



**Sellafield Ltd**

**MPO\_NPI\_003\_SL**

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# **Sellafield Volume Products Supplier Manual**

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# 1 Introduction

This manual defines a common set of standards and processes to ensure the development and quality of volume manufactured items throughout their lifecycle, while achieving value for money for the UK taxpayer.

The utilisation of the processes in this document will help to mitigate the risk in delivering safe, predictable and reliable volume manufactured products to Sellafield Ltd. In addition, this supports product development through a structured, auditable process and checklists.

A New Product Introduction (NPI) process has been established within Sellafield Manufactured Products Organisation (MPO) to support the management and introduction of products manufactured in volume and this manual provides the framework for the supplier to develop new products incorporating the applicable parts of the Sellafield Ltd. Contract Quality Requirements Manual (CQR) relevant to manufactured products.

This manual and the processes defined within it are designed to facilitate collaborative communication between the Integrated Product Team (IPT) which is a multi-disciplined cross functional team (managing the development of the product) consisting of both the Sellafield project functions and the supply chain project team.

A key benefit of deploying this process is improved right-first-time quality, thus minimising the need for concessions, rework or permits.

In this manual, the following verbal forms are used:

- "shall" indicates a requirement.
- "should" indicates a recommendation.
- "may" indicates a permission; and
- "can" indicates a possibility or a capability.

Furthermore, the following terms are used:

- "[the] supplier" indicates the organisation supplying the identified product or service; and
- "[the] customer" the Sellafield MPO organisation developing the product.

## 1.1 Scope

This process must be completed for all volume manufactured products identified by Sellafield, including the following:

- New manufactured products
- Changes to manufactured products introduced using advanced product quality planning (APQP)
- Manufactured product reintroduction (legacy components)
- A change of source (change of supplier or supplier's facility)
- Changes to the manufacturing method
- Volume increases that require changes to the manufacturing process or the introduction of new processes

## **1.2 About the Sellafield Manufactured Product Organisation (MPO)**

Manufactured Products (MPO) is an organisation within Sellafield Ltd created with a single guiding mind for the delivery of volume manufactured products to support Sellafield missions into the future.

Working alongside the Supply Chain Directorate, MPO's task is to ensure a consistent, repeatable supply of high integrity containers required for the safe storage of nuclear material, spent fuels or waste.

The MPO acts as an Intelligent Customer (IC) and through multi-disciplined IPTs will create consistency of supply and standardisation of processes, helping to ensure products can be delivered through a stronger supply chain at the required at volume, time they are required, quality and cost.

## **1.3 Supplier Multifunctional Team Structure**

The supplier shall provide a multifunctional project team of suitably qualified experienced persons (SQEPs). Section 4.1 provides detail of the requirements of SQEP.

Sellafield Ltd is committed to working together with its supply chain to deliver excellence in everything it does, and to having the right people with the right skills in place at the right time.

This requires the Sellafield Integrated Product Team (IPT) and its supply chain to develop a supportive relationship, in which they work together to deliver to the required standards, identify opportunities to improve performance, prevent concerns escalating and resolve issues promptly through the following:

- Open and honest communication
  - Raising queries and concerns as they become known – at all levels and tiers throughout the supply chain
  - Understanding and compliance is checked at all levels and tiers of the supply chain, ensuring that specifications, requirements and identified processes are flowed down, understood and met
- Sharing learning
  - Identifying and building on best practice
  - Utilising learning from experience (LFE) to prevent issues and improve performance
- Focused improvement
  - Having the right measures
  - Using the right tools
  - Looking at the right things
- Structured problem-solving
  - Basing decisions on data
  - Addressing the root cause
  - Implementing robust corrective and preventative actions

## **1.4 Importance to Nuclear Safety**

Nuclear safety means protecting people and the environment against both radiation risks and the safety of facilities and activities that give rise to the radiation risks (according to the International Atomic Energy Agency [IAEA], see reference

IAEA SF-1 section 6.1). To achieve this aim, Sellafield Ltd requires its supply chain to deliver products to the agreed specifications and standards.

