders and driving continual improvement and innovation through appropriate targets and goals.

- 2.2.16 Rolls-Royce SMR Limited policies welcome and encourage challenge along with the requirement to report concerns, speak up and ask, if unsure.
- 2.2.17 These policies demonstrate Rolls-Royce SMR Limited commitment to support E3S, quality, nuclear safety culture and continual improvement.

## 2.3 Integrated Management System (IMS)

- 2.3.1 Rolls-Royce SMR Limited has developed and established an Integrated Management System (IMS) to enable the business to fulfil its responsibility for safe delivery and the effective management of its business.
- 2.3.2 The IMS is structured to enable the business values, requirements, and expectations to be embedded through a Governance, Risk & Compliance Framework [20], Code of Conduct and supporting policies, manuals, value streams, processes and procedures, task instructions, standards, templates and guidance (Figure 17.1 2).
- 2.3.3 The IMS has been developed to comply with applicable external legal, regulatory and nuclear industry standard requirements and expectations, including shared learning from guidance and RGP listed above.
- 2.3.4 The IMS has been externally certified to ISO 9001, 19443, 45001, ISO 14001, ISO 27001 and continues to be assessed as part of the ISO certification program.

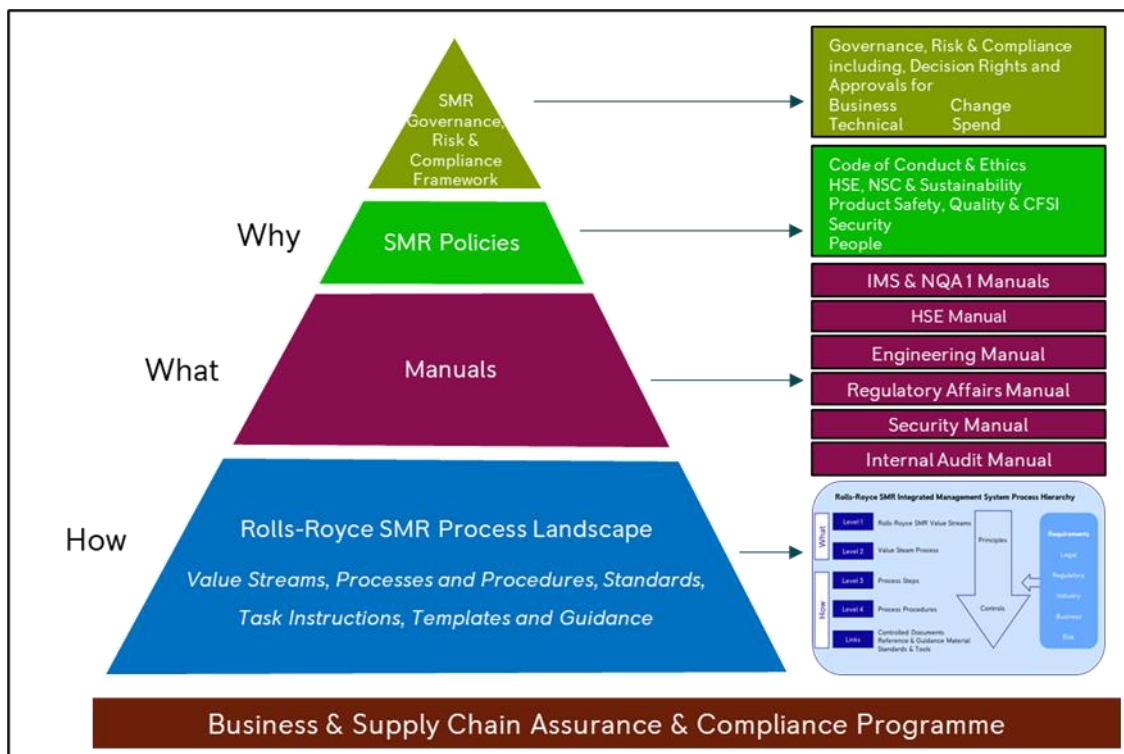
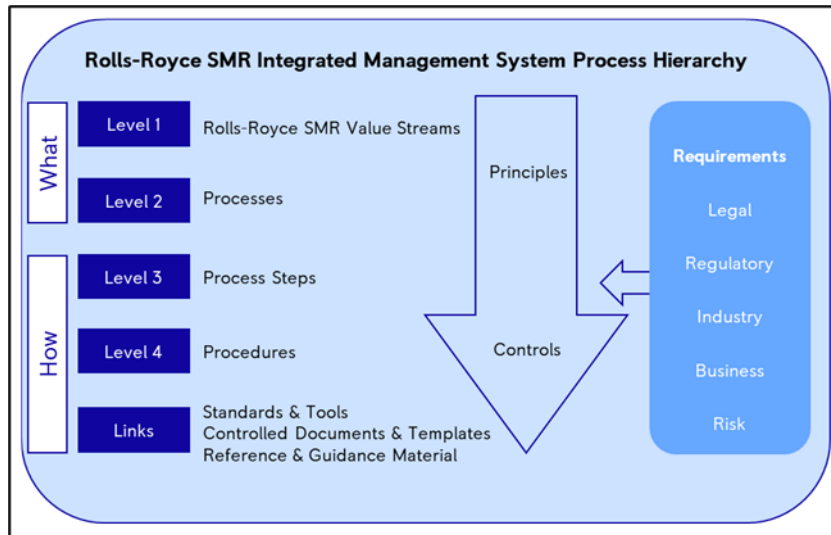


Figure 2-2: Rolls-Royce SMR Limited IMS Framework

2.3.5 The IMS Process Landscape provides a simple and agile framework of end-to-end value streams, integrated management and functional supporting and enabling procedures, processes and guidance to deliver Rolls-Royce SMR Limited vision, strategy and objectives and provides a foundation for business excellence.

2.3.6 The IMS Process Hierarchy (Figure 17.1 3) is composed of four levels:

- Level 1 and 2 – Value streams and processes describing ‘what’ is required,
- Level 3 and 4 – Process steps and supporting procedures describing the ‘how’.



**Figure 2-3: Rolls-Royce SMR Limited Business Process Landscape**

2.3.7 Responsibilities associated with the management system are defined in the IMS Manual [21], and subsequently the Health, Safety and Environment Manual [22], the Regulatory Affairs Group Functional Manual [23] and the Security Manual [24].

2.3.8 For Rolls-Royce SMR Limited to deliver its vision and consistently meet customer, regulatory and stakeholder expectations and needs, a set of high-level IMS objectives have been defined and are documented in the IMS Manual [21].

2.3.9 These objectives are reviewed on a continual basis to ensure the IMS meets internal and external requirements and expectations.

2.3.10 Embedding of key activities into the IMS is achieved by a set of defined principles. A principle is a fundamental statement that serves as the foundation for the management system.

2.3.11 Effectiveness of the IMS is carried out through the Rolls-Royce SMR Limited assurance arrangements (Section 3.12) and through periodic business reviews as required by Rolls-Royce SMR Limited procedure M3.1.2-1 - Define Management System requirements [25], which are conducted to assess and evaluate business performance, effectiveness of processes, risks, issues and opportunities.



- 2.3.12 The IMS and its supporting arrangements are updated as the business develops and matures.
- 2.3.13 Development of the Design and E3S Case is carried out in line with the IMS Level 3 Process C3 – Develop Solution, and its supporting processes and procedures. Further details are captured in Section 4 of this Topic Report.

## 3 Specific Elements of the Management System

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### 3.1 Organization Arrangements

- 3.1.1 The Rolls-Royce SMR Limited Board (RR SMR Board), which includes representatives from Rolls-Royce plc as well as other shareholder representation, are ultimately accountable for the management system, ensuring that it is established, implemented, assessed, and improved, and is effective for meeting the business objectives.
- 3.1.2 The Rolls-Royce SMR Limited Executive Leadership Team (ELT) are accountable and responsible for the day-to-day management and governance of their delivery programs, or enabling function, setting strategic aims, providing leadership to put these into effect, and supervising the management of the business to ensure effective implementation of business strategic vision, mission and values. These responsibilities are operationally discharged through setting policies, delegation of authority, organizational and management structures, committees and the IMS arrangements described in this document.
- 3.1.3 The Rolls-Royce SMR Limited team structure responsibilities are:
- 3.1.4 Strategy and Business Development team are responsible for the growth of the Rolls-Royce SMR Limited business covering our market strategies and prioritization; our customer relationship development to generate a differentiated position for RR SMR; and the creation of strategic partnerships to bring capability, market access and funding.
- 3.1.5 Corporate and Government Affairs function is responsible for all government affairs, communications, policy and engagement with investors in our business as well as safeguarding our brand publicly. One of the core focuses of Corporate Affairs is to publicly build and maintain the reputation of our business with consumers, Government and wider industry.
- 3.1.6 The Finance function is responsible for the management of financial activities for Rolls-Royce SMR Limited, ensuring the financial requirements of all key stakeholders are adhered to. The Chief Finance Officer is also responsible through the Chief Information Officer (CIO), for the Information Technology (IT), including the Cyber Security function who are focused on ensuring we enable the business with the right systems and processes to drive business performance, and that those systems provide adequate protection to the business.
- 3.1.7 The Commercial Team support our key priorities, delivering our orders and establishing the commercial relationships we hold with key partners and suppliers. The Commercial Team work collaboratively in the Customer facing and Supply Chain space as well as closely with our General Counsel, bringing the business together and providing commercial oversight to our operations.
- 3.1.8 The Engineering function is responsible for all aspects of engineering capability and delivery across the Rolls-Royce SMR Limited enterprise. This includes the role of Chief Engineer, with full accountability for the engineering design, verification, validation and delivery programs,

acceptance and governance of all engineering solutions and definitions, as part of the integrated power station solution and all matters related to ensuring product safety.