A key focus for Sellafield Ltd is ensuring that all supply chain personnel understand how the supplier, the manufactured products, and their role impact upon nuclear safety, and how the failure of a product can impact upon the associated plant and have wider consequences.

The supplier shall interpret Sellafield Ltd.'s design intent into the planning, manufacturing, testing and validation of the product, and this shall be realised in the quality of the supplier's workmanship. Suppliers and associated sub-suppliers must understand how their workmanship quality can impact nuclear safety.

There are eight internationally accepted principles of a robust nuclear safety culture:

- Everyone is personally responsible for nuclear safety
- Leaders demonstrate their commitment to nuclear safety
- Trust permeates the organisation
- Decision-making reflects a safety-first attitude
- Nuclear technology is recognised as being special and unique
- A questioning attitude is cultivated among everyone in the nuclear industry
- Organisational learning is embraced
- Nuclear safety undergoes constant examination

The supplier shall establish and promote an effective nuclear safety culture within its organisation and its supply chain by doing the following:

- Reflecting the requirements of nuclear safety in its quality management system (QMS)
- Ensuring there is a collective understanding of the key aspects of nuclear safety
- Developing a nuclear safety culture
- Creating a culture of learning and questioning at all levels of the organisation regarding nuclear safety
- Ensuring all personnel involved in the provision of work for Sellafield Ltd understand any nuclear safety implications of the failure of the product to meet the specified design intent
- Ensuring that all personnel are aware of the implications of products that are counterfeit, fraudulent and suspect items (CFSI) being deployed on the Sellafield site
- Managing the transition from planning, to manufacturing, to testing, to validation and to sharing knowledge with all personnel

## **1.5 Quality Management System (QMS) Requirements – ISO 9001**

See the References section for a list of the applicable standards.

All suppliers shall maintain a QMS compliant with the latest edition of ISO 9001. The QMS shall be certified by a certification body accredited by the United Kingdom Accreditation Service (UKAS), or internationally accepted equivalent, as defined by the International Accreditation Forum (IAF).

To demonstrate its maintenance of the QMS, the supplier shall do the following:

- Prepare and execute an internal audit plan and corrective actions.

- Inform Sellafield Ltd of all major non-conformities to the QMS, as identified through an external audit.
- A suitably qualified and experienced quality management representative shall be appointed to ensure effective implementation of the QMS arrangements.
- Ensure all personnel executing the contracted scope of work are aware of and understand the QMS, including all amendments relevant to the scope of work.
- Maintain a documented lessons learnt / LFE process to improve systems and processes.
- Identify the applicable statutory and regulatory requirements, ensure there is access to these requirements, determine how they apply, and implement them when providing product(s) or service(s).
- Have in place an up-to-date business continuity plan (BCP) to identify potential risks, mitigate threats to the organisation and recognise the impacts to operations those threats, if realised, might cause. The supplier shall test and review the BCP regularly.

## **1.6 Regulatory Oversight**

Sellafield Ltd and its regulators, such as the Office for Nuclear Regulation (ONR), reserve the right to undertake oversight of the supplier's management system arrangements and all work being delivered within the contract scope, including sub-contracted work.

Oversight may be by means of assessment, inspection, verification, surveillance, or formal audit. The supplier shall communicate this requirement to its sub-suppliers.

### **1.6.1 Relevant Legislation/Regulation**

This document has been generated with consideration of the relevant health and safety legislation. Where appropriate, the applicable legislation has been referenced throughout this document; however, the publications below and within section 6.1 identify the relationship to relevant legislation/Regulations and support Sellafield Ltd and the supplier in complying with legal requirements:

- ONR Licence Condition Handbook
- ONR Technical Assessment Guide NS-TAST-GD-077 (TAG 077)
- IAEA SF-1

## **1.7 Intelligent Customer (IC)**

The MPO acts as the volume, manufactured products IC for Sellafield Ltd, and it applies the appropriate level of oversight of QMS arrangements regarding manufactured products, depending on the nuclear, safety, security, and environmental consequences.