- 3.1.9 The Operations Team comprises Manufacturing, Supply chain, Planning, Logistics, Operational Quality and Manufacturing Engineering with a focus on delivery readiness, creating a value chain with both internal (factories), external supply chain, along with digital and technology enabled installation and assembly of our RR SMR Power Station to schedule, cost and licensee arrangements.
- 3.1.10 Internal Audit function (under the Chief Finance Officer) is responsible for the provision of an internal audit service to the business supported by a small team of auditors. Internal Audit provides an independent assurance and consultancy service intended to drive improvements in organizational effectiveness, with a focus on risk management, the organization's control environment and governance arrangements.
- 3.1.11 People function includes responsibility for the management of our employee relations through business partnering, engagement and organizational effectiveness, Equity, Diversity & Inclusion (EDI) activities and talent management. The function is also responsible for Learning and Skills development, strategic workforce planning and our Reward and Recognition.
- 3.1.12 General Counsel function ensures that we conduct business in a responsible, ethical and compliant manner. This includes responsibility for our business-wide legal and compliance function including Corporate Governance, Data, Privacy, Export Control, Ethics & Compliance and Intellectual Property.
- 3.1.13 The Safety and Regulatory Affairs Function is responsible for the business Health, Safety, Environment, Sustainability and Quality (HSEQ), Security, Regulatory Affairs and Nuclear Assurance. These functions ensure that the Rolls-Royce SMR Limited Integrated Management System and arrangements keep our people and the environment safe and secure and that we are compliant with the associated regulatory requirements.
- 3.1.14 Program Management Office provides project and program management services to the business, collating updates and progress reports for the wider Rolls-Royce SMR Limited Company.
- 3.1.15 The Safety and Regulatory Affairs Function Directorate includes the following groups and functions:
- 3.1.16 The Regulatory Affairs Group is led by a Head of Regulatory Affairs who reports directly to the Safety & Regulatory Affairs Director. The Regulatory Affairs Group is responsible for providing E3S input to the engineering design through the definition of requirements and provision of expert guidance, setting the standards and informing the study of RGP, development and management of the E3S Case (or equivalent safety analysis report) and setting the strategy for and execution of the strategy for acquisition of licences and permits globally in support of deployment of the Rolls-Royce SMR power station.
- 3.1.17 The Security Group provide informed security and safeguards input for the design, which is provided via the Regulatory Affairs Group under an integrated E3S input. They also set

Security Policy and deliver governance and assurance over the business. The Security Group sits within the Safety and Regulatory Affairs Directorate. The group provides a security function for the whole of the business. This includes personnel security, physical security for company facilities, cyber security and information security. The policies and procedures in place recognise the specific requirement for a civil nuclear business and the pertinent legal obligations and regulations. The development and management of the Nuclear Security Case for the RR SMR is also undertaken by the Security Group as part of an integrated E3S Case.

- 3.1.18 The Safety & Regulatory Affairs function is subject to assurance by the Nuclear Assurance team as is the rest of the business. Assurance is provided by Independent Oversight activities and Independent Peer Review in line with the relevant process framework. The activities form part of the Total Assurance integrated assurance plan and arrangements.
- 3.1.19 The HSEQ Organization forms part of the Safety and Regulatory Affairs Function and provides business wide governance, advice and guidance on matters relating to Health, Safety, Quality and the Environment. Conventional health and safety input into the design as part of a coordinated E3S input is provided through the HSEQ function. The Head of HSEQ also has delegated responsibility for coordinating the development and implementation of the IMS development and deployment program, IMS governance, assessment, and continuous improvement.
- 3.1.20 Rolls-Royce SMR Limited demonstrates leadership and commitment to the management of E3S through:
- The establishment and deployment of policies and objectives,
  - Clear roles and responsibilities identified and maintained through the Board of Directors, Executive Leadership Team, Safety and Regulatory Affairs Director and the wider Rolls-Royce SMR Limited teams,
  - Providing direction and governance on culture through the Rolls-Royce SMR Limited values, behaviors, and supporting policies, which encourages safe behaviors throughout the organization and is aligned with the core values and behavior traits defined by the World Association of Nuclear Operators (WANO) and International Atomic Energy Authority (IAEA),
  - Optimization of the design in accordance with As Low as Reasonably Practicable (ALARP), Best Available Techniques (BAT) and Secure and Safeguards-by-Design approaches in the UK,
  - Reviewing the deployment of the arrangements on a regular basis through business reviews to ensure continual improvement.

## 3.2 Governance Arrangements

- 3.2.1 The Business Governance, Risk & Compliance Framework [26] defines, at the highest level, an overarching view of the business requirements, how these are met and governed by the Rolls-

Royce SMR Limited Board and ELT, the accountabilities, and the supporting governance and risk management framework.

3.2.2 By implementing this framework, this supports the achievement of the E3S objective of 'protecting people and the environment from harm' and takes into account the interfaces between E3S.

3.2.3 This framework also supports the delivery of the Rolls-Royce SMR Limited Vision, Mission, Values and Strategy supported by delivery programs, management plans, a competent and capable organization, governed by a framework of Delegation of Authority (DoA), committees, procedures and controls.

### **3.3 Key Bodies in Support of Management of E3S and Quality Assurance**

3.3.1 A description of the key bodies in support of Management of E3S and QA are as follows:

- The Rolls-Royce SMR Limited Board is the primary executive function where major business decisions and directions are sought. The Rolls-Royce SMR Limited Board addresses all aspects of business operations, ensuring that the Business Plan and objectives are being maintained and that all corporate policies are adhered to. The Audit and Risk Committee is a Rolls-Royce SMR Limited board committee which takes place quarterly and its purpose is to ensure the integrity of the financial reporting and audit process and to oversee the maintenance of sound internal control and risk management systems,
- Product Safety Review Board (PSRB) ensures that products are safe by design whilst ensuring that the environmental impact of the product is minimized and that it is secure-by-design. The focus of the board for products in the design and verification phases (including significant product upgrades) is to identify and mitigate the hazards inherent in the design by setting and meeting safety requirements, and to ensure that lessons from previous products are incorporated,
- The Design, Safety and Environmental Advisory Committee (DSEAC) provides independent advice to the Chief Executive Officer (CEO) of the business in relation to matters of design philosophy, nuclear safety, radiological environmental protection, and security in relation to the proposed design and layout of, and the associated E3S Case developed to support the development of the Rolls-Royce SMR design.
- The Executive Leadership Team (ELT) has implemented an operational governance structure within the business designed to provide robust review, oversight and control to support effecting decision making, the review and management of business risks and of operational effectiveness of the business. This is conducted through the ELT Sub-Committees such as:
  - Business Approvals Sub-Committee (BASC) is the focal point for decision making and internal assessment on change programs or significant capability builds delivered through medium and major change initiatives,

- Program Sub Committee (PSC) is the management review of the integrated business wide program, cost schedule and operations. Key program risks are reviewed and discussed to provide assurance that risk mitigation actions are having the desired effect and to discuss/identify new emerging key program risks,
- The Health, Safety, Environment and Quality (HSEQ) Sub - Committee reviews, and where appropriate, makes decisions that support and govern the Rolls-Royce SMR Limited HSEQ vision, strategy and delivery program. The review includes both the HSEQ enablers and business performance to ensure the management arrangements are adequate and continue to be effective in satisfying the Rolls-Royce SMR Limited business stakeholder, industry and HSEQ assurance program and expectations,
- The Strategic Security Sub-Committee provides strategic direction and management reviews on all security activities, including but not limited to Cybersecurity across the Company, including alignment and priority of activities against key business strategic goals as well as risk acceptance, resolution of audit issues, accountability for the Integrated Security Management System and includes review of Statement of Applicability (SoA) as defined by ISO 27001 and continuous improvement.