Further detail regarding Intelligent Customer guidance can be obtained from:

- ONR Technical Assessment Guide NS-TAST-GD-049 (TAG 049)

As outsourcing continues to gain popularity with commercial-sector businesses and public sector bodies, the importance of a strong and well-resourced IC functional team has become increasingly important. With the skills and commercial

awareness to drive the maximum value from complex customer–vendor relationships, the IC supports its suppliers for mutually beneficial outcomes.

## **1.8 Supplier Performance Management**

The supplier shall demonstrate performance through metrics, which shall include but not be limited to delivery performance, right first time (RFT), overall equipment effectiveness (OEE), scrap, rework, quality, customer complaints/rejects, concessions/ permits, and health and safety.

Each metric shall have clear targets and associated Continuous Improvement (CI) activities that drive and improve performance.

### **1.8.1 Key Performance Indicators (KPIs) and Key Process Variable (KPVs)**

Project KPIs and KPVs shall be agreed upon with Sellafield Ltd at the opening meeting in the form of a KPI / KPV schedule.

The KPI / KPV schedule shall include details of the following:

- The process itself
- Agreed KPIs / KPVs to underpin the performance of the process



## 2 Introducing Sellafield New Product Introduction (NPI)

The Sellafield Ltd NPI process encompasses all activities conducted by Sellafield Ltd and its suppliers to define, develop and launch new products, and to improve existing products. It has been developed in recognition that to develop repeatable, capable products a high level of collaboration is required between SL and the supplier in developing both the product and the process for manufacturing the product.

The NPI process strengthens the relationship and trust between Sellafield Ltd and its supply chain, through concurrent engineering, product quality planning, lean design, manufacturing, and the supply chain.

The process has six phases, described as follows. Suppliers contribute to the NPI process from phase 2 and through to phase 6. The supplier deliverables use the basis of APQP (Advanced Product Quality Planning) which is a process developed and used in several other industries to develop repeated volume products. An overview of the process is given below and the requirements for the supplier as part of this process are detailed in the remainder of this manual.

A Sellafield Ltd Integrated Product Team (the IPT) manages the NPI process and supports suppliers in achieving product and process requirements.

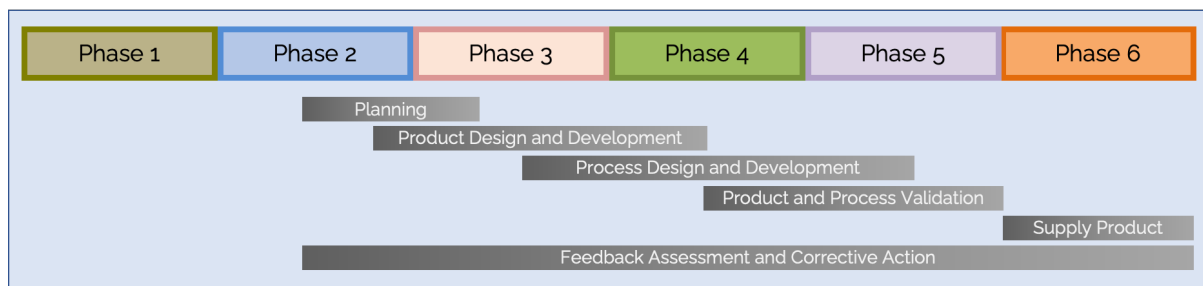


Figure 1: Sellafield NPI process

### 2.1 Phase 1 – Customer Requirements and Delivery-solution Capture

The production supplier is selected during phase 2; therefore, it has no actions in phase 1 of the NPI process. However, the outcome of phase 1 is critical to delivering a product that meets all product and business requirements, and so it is presented here for information.