3.3.2 These governance arrangements support Rolls-Royce SMR Limited in establishing behavioral expectations to foster a strong nuclear safety culture (See Section 6).

## 3.4 Organizational Capability

3.4.1 Rolls-Royce SMR Limited continue to develop an organization that supports the progression of design maturity, fit for the purpose of delivering an adequate design and supporting E3S justification. The organization has been sized based on respective organizations and the maturity of the business. Rolls-Royce SMR Limited take into account previous experience in key roles and look for diversity in knowledge and experience. This has involved a recruitment program that continues to populate the organization with competent individuals via an established recruitment process.

3.4.2 Key competences and mandatory training qualifications are set out in each job description and defined by suitably qualified and experienced persons. Persons are then recruited against these job descriptions in line with the company governance. Once onboarded into Rolls-Royce SMR Limited, individuals are assessed for these key competencies and other competence. Any gaps in competence are addressed by provided training or development opportunities. Results are recorded in the Rolls-Royce SMR Limited SMaRt Learning system.

3.4.3 For some niche roles where it is deemed appropriate and where the recording of experience is important in demonstrating competence, 'On the Job Training' manuals are maintained and recorded to aid in the demonstration of competence.

3.4.4 Supply chain partners are engaged, from time to time, to provide specialist competence that Rolls-Royce SMR Limited does not require in the long term, cannot be sourced from the open

market in sufficient timescales and/or to accommodate peaks in the workload. Assurance of the competency of supply chain partners is managed by suitably competent individuals as part of Rolls-Royce SMR Limited business arrangements.

### **3.5 Resource Management**

- 3.5.1 Recruitment for Rolls-Royce SMR Limited is carried out in line with the Rolls-Royce SMR Limited process, S1.2.1-1 Manage Recruitment [27] which sets out the requirement to identify competence criteria for the post.
- 3.5.2 Rolls-Royce SMR Limited Head of Functions and supporting Managers, reporting to the appropriate Executive Leadership Team member, are responsible for ensuring that resources that are essential to the implementation of the strategy for the management system and the achievement of the organizations' objectives are identified and made available.
- 3.5.3 Resources are delivered into an Organizational Design and assigned through Work Packages relevant to the delivery of the Program. As the business develops the Organizational Design will change as a result of Strategic Workforce Planning which enables the business to use its capabilities in the right way as well as develop and retain skills for the future business state.
- 3.5.4 Rolls-Royce SMR Limited arrangements for intelligent customer capability are captured in the Supplied Products and Services Management Plan [28] which has been developed in line with international good practice and the guidance of ONR Technical Assessment Guides [9].

### **3.6 Learning and Development – Competency Framework**

- 3.6.1 Rolls-Royce SMR Limited utilize a competency framework which is used to assure competent resource in relation to business activities. The Rolls-Royce SMR procedure – S1.1.4-1 Develop Competence Framework [29] defines how Rolls-Royce SMR Limited develops and presents its Competency Framework(s). The Rolls-Royce SMR Competence Framework(s) are developed and used by employees to show business best practice, and that we are working to nuclear industry standards.
- 3.6.2 Rolls-Royce SMR Limited take a systematic approach to assessing competence and maintaining core capabilities. The arrangements ensure that all employees and third party contractors have the required level of competence to safely perform routine and emergency roles, meeting all E3S requirements.
- 3.6.3 The Rolls-Royce SMR Limited process – S1.3.1-1 Assess Competence [30] defines how Rolls-Royce SMR takes a systematic approach to assessing competence by making and implementing adequate arrangements. The arrangements ensure that competencies are mapped to roles with targets levels set per competency and that all employees and secondees have the required level of competence to safely perform routine and emergency roles, meeting all safety requirements, including compliance with regulatory and international standards. Skills Assured, an online, secure competence management system is utilised to review the competence of our workforce against their posts. This shows any skills or knowledge gaps where additional training/support can be provided.

- 3.6.4 The competency assessment is a two-step assessment process starting with a self-assessment, where colleagues score themselves and provide evidence against each competency, this is followed by a review completed with the colleague's people leader during which experience, knowledge and evidence is reviewed and, where needed, a Talent and Development plan can be put in place to support any gaps identified.
- 3.6.5 Subsequently any required training is undertaken in line with the Rolls-Royce SMR Limited procedures – S1.3.3-1 Undertake Training [31] and S1.3.4-1 Undertake Training Evaluation [32]. This enables individuals to be provided with the knowledge and skills required to enhance their competency, supported by their behaviors and experience.
- 3.6.6 For third-party contracting partners, Rolls-Royce SMR Limited apply the necessary arrangements in line with the Supplied Products and Services Management Plan [28] to ensure adequate competence of personnel. This document also defines the requirements of Rolls-Royce SMR Limited colleagues executing the role of Intelligent Customer to ensure competent contract personnel are deployed in their scope of work.

## 3.7 Procurement Control

- 3.7.1 Rolls-Royce SMR Limited have developed a Supply Chain Organization to deliver a sustainable, fit for purpose (in line with required quality standards), right first-time products, services and outcomes, on time and in budget whilst demonstrating value for money. It takes into account international good practice and the guidance provided in the ONR Technical Assessment Guides; NS-TAST-GD-077 Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services [33] and NS-TAST-GD-049 Licensee Core Safety and Intelligent Customer Capabilities [34].
- 3.7.2 The organization has been developed to enable effective partnering within the business, embrace and drive the intelligent customer approach and is meaningful to the supply chain markets.
- 3.7.3 Rolls-Royce SMR Limited will maintain control of procurement activities through compliance with the IMS process S4 - Manage Supplier [35], which captures the arrangements for defining products and services, supplier evaluation, assessment and selection along with the sourcing and contracting of the supplier and subsequent review and release of the product or services.
- 3.7.4 Rolls-Royce SMR Limited monitor and manage supplier performance in line with the Rolls-Royce SMR Limited procedure, S4.7.1 Monitor and evaluate supplier performance [36], which involves the collection and analysis of supplier performance data.
- 3.7.5 Rolls-Royce SMR Limited are deploying an intelligent customer framework to ensure it has adequate control over goods and services provided by the supply chain. These arrangements are documented in the Supplied Products and Services Management Plan [28].
- 3.7.6 The Supplied Products and Services Management Plan [28] includes the arrangements for specification of requirements, oversight of work carried out and an understanding of the implication of results or conclusions.

- 3.7.7 Intelligent Customer Capability includes anything that has a significance to E3S such as design activity, E3S Case production and the purchase of items with E3S functionality.
- 3.7.8 Rolls-Royce SMR Limited cascade QA requirement to suppliers of products and associated services as contract appendices via Rolls-Royce SMR Limited Supplier Management Systems Requirement (SMSR) document [37]. This document specifies requirements associated with the supplier and sub-supplier quality and business management system and includes but is not limited to Nuclear Safety Culture, Security, Export Control, Contract deliverables, Counterfeit Fraudulent and Suspect Items (CFSI) Prevention, Lifetime Quality Records, Inspection control, competency of personnel as well as other requirements. These requirements are determined based on safety classification and quality assurance grades determined in technical specifications which describe the contract scope of work.
- 3.7.9 During the supplier down-selection phase, Rolls-Royce SMR Limited Supply Chain Quality Assurance team conduct an assessment audit against the SMSR document [37] through procedure S4.3.2-1 Approve Supplier and Conduct Surveillance [38] to determine the level of quality assurance arrangements established by suppliers and identify any gaps and risks related to supporting the successful delivery of safety classification of works that the supplier is undertaking. Suppliers are expected to demonstrate an appropriate level of compliance prior to any works commencing. To verify that the supplier is maintaining the required level of quality assurance, Rolls-Royce SMR Limited Supply Chain Quality Assurance team utilise a Supplier Audit program to undertake assessments dependent on assessment audit outcomes, risk levels and contract progress.
- 3.7.10 Technical service providers supporting the development of the Rolls-Royce SMR Limited are confirmed as competent to undertake contracted scopes of work through the Rolls-Royce SMR Limited supplier qualification process, Rolls-Royce SMR Limited process S4.3.1-1 Evaluate capability of supplier [39].
- 3.7.11 Supplier risk management is covered by the S4.7.3-1 – Manage Supplier Risk [40] procedure which defines the methodology for identification and management of risk which should be deployed across the entire S4 Manage Supplier Stream.
- 3.7.12 The procedure ensures, effective risk and opportunity management to support the Supply Chain function to achieve its objectives by:
- Reducing the likelihood and mitigating the possible impact of threats,
  - Improving visibility and communication of potential issues and threats,
  - Identifying and exploiting opportunities that might benefit the organization.
  - Improving decision-making and accountability by encouraging the identification and discussion of risks,
  - Informing budget allocation, procurement and contract management and the management of contingency to ensure that funds are used effectively,
  - Helping the function become more responsive to new challenges and uncertainties.

- 3.7.13 The arrangements captured in this section support the demonstration of Rolls-Royce SMR Limited Intelligent Customer capability.

## 3.8 Document and Records Control

- 3.8.1 Documents are produced, stored and maintained in line with the standard for Management of Documented Information (Records) [41]. All documents and records produced have their 'Retention Category' identified on the document or record.
- 3.8.2 Engineering documentation is prepared in accordance with the Rolls-Royce SMR Limited Engineering Management Manual [42] and subsequent Rolls-Royce SMR Limited process, C3.2.1-4 Technical Checking and Approval Process [43].
- 3.8.3 The E3S Case documents are Independently Peer Reviewed (IPR) in accordance with Rolls-Royce SMR Limited S2.3.2-2 Conduct Assurance Activity (Independent Peer Review) [44], which supports the Total Assurance Model detailed in Section 3.12. An IPR plan is generated which considers the global / holistic considerations and intelligence on areas of concern that are gained by the Independent Nuclear Assurance team and previous IPR activities to inform on areas that IPR should focus more on. The implementation of the IPR plan can therefore lead to additional documents being subject to IPR to provide additional levels of assurance.
- 3.8.4 The arrangements for marking of business sensitive information are captured in Rolls-Royce SMR Information Classification and Handling Standard [45]. This standard describes the specific markings to be aligned with business sensitive information. This standard is supported by adjacent standards relating directly to the Management of Sensitive Nuclear Information, Management of Export Control Requirements Standards, Commercial Markings Standard, inclusive of third-party artefacts and privacy (described within General Data Protection Regulation (GDPR) and Data Protection Act (DPA) clauses).

## 3.9 Program Management

- 3.9.1 Rolls-Royce SMR Limited has developed suitable project and program management arrangements which capture the development of baselines, schedule and interface management, cost management, risk and opportunities management, performance and change management and reporting.
- 3.9.2 The Program Directorate has responsibility for the business and RR SMR reporting. The Program Directorate is responsible for the IMS S9 – Manage Program and Project [46] which covers the management of the lifecycle of a program or project from initiation to close including how to report, control budget, manage risk, change control and planning. This provides a set of guidelines and expectations for any local projects to operate within.
- 3.9.3 Licensing projects are owned by the Safety and Regulatory Affairs Function. The Safety and Regulatory Affairs Director and the Head of Regulatory Affairs have responsibility for delivery of these Licensing projects. Requirements are managed and delivered in accordance with the Regulatory Affairs Group Functional Manual [23] which details how the function operates and who sits within the organization. Within the Program Directorate there is a team of Project Managers who help enable the Safety and Regulatory Affairs team by locally applying

business project management framework against the requirements of the Licensing project. This is done through project specific Project Management Plans which is covered in 3.10.

### **3.10 Project Management Plans**

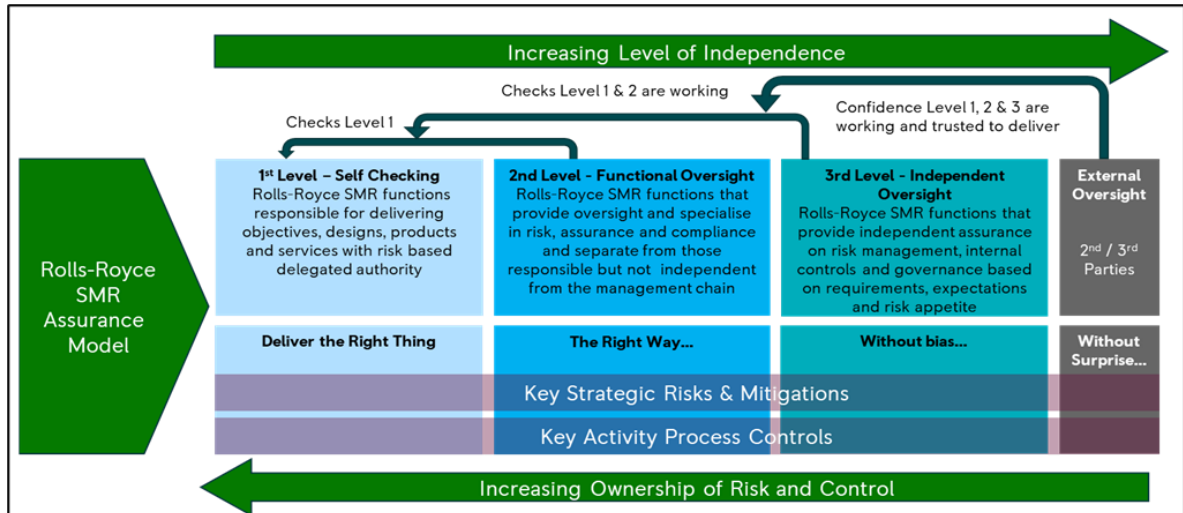
- 3.10.1 Rolls-Royce SMR Limited procedures S9.2.1-1 Establish Control System [47], defines the requirement to capture project arrangements within a Project Management Plan which is supported by individual management plans covering all aspects of the project including governance, assurance, resource, communication and costs.

### **3.11 Control of Non-Conformance and Corrective Action**

- 3.11.1 Rolls-Royce SMR Limited manages non-conformance (deviations) in line with S2.4.1-1, Respond to Compliance Deviations (Audit & Assurance) [48] and S2.4.1-2 Respond to Compliance Deviation (Business/Product) [49] procedures. The procedures cover the reporting and management of non-conformances, including assurance and compliance audit review findings and actions. These are recorded and tracked using an IT system tool called My Compliance.
- 3.11.2 Non-conformances are categorized based on the impact and severity, definitions of which are included in the above processes.
- 3.11.3 The approach and level of problem resolution and investigation is based on a deviation sentencing matrix defined within Rolls-Royce SMR Limited procedure, S2.4.1-2, Respond to Compliance Deviations (Business/Product) [50]. This ensures appropriate root cause analysis techniques are applied and effective preventative and corrective actions are taken. The process concludes with the requirement to confirm the effectiveness of the resolution and capturing of appropriate lessons learned.
- 3.11.4 The number of findings, type and status are measured and reviewed monthly. Trend analysis is carried out and learning built into continuous improvement activities.

### **3.12 Total Assurance Model**

- 3.12.1 Rolls-Royce SMR Limited have developed an integrated assurance program which is risk informed and operates a 'Total Assurance' Model (Figure 17.2 4).



**Figure 3-1: Rolls-Royce SMR Limited Total Assurance Integrated Program**

3.12.2 This process is implemented in accordance with the Rolls-Royce SMR Limited processes below:

- Rolls-Royce SMR Limited process, S2.3.1-1, Develop Integrated Assurance Program [51],
- Rolls-Royce SMR Limited process, S2.3.2-1, Conduct Assurance Activity [52],
- Rolls-Royce SMR Limited process, S2.3.2-2, Conduct Assurance Activity (Independent Peer Review) [53],
- Rolls-Royce SMR Limited process, S2.3.3-1, Conduct Concurrence [54].

3.12.3 The Total Assurance Model identifies three levels of assurance from self-checking, functional oversight and independent oversight.

3.12.4 Internal self-checking controls and reviews are based on a complementary set of arrangements including delegated authorities and accountabilities, policies, procedures, systems, document templates and stream reviews. All decision rights delegated authorities / accountabilities are documented and approved.

3.12.5 Functional Oversight involves assurance functions using a risk based, integrated audit and assurance program to review compliance to procedures and internal controls. The integrated audit and review assurance program is developed by the Rolls-Royce SMR Limited Assurance Manager (Quality). The development of the program is supported by all assurance and risk functions, and appropriate Process Owner and Program Leads. The assurance program is delivered using suitably qualified and experienced auditors that are independent from those performing the task.

The Nuclear Assurance Team are responsible for providing Independent Oversight (which includes Independent Peer Review) which assures the E3S performance and culture of the business against the standards expected of the nuclear industry and its regulators.