At the start of phase 1, the MPO creates an internal cross-functional IPT. The IPT discusses, considers, challenges, and agrees to the requirements of the Sellafield Ltd Facility Programme requesting the product.

The facility shall not define the product or its specifications but the requirements of the project.

The IPT assesses and proposes the potential product technologies and manufacturing processes to be considered in the next phase. Through market engagement suppliers shall be encouraged to identify additional technologies and potential innovations.

The phase ends when the IPT understand and agrees with the facility's requirements, and consequently, the IPT has identified potential technology solutions and manufacturing processes.

## **2.2 Phase 2 – Product Concept**

From a supplier perspective, this is the tendering phase; however, there are two other key milestones: selecting the technology concept and manufacturing processes, plus baselining the product concept. Once the contract is placed the successful supplier becomes a key member of the IPT, and contracts shall mandate the supplier's contribution to the NPI process and the completion of the APQP activities, for both the first-tier supplier and agreed sub-suppliers.

The phase closes with confirmation that the selected concept shall meet the customer's requirements. Supplier Funding for Phase 3 Product design support is released.

## **2.3 Phase 3 – Detailed Product Design**

During this phase, Sellafield Ltd complete the detailed product design with design and manufacturing support from the supplier. The supplier shall attend and support the design reviews providing manufacturability assessment and Design for Manufacture support within the design process. The supplier then produces any required prototypes to verify that the design meets the customer's requirements.

The phase ends with the confirmation of the manufacturing feasibility of the design and its 'production intent' release. Supplier Funding for Manufacturing tools and gauges and validation parts is released.

## **2.4 Phase 4 – Manufacturing Process Development**

During this phase, the supplier manufactures, installs and commissions its manufacturing facility, and then confirms it can manufacture the product to meet the specification and achieve the customer's requirements.

Engineering change management (ECM) commences, incorporating the changes to the product and process required to optimise manufacture, fit, form, function, mature supplier controls and the manufacturing method.

The phase ends with production equipment able to produce parts from the production tooling and equipment from the production process and the 'final production' design is released to the supplier.

## **2.5 Phase 5 – Manufacturing Process Validation**

This phase confirms that the manufacturing process meets the product specification at the required volume / rate.

The supplier completes Run@Rate trials and provides a Production Part Approval Process (PPAP) evidence file and Part Submission Warrant (PSW) to demonstrate the APQP process is complete (section 3.4.3).

The phase ends with an agreement to raise the production order and commence volume production.

## **2.6 Phase 6 – Volume Production**

This phase starts with the commencement of volume manufacturing. The IPT maintains project support until the supplier achieves a sustained level of performance over either a predefined period or a quantity of manufactured products.

The IPT works with the supplier to deliver Continuous Improvement.

### 3 Advanced Product Quality Planning (APQP)

APQP provides a structured methodology for planning, implementing, validating, and verifying product development to ensure it conforms to the product and process requirements and specifications. As a result, it drives quality assurance (QA) to give increased confidence in the manufacturing process.

The APQP process first started development in the 1980s by Ford, Chrysler, and General Motors to provide a common process for managing supplier product introductions. Since the 1990s it has been an established tool across the automotive industry and expanded into industries outside of the automotive industry.

It guides suppliers to develop capable and repeatable processes and systems, and it contributes directly to a supplier's ability to deliver products that meet Sellafield Ltd.'s requirements.

The Plan-Do-Check-Act (PDCA) cycle is the basis of all activities in the APQP process, and it optimises the outcomes of the NPI and APQP processes.