### **3.13 Knowledge Management and Learning from Experience**

- 3.13.1 Knowledge Management (KM) is an important activity as it can reduce the amount of time spent searching for information, reduce rework and encourage collaboration.
- 3.13.2 Rolls-Royce SMR Limited utilize a structured approach to planning and capturing of knowledge and sharing of RGP within the organization which is presented in the Rolls-Royce SMR Limited Knowledge Management Framework Summary [55].
- 3.13.3 Rolls-Royce SMR Limited uses shared learning from industry international standards and regulations (such as International Atomic Energy Agency, Office for Nuclear Regulation, Health and Safety Executive etc.); from external groups (such as World Nuclear Association (WNA), Electrical Power Research Institute (EPRI), and Safety Directors Forum Working Groups. This also includes shared learning and Operational Experience (OpEx) from investors (primarily Constellation, ČEZ and Rolls-Royce Group) and the supply chain.
- 3.13.4 This learning is embedded into the development of the E3S Case, development of the design, IMS procedures, arrangement, enablers, training and culture programs.
- 3.13.5 Rolls-Royce SMR Limited also makes every effort to consider learning from other industries and similar programs as part of this knowledge capture and sharing.
- 3.13.6 In support of continues improvement, at appropriate stages within project and programs, facilitated learning from experience events are held to capture areas for improvement, and what's working well. These are reviewed and embedded into processes and arrangements.
- 3.13.7 As part of our organizational maturity, Rolls-Royce SMR Limited has plans in place to deploy an in-house developed Lessons Learnt database across the organization. The deployment will also include the arrangements required for effective logging, assessment, implementation and dissemination of lessons learned across the organization.

## 4 E3S Case and Design Management Arrangements

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### 4.1 E3S Case Arrangements – Management of the E3S Case

4.1.1 Rolls-Royce SMR Limited are developing a hierarchical E3S Case with three tiers of documentation, structured through a high-level Claims, Arguments, Evidence (CAE) approach, described in E3S Case Chapter 1: Introduction [56].

4.1.2 The E3S Case top level documentation is structured in line with IAEA SSG-61 [1] and US NRC Regulatory Guide 1.70 [2]. The UK E3S Case will form the basis of development for the Preliminary Safety Analysis Report (PSAR) and Final Safety Analysis Report (FSAR) in the USA in subsequent licensing phases.

4.1.3 The development and management of the UK E3S Case is governed by a suite of arrangements that flow down from the Regulatory Affairs Group Functional Manual [23]. This includes:

- E3S Requirements and Analysis Arrangements [57], which describes the arrangements and document hierarchy for the input of E3S into the design. It also describes the analyses performed in support of, and confirmation of, design choices in the evolution of the design. The document is part of the IMS and refers out to a series of company standards that describe further details of specific E3S analysis methods and their integration with design processes,
- E3S Case Development and Management Arrangements [58], which describes the objectives, integrated approaches, structure and content, and governance for the development and management of the integrated E3S Case as the generic design matures. It describes how the “golden thread” is demonstrated for the E3S Case, including the use of both a high-level CAE structure and the allocation and verification of E3S requirements from the analysis onto the design. The document is part of the IMS and refers out to supporting guidance such as the E3S Case style guide.

### 4.2 As Low As Reasonably Practicable, Best Available Techniques, Secure by Design, Safeguards by Design

4.2.1 The following principles seek to ensure that nuclear facilities and associated processes and activities are optimised to ensure maximum protection of workers, members of the public and the environment until such a point that the benefits of implementing further protection measures becomes grossly disproportionate to the cost of doing so.

- As Low As Reasonably Practicable (ALARP) – a requirement under the UK Health and Safety at Work Act (1974) [59] to ensure that risks to health, safety or welfare of employees are kept to a minimum and that persons not in their employment are not exposed to unnecessary or disproportionate risks to their health or safety. ALARP is not prescriptive but goal setting, placing a requirement on the duty holder to demonstrate risks have been minimized; the judgement made, being a balance of risk versus sacrifice weighted in favour of health and safety. The same ALARP principles

also apply to the demonstration of the application of Best Available Tools/Techniques (BAT), as part of compliance with Environmental Law,

- BAT – demonstrate the use of BAT to minimize the impacts on members of the public (and the environment) arising from radioactive substance activities (and other industrial processes) to levels that are ‘As Low As Reasonably Achievable (ALARA)’. Further information is captured in the Approach for Optimisation through the Application of BAT report [60],
- Secure By Design (SByD) – demonstrate a secure design from theft, sabotage, compromise of sensitive material and protection against diversion of nuclear material from peaceful uses are fundamental precepts underlying the UK nuclear licensing and environmental permitting legislation,
- Safeguard by design – including the consideration of international safeguards throughout all phases of a nuclear facility project, from the initial conceptual design to facility construction and into operations, including design modifications and decommissioning.

4.2.2 The responsibility is with the design lead with input from stakeholders from Safety and Regulatory Affairs, to demonstrate that the risk presented by the design to the public, workers and the environment is ALARP and applies BAT, and that the power station is secure by design and safeguarded by design. Designs are reviewed by the Engineering Interface Team against these principles and their inclusion in the design process demonstrated in accordance with the Rolls-Royce SMR Limited process, C3.2.2-3 Engineer safe, secure, safeguarded and environmentally sound products [61].

4.2.3 The design decision making process is used for undertaking optioneering, presented in the Rolls-Royce SMR Limited process, C3.2.2-2 Conduct Design Optioneering [62]. The justification of design decisions with respect to reducing risks to ALARP, applying BAT, and ensuring SbyD and secure by design, is recorded in the Rolls-Royce SMR Limited Decision Record Template [63]. This also documents the consideration of sustainability and balance of social, environment and economic impacts in the decision process. This process allows for E3S analysis to feed into the design.

4.2.4 Use of decision record templates for all design decisions enables a consistent approach across the full RR SMR design and ensures that the benefits and disadvantages of all key decisions are captured and documented with respect to reducing overall E3S risks.

4.2.5 Further detail on principles of ALARP, BAT, SbyD and safeguards by design can be found in E3S Case Tier 1 Chapters 24, 27, 32 and 33 respectively [64-67].

## 4.3 Configuration and Requirement Management

4.3.1 The Rolls-Royce SMR Limited design is being developed through a combined systems engineering and E3S assessment approach. Rolls-Royce SMR Limited will utilise, where appropriate, a set of systems engineering and robust design techniques in order to ensure

that the integrated design solution is optimised to meet all key requirements, including E3S requirements that support demonstration that risks are acceptable and reduced to ALARP.

## 4.4 Reference Designation System – Power Plants

- 4.4.1 Reference designation for Structure, System and Components (SSC) within the RR SMR power station scope is implemented in accordance with the Reference Designation System-Power Plants (RDS-PP®).
- 4.4.2 RDS-PP® is internationally recognised and is referenced within the International Electrotechnical Commission (IEC)/International Organization for Standardization ISO 81346 series of standards (industrial systems, installations and equipment and industrial product – structuring principles and reference designations). RDS-PP® provides a unique designation for each plant object throughout planning, licensing, construction, operation, maintenance, and decommissioning.
- 4.4.3 The RDS-PP® designation and hierarchy is used to assess relationships and potential change impacts.

## 4.5 Requirements Identification

- 4.5.1 Requirements are developed for the RR SMR Limited through the design and analysis processes. This includes E3S requirements, which are a specific sub-set of requirements as described in E3S Case Chapter 1: Introduction [56]. Further information on the derivation and integration of E3S requirements into the engineering processes is described in E3S Requirements and Analysis Arrangements [57].

## 4.6 Requirements Management

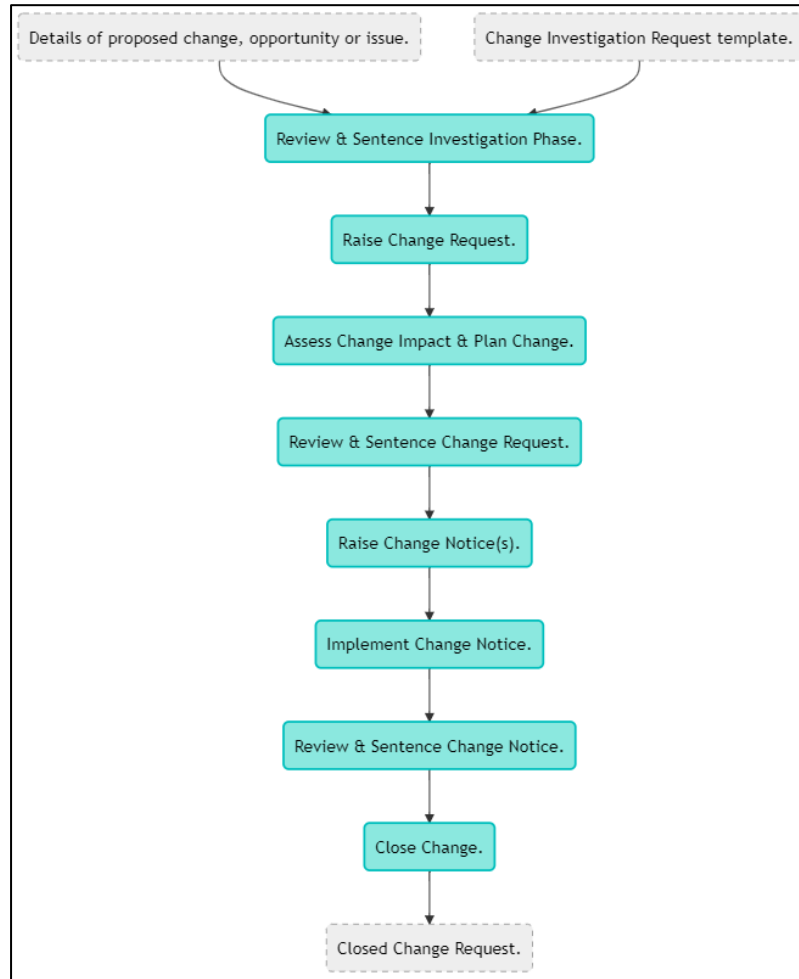
- 4.6.1 Requirements are captured within the project's requirements management database, in a structure that aligns to the functional product breakdown for the power station. As part of the systems engineering approach, requirements are flowed from the program to power station, to system and then to sub-system/component level in a clear, consistent, integrated and traceable approach. The resultant hierarchical design then undergoes progressive verification and validation to demonstrate evidence-based compliance with the requirements set, and to give confidence that the solution meets the operational needs of the program/customer.
- 4.6.2 Requirements management is a continuous process, applicable throughout the project delivery lifecycle. Requirements will be managed such that at each stage of definition or phase of project, there is a clearly defined and agreed set of approved requirements. Any change or addition to these requirements is managed and communicated, with clear traceability of the reason for change and the impact of that change on the activity/design definition.