Applying the PDCA cycle enables the following:

- The realisation of understanding and consistency in meeting requirements
- The consideration of processes in terms of added value
- The achievement of effective process performance
- The improvement of processes based on the evaluation of data and information

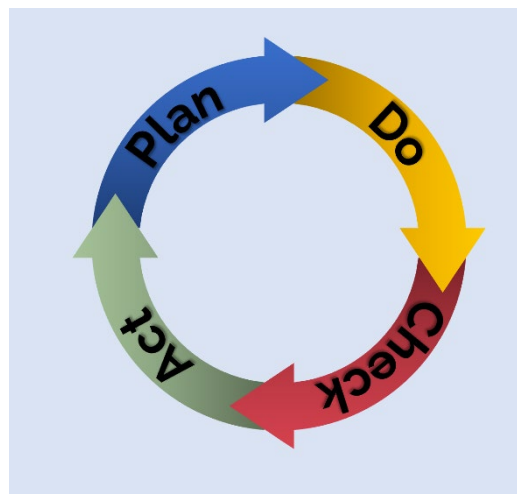


Figure 2: Plan-Do-Check-Act (PDCA) cycle

Once in volume manufacture, the supplier shall review performance and seek improvement opportunities.

APQP supports the NPI process and remains as the structure of manufacturing control throughout the product's production lifecycle. APQP documentation is live and shall be updated whenever there are changes to a product or any aspect of the manufacturing process.

APQP applies to the Sellafield Ltd product and all the components and processes produced or used by the first-tier supplier and sub-suppliers agreed between the supplier and the IPT.

The supplier leads APQP and assembles an internal cross-functional team, usually composed of engineering, manufacturing, material planning and logistics (MP&L), procurement and quality personnel. APQP facilitates communications between all personnel and activities involved in the programme, ensuring all the required steps are completed on time and at acceptable levels of quality and cost.

Suppliers will have a working knowledge of the five core tools of Advanced Quality Planning:

1. Advanced product quality planning (APQP)
2. Failure mode and effect analysis (FMEA)
3. Statistical process control (SPC)
4. Measurement system analysis (MSA)
5. Production Part Approval Process (PPAP)

APQP for Sellafield Ltd has thirty-three elements. Each element of APQP requires evidence of successful maturation and completion, in line with the phased NPI process.

To track the ongoing development, the APQP status will be assessed using an APQP checklist. The supplier shall update and share their APQP status via the checklist at regular intervals. Typically, this would be monthly, and as agreed by the IPT during the Opening Up meetings. The APQP status will form part of the project KPI's.

At the end of each NPI phase, the IPT shall verify the outcome of each element with the supplier, using the checklist, and agree to any remedial activities.