## 4.7 Configuration Management for the Design, E3S Case and Design Reference

- 4.7.1 The RR SMR is currently in the design phase and the E3S Case is developing alongside it, with E3S analysis informing the design.
- 4.7.2 Rolls-Royce SMR Limited utilizes a Master Records Index (MRI) [68] which will at any given RD contain all artefacts relating to the design and its justification for the whole power station at that point in time.
- 4.7.3 The E3S Case Route Map is a 'live' tool used by the E3S Case team to manage the E3S Case as it develops alongside the design. It is developed in conjunction with the relevant engineering and analysis teams to provide confidence in the completeness of the CAE for each chapter of the E3S Case. It also provides a forward trajectory of level 2 and level 3 information as the E3S Case is developed alongside the maturing design.
- 4.7.4 Rolls-Royce SMR Limited has used a subset of the MRI, aligned with the E3S Case Route, to define the Design Reference Report [71], which meets the requirements of the Design Reference (DR) for the UK GDA. The DR report defines the baseline design reference configuration that the GDA submissions refer to at a point in time, known as a DRP. A number of agreed documents listed in the DRP report are submitted to the UK Regulators via the Master Document Submissions List (MDSL) in line with GDA operating instruction, Regulatory Correspondence [69].
- 4.7.5 The DRP report lists all of the current design documents that define the RR SMR design.
- 4.7.6 The DR will be frozen at regular DRPs, which will result in an up-issued DRP report. The DRPs will be in line with the internal design baselines on which the E3S Case issues are based, ensuring that each issue of the E3S Case is consistent with a DRP plus agreed changes, or at other key points as defined by Rolls-Royce SMR Limited. The final issue of the E3S Case submitted within GDA will align exactly with an agreed DRP.

## 4.8 Change Management for the Design, E3S Case and Design Reference

- 4.8.1 Rolls-Royce SMR Limited uses an integrated change control process to manage change to the design, the E3S Case and to the Design Reference (for GDA) to increase consistency and reduce potential errors or omissions. The high-level steps of the integrated change control process are provided in Figure 17.3 1.



**Figure 4-1: Change Control Process Flow**

- 4.8.2 The change control process enables the identification of resulting document changes that are part of the E3S Case, i.e., those in the E3S Case Route Map. Accompanying guidance is detailed within the Rolls Royce SMR Limited process, C3.2.1-9 Manage Change [70].
- 4.8.3 The Configuration Management Plan [71] establishes the overall configuration principles for the entire Rolls-Royce SMR power station and the methods that maintain integrated change control between the interfacing parts, assemblies, systems, islands, and the wider civils structures.
- 4.8.4 The Rolls-Royce SMR Limited process, C3.2.1-9 Manage Change [70] establishes the change management approach for Rolls-Royce SMR Limited and describes when to introduce change, the types of change and how it is enacted.
- 4.8.5 Guidance on the Execution of the Change Control Process for Engineering and E3S Changes across the Rolls-Royce SMR business [72] provides additional detail on how Rolls-Royce SMR Limited enacts change control, including how to assess the impact of proposed changes to the RR SMR design, and determine whether the impact would be acceptable or not, then

either accept, reject or defer the change as a result. Part of this impact assessment includes determining the E3S impact and impacts to the E3S Case.

- 4.8.6 Rolls-Royce SMR Limited implemented change control of the RR SMR design, upon declaration of the design within the Design Reference Report [73].
- 4.8.7 All changes are collated and referenced in the DRP report [73] for the purposes of the UK GDA and all changes and impacts to E3S documentation are identified and managed through the integrated change management process defined in the Rolls-Royce SMR Limited process, C3.2.1-9 Manage Change [70] which incorporates change impact assessment, categorisation, approval authorities and governance arrangements.
- 4.8.8 Changes in accordance with Rolls-Royce SMR Limited process, C3.2.1-9 Manage Change [70] and supporting Rolls-Royce SMR Limited guidance, are recorded and managed within the Rolls-Royce SMR Limited Product Lifecycle Management (PLM) tool, Teamcenter®. Teamcenter holds the record of each change and specifies documents and records that are impacted, referenced and introduced by the change. Teamcenter is also used to manage the governance, review and approval of changes in accordance with the arrangements referenced above.

## 4.9 Regulatory Affairs Group Functional Manual

- 4.9.1 The Regulatory Affairs Group Functional Manual [23] describes how Regulatory Affairs Group provide the E3S principles, requirements, inputs and how these are delivered across the business, specifically that the design meets the needs of the Rolls-Royce SMR Limited business.
- 4.9.2 The Regulatory Affairs Group is responsible for providing E3S input and analysis to the engineering design through the definition of requirements and provision of expert guidance, setting the standards and informing the study of RGP, development and management of the E3S Case (or equivalent safety analysis report) and setting the strategy for and execution of the strategy for acquisition of licences and permits in the UK and overseas in support of deployment of the RR SMR.
- 4.9.3 The Engineering directorate are the owner of the generic E3S Case pending its handover to the eventual operator/licensee.

## 4.10 Design Assurance

- 4.10.1 Engineering documentation that forms arguments and evidence for the E3S Case is prepared in accordance with the Rolls-Royce SMR Limited Engineering Management Manual [42] which includes four levels of Engineering Governance, the Rolls-Royce SMR Limited process, C3.2.1.-1 Engineering Program and Maturity (MR) Gate Review [74], the Rolls-Royce SMR Limited process, C3.2.1-2 Definition Review (DR) Process [75], Rolls-Royce SMR Limited process, C3.2.1-3 Gated Review (GR) Process [76] and Rolls-Royce SMR Limited process, C3.2.1-4 Technical Checking and Approval [77].

## 4.11 Engineering Approval and Delegated Authority

4.11.1 The Chief Engineer/Engineering Director has the accountability for release / approval of all engineering output in the program and the accountability to ensure the product safety and quality. This is exercised in line with Delegate Engineering Authority [78] which includes E3S experts. The E3S analysis verifies and provides feedback into the engineering design and subsequently the engineering output. Finally, the E3S assurance described below complements the engineering review to provide thorough multi-angled governance and assurance.

## 4.12 E3S Assurance

4.12.1 E3S Case documentation, including level 1, 2 and 3, follows the same Technical Checking and Approval Process [77] as other engineering documentation, and is also supported by Rolls-Royce SMR Limited process, S2.3.2-2 “Conduct Assurance Activity (Independent Peer Review Procedure) [53]. Level 1 chapters of the E3S Case are submitted through additional levels of governance over and above technical checking, including IPR, approval reviews by senior leadership, and the DSEAC in line with the E3S Case Development and Management Arrangements [58].

4.12.2 Governance over E3S activities in Rolls-Royce SMR Limited is provided through the Safety and Regulatory Affairs Director who maintains active line management and oversight of E3S activities through the Head of Regulatory Affairs, E3S Case Manager and independent nuclear oversight via the Head of Nuclear Assurance. The Head of Nuclear Engineering & E3S Assurance is responsible for the organizational framework that assures the plant design definition achieves nuclear specific E3S objectives.

4.12.3 Heads of the Safety and Regulatory Affairs Function provide governance oversight and technical approval of work undertaken in their defined areas of responsibility.

4.12.4 The Nuclear Assurance team deliver IPR of the E3S Case as it matures. This requires documentation of E3S significance to be subject to an appropriate depth and breadth technical review by competent persons, who are fully independent of those who produced, reviewed, and approved them, to provide additional assurance that the document is valid and fulfils its intended purpose.

4.12.5 The DSEAC provides independent review and challenge to the E3S Case (see Section 4).

4.12.6 Further details on the governance arrangements for the E3S Case are described in the E3S Case Development and Management Arrangements [58].

## 4.13 Commitments and Assumptions

4.13.1 Rolls-Royce SMR Limited utilises a process ‘Identifying, Recording, and Tracking GDA and Licensing Assumptions and Commitments’ [79]. This process captures the arrangements for the capture and recording of assumptions and commitments in the E3S Case that are placed on future duty holders, and how they are shared with future licensees.

- 4.13.2 Assumptions and commitments will be raised through the development of the E3S Case. Each assumption and commitment, along with the corresponding route for identification, tracking and recording, will be recorded in the Assumptions and Commitments (AC) for future Duty Holders Register [80] that is appropriately linked to the E3S Case, noting this will be facilitated by the case management software as described in Section 4.

## 4.14 Operational Limits and Conditions

- 4.14.1 Operational Limits and Conditions (OLCs) are derived through the design and safety analysis processes, which will be captured in RR SMR's requirements management database and eventually extracted as appropriate to develop Technical Specifications for the RR SMR power station. The process for managing the flow of OLCs into operational documentation is outlined in E3S Case Level 1 Chapter 16: Operational Limits and Conditions [81]. OLCs are currently being identified and will be transferred into operational documentation and presented first in Version 4 of the E3S Case.

## 5 Continuous Improvement of Arrangements

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### 5.1 Monitoring and Assessment

- 5.1.1 Rolls-Royce SMR Limited is a learning organization that observes and measures the effectiveness of the management system which supports the identification of opportunities for improvement.
- 5.1.2 The effectiveness of the IMS is evaluated through the Assurance arrangements identified in Section 3.12. and through periodic business reviews as required by Rolls-Royce SMR Limited process, M3.1.2-1, Define Management System Requirements [82], which are conducted to understand business performance, effectiveness of processes, risks, issues and opportunities.
- 5.1.3 Non-conformances are recorded and managed in line with Rolls-Royce SMR Limited procedures, S2.4.1-1 Respond to Compliance Deviations (Audit & Assurance) [83] & S2.4.1-2 Respond to Compliance Deviations (Business/Product) [84]. These procedures include the identification of corrective actions to eliminate causes of non-conformance and preventing recurrence.
- 5.1.4 The Rolls-Royce SMR Limited Total Assurance Process, detailed in Section 3.12. of this chapter, details the assurance activities that support the evaluation of the management system in the form of a three-tier process, from self-checking, functional oversight and internal oversight.
- 5.1.5 Rolls-Royce SMR Limited have introduced IMS process health checks which are carried out by Process Leads as a self-checking review of their respective processes against a standard set of criteria. This activity enables the identification of improvements whilst also identifying system wide trends.
- 5.1.6 Rolls-Royce SMR Limited utilise a process for Continuous Improvement, identified in Rolls-Royce SMR Limited process, M3.6.1-1 Deliver Continuous Improvement [85], this provides a structured approach to improvement, based on the Shewhart Cycle of Plan, Do, Check, Act (PDCA), which captures the expectations of knowledge management and lessons learned.

In order to deploy this process Rolls-Royce SMR Limited have developed a Continuous Improvement Framework [86]. This framework ensures continuous improvement opportunities are prioritized within the business.

### 5.2 Performance Monitoring and Improvement

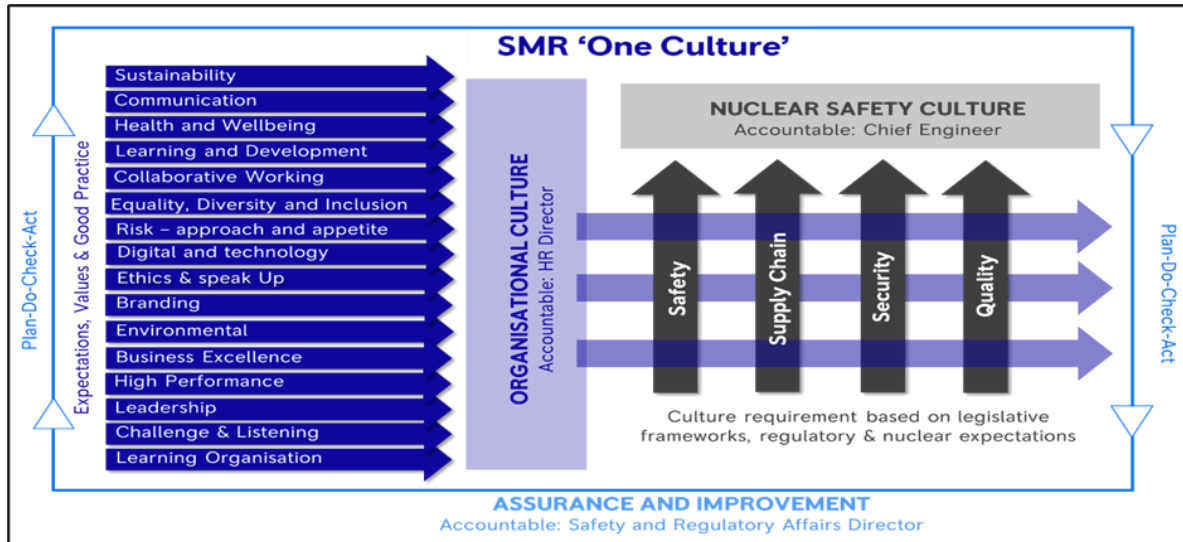
- 5.2.1 Rolls-Royce SMR Limited have developed a suite of Key Performance Indicators (KPIs) for the business which are reviewed on a periodic basis to ensure performance targets are achieved and improvements are identified and implemented. The performance measure for part of the Plan Do Check Act lifecycle and provide indicators on the performance and effectiveness of the arrangements and identify areas for improvement and / or good practice.

## 6 Nuclear Safety Culture

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### 6.1 Rolls-Royce SMR Limited Nuclear Safety Culture Arrangements

- 6.1.1 Adoption of a robust Nuclear Safety Culture is a fundamental requirement for everyone working within the nuclear industry. Rolls-Royce SMR Limited believe a healthy Nuclear Safety Culture is central to long-term success because the decisions made today will be felt for years to come.
- 6.1.2 The Rolls-Royce SMR Limited Nuclear Safety Culture Policy [12] sets out the commitment for a positive nuclear safety culture. It defines everyone as a leader and ambassador for our Nuclear Safety Culture and commits to speaking on safety, acting safely, focusing on maintaining safety standards, engaging others in our culture and initiatives and recognising and praising colleagues who behave safely.
- 6.1.3 The policy aims to create an environment where our values and behaviors support our collective commitment to ensuring the protection of people and the environment from our activities and the harmful effects of ionising radiation.
- 6.1.4 Our Nuclear Safety Culture expectations flow through to the Supply Chain via the Supplier Management System Requirements document [37] and is validated by the supplier Quality team. We work with suppliers to develop and maintain the knowledge and behaviors necessary for a positive nuclear safety culture.
- 6.1.5 In support of the deployment of the Nuclear Safety Policy, key deliverables have been identified to implement the arrangements, including development of the approach and the introduction of a Steering Group, supported by a maturity model based on the Nuclear Safety Culture Assessment Framework, which we use to assess its maturity in relation to nuclear safety culture arrangements; thus, contributing to the development of a strong organization and nuclear safety culture.
- 6.1.6 Our culture program brings together nuclear safety culture and organizational culture (Figure 17.5 1), enabling commonality. This is conducive to developing a learning organization and working across co-supporting culture streams.



**Figure 6-1: Rolls-Royce SMR Limited Culture Program**

- 6.1.7 The culture program is based on the IAEA Harmonized Safety Culture Model [87], which defines the traits and attributes observed when a strong safety culture is present and takes into account RGP and operational experience.
- 6.1.8 The culture program continues to evolve, grow, and mature in line with business maturity, experience, expectations and ambition. However, the program will remain consistent with the following goals:
- A program which enables us to meet the needs of customers from around the world,
  - Establish measures to baseline Nuclear Safety Culture and ensure ongoing assessment and continuous improvement,
  - Provide systems, processes and practices that enable and encourage safe behaviors,
  - Create a psychologically safe working environment where everyone has a voice.
- 6.1.9 To continually improve and drive the focus, we undertake activities to help develop and promote a positive working environment and thriving nuclear safety culture. These include Culture 'SMaRt Starts' that carry themes and topics each month, leadership engagement tours and workplace inspections, nuclear safety culture benchmarking supported by key performance indicators to ensure continuous improvement, nuclear safety culture campaigns and the delivery of nuclear safety culture training. These activities are key to demonstrating visible leadership and employee engagement to support a strong safety culture.
- 6.1.10 Our Nuclear Safety Culture approach is deployed via the Nuclear Safety Culture Policy [12], into the Health, Safety & Environment Vision, Strategy and Objectives. Nuclear Safety culture is governed by the HSEQ Sub-Committee and further supported by the Organizational Culture Working Group, all of which are subject to regular review and assurance activities.

## 6.2 Sustainability

- 6.2.1 We know that we, and the nuclear industry, play a vital role in the decarbonisation of energy production, supporting the global transition to Net Zero. As a responsible, ethical, company we recognise that developing a sustainable product is not enough and that to succeed the operation of the company must also be sustainable. Our sustainability program is focused on understanding the impact we have on the world, and our ability to support society in achieving higher standards of living through sustainable development.
- 6.2.2 The United Nations (UN) Sustainable Development Goals (SDGs) were unanimously adopted by all 193 UN Member states and are globally recognised as the most comprehensive, credible set of sustainability goals, aiming to address the key economic, social, environmental and governance challenges of our time. The SDGs provide a common set of global priorities, actions, and language to help consistently communicate the impacts and performance of organizations. These SDGs are considered in the RR SMR design through assessment against the 20 key design objectives during the design decision-making process, described in E3S Case Level 1 Chapter 1 [56].
- 6.2.3 The SDG Compass has been chosen as the framework for the development of the sustainability program. This framework requires an organization to develop their understanding of the SDGs and prioritize key areas of focus to maximize positive and minimize negative impacts.
- 6.2.4 An initial sustainability materiality assessment has been undertaken to prioritise sustainability topics according to the significance of the impact, importance to stakeholders, and the ability of our organization to influence those topics. The materiality assessment was informed by a series of workshops with stakeholder representatives, mapping the aspects of sustainability across our value chain. The results of the materiality assessment were analyzed and aligned to the UN SDGs identifying six key SDGs through which our organization can have the greatest influence and contribution towards sustainable development:
- SDG 7: Clean, Affordable Energy for All – Supported through the development and deployment of the RR SMR which will produce low carbon energy at an affordable price, to power industry and the electrical grid across the globe, promoting investment in clean technology. Energy efficiency and use of clean energy will be a focus for all our facilities,
  - SDG 12: Responsible Consumption and Production – Supported through the design development through consideration of resource efficiency and waste minimisation throughout the life cycle of the RR SMR and our facilities. Partnering with suppliers to cultivate sustainable procurement practices,
  - SDG 8: Decent Work and Economic Growth – Supported through the creation of a safe, secure and inclusive working environment for all. Development of a Supply Chain Strategy that supports creation of decent jobs and the growth of small to medium sized businesses whilst respecting and promoting human rights,

- SDG 11: Sustainable Cities and Communities – Supported through the localized production of affordable, clean energy to support decarbonisation of industry, and the electrical grid. The design of facilities and the RR SMR will minimize adverse impacts on the environment and local communities and seek to maximize beneficial impacts,
  - SDG 13: Climate Action – Supported through the deployment of the RR SMR to decarbonise energy which will support the development of a more resilient and adaptive energy supply. The design of our manufacturing facilities and business will account for climate adaptation measures. Improvement of education and awareness of sustainable development and climate change mitigation, adaptation and impact reduction will be supported internally and externally,
  - SDG 16: Peace, Justice and Strong Institutions – Supported through our commitment to conduct ourselves fairly, transparently, and in compliance with legal and regulatory requirements and operate a zero-tolerance approach to corruption in all its forms. These values will be reinforced through collaboration with our supply chain partners.
- 6.2.5 The materiality assessment will be reviewed, to allow us to continuously improve, and ensure we meet the evolving expectations of our stakeholders.
- 6.2.6 To develop and drive our sustainability program a Sustainability Working Group operates and is sponsored by our Safety and Regulatory Affairs Director. The working group will provide quarterly updates to our Executive Leadership Team and forms part of our business governance structure. The group is a cross functional collaboration which will provide a formal structure, helping to drive our sustainability strategy and provide a reporting mechanism for the business in this key area.
- 6.2.7 Our Sustainability Policy [13] sets out the company’s commitment to sustainability, including environmental, social and governance commitments. The policy outlines accountability for sustainability and promotes learning and continuous improvement, as well as pressing the importance of collaboration with our partners, value chain and local communities. The approval of our sustainability policy demonstrates a commitment to developing a sustainability program to integrate sustainability into our day-to-day operations and decision making through a balanced consideration of environmental, social, and economic impacts.
- 6.2.8 To support the implementation of the sustainability policy the following aspects continue to be developed and evolved:
- Understanding and evolving our existing environmental, social and governance baseline, including emissions baselining and future scenario modelling,
  - Defining sustainability ambitions for Rolls-Royce SMR Limited and key business functions,
  - Establishing SMART objectives and KPIs across the business, including science-based targets for emissions reductions to meet our commitment to net zero,



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- Developing strategies to support these objectives, including a carbon reduction/avoidance plan, social value strategy, inclusion strategy and sustainable development strategy for our future facilities,
- Development of training materials and internal and external communication plans to raise awareness and build on our mandatory training on BAT and sustainability, environmental awareness, equity diversity and inclusion, psychological safety and product safety. As well as building on our internal sustainability hub, intended to enhance our people's understanding of what we're doing as a business and where to learn more about sustainability issues,
- SMaRt culture program.

6.2.9 Our sustainability program is supported by an assurance program which utilises a maturity model to monitor performance and support continuous improvement.

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## 8 Acronyms and Abbreviations

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AC	Assumptions and Commitments
ALARA	As Low As Reasonably Achievable
ALARP	As Low As Reasonably Practicable
ASCE	Assurance and Safety Case Environment
ASME	American Society of Mechanical Engineers
BAT	Best Available Techniques
CAE	Claims, Arguments, Evidence
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CIO	Chief Information Officer
CFSI	Counterfeit, Fraudulent and Suspect Items
CV	Curriculum Vitae (Resumé)
DoA	Delegation of Authority
DL	Document List
DPA	Data Protection Act 2018
DR	Design Reference
DRP	Design Reference Point
DSEAC	Design, Safety and Environment Advisory Committee
E3S	Environment, Safety, Security and Safeguards
EA	Environment Agency
ELT	Executive Leadership Team
EPRI	Electric Power Research Institute
FCD	Final Concept Definition
FOAF	First of a Fleet

GDA	Generic Design Assessment
GDPR	General Data Protection Regulation 2018
GER	Generic Environment Report
GR	Gated Review
GSR	Generic Security Report
HSEQ	Health, Safety, Environment and Quality
HSSEC	Health, Safety, Security, Environment and Culture
IAEA	International Atomic Energy Agency
IEC	International Electrotechnical Commission
IMS	Integrated Management System
IPR	Independent Peer Review
ISO	International Organization for Standardization
KM	Knowledge Management
KPI	Key Performance Indicator
MDSL	Master Document Submissions List
MR	Maturity Review
MRI	Master Records Index
MSA	Managed Service Agreement
NRC	Nuclear Regulatory Commission
NRW	Natural Resources Wales
OLC	Operational Limits and Conditions
ONR	Office for Nuclear Regulation
OI	Operating Instruction
PCSR	Pre-Construction Safety Report
PDCA	Plan, Do, Check, Act
PMO	Program Management Office



PMP	Project Management Plan
PSA	Probabilistic Safety Assessment
PSC	Program Sub Committee
PSRB	Product Safety Review Board
QA	Quality Assurance
RD	Reference Design
RDS-PP®	Reference Designation System - Power Plants
REDV	Requirements, Evidence, Design Definition, Verification and Validation
RI	Regulatory Issue
RO	Regulatory Observation
RP	Requesting Party
RQ	Regulatory Query
RR SMR	Rolls-Royce Small Modular Reactor (Design)
Rolls-Royce SMR Limited	Rolls-Royce Small Modular Reactor (Organisation)
RSR	Radioactive Substances Regulation
SAP	Safety Assessment Principle
SDG	United Nations Sustainable Development Goals
SoW	Statement of Work
SMSR	Supplier Management System Requirements
SSC	Structure, System and Component
SyAP	Security Assessment Principle
SByD	Secure-By-Design
TCR	Technical Change Review
UK	United Kingdom
US	United States
USA	United States of America



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UN United Nations

WANO World Association of Nuclear Operators

WNA World Nuclear Association