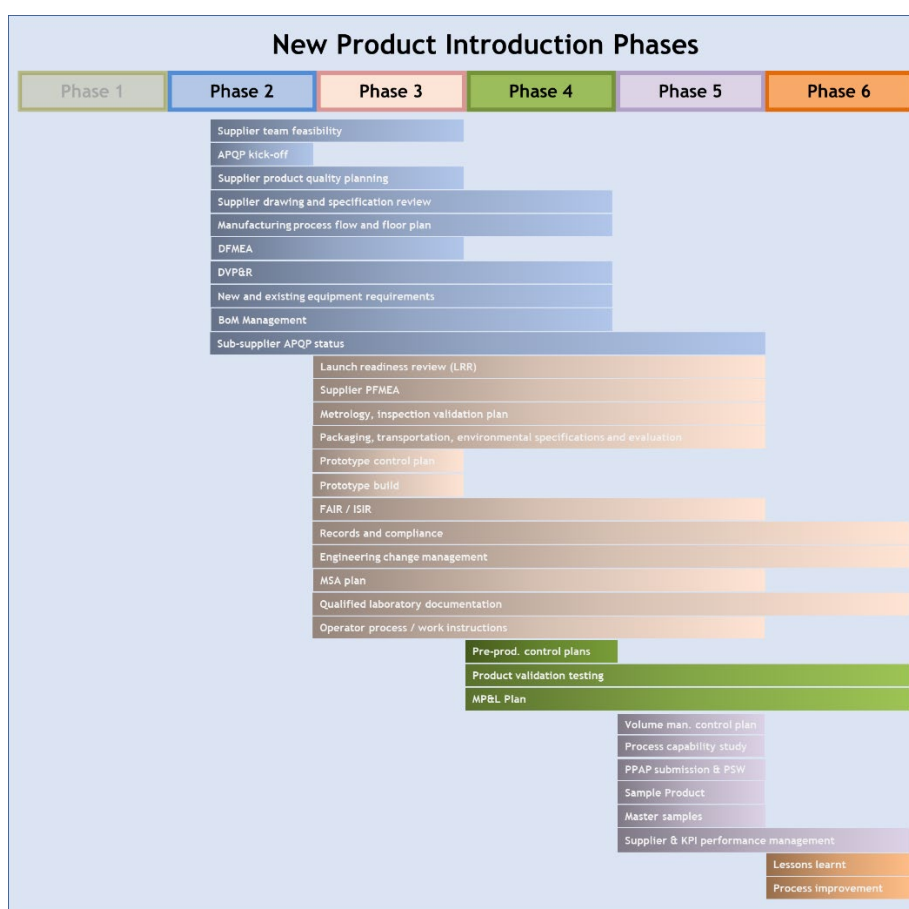


Figure 3: APQP elements and NPI process

Figure 3 shows the APQP elements and the NPI phase(s) in which they start and end. Should the supplier not achieve any element or find the element is unachievable, the supplier shall obtain written approval from the IPT to proceed and concede that specific element or part of the element.

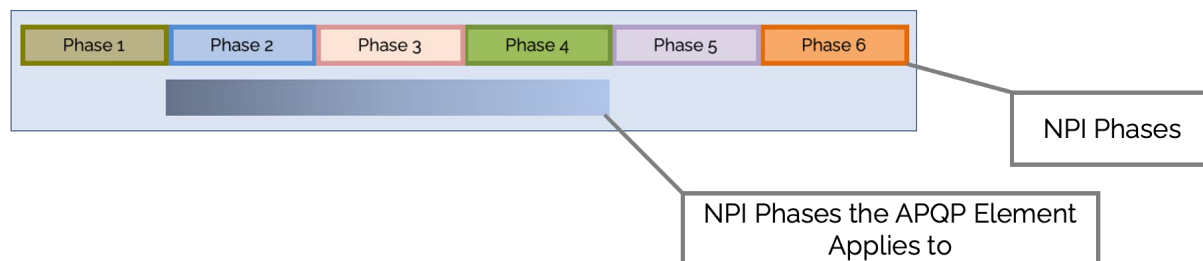


Figure 4: Example of how the APQP links to the NPI process

The remainder of this section describes each APQP element, and each element is accompanied by an image showing the NPI phases during which it takes place. In the example in Figure 4, the APQP element starts in phase 2 and ends in phase 4.

The level of maturity and deliverables required against each APQP element at the end of each NPI phase are defined in Appendices A to E.

### 3.1 Product Concept

#### 3.1.1 Supplier Team Feasibility Review and Commitment

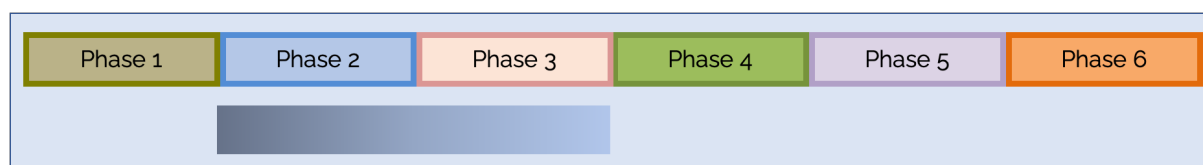


Figure 5: How the APQP links to the NPI process for supplier team feasibility review and commitment.

This supplier team feasibility review ensures that the supplier cross functional project team understand, agree, and sign off the team feasibility commitment. In addition, this confirms that the supplier and its associated supplier base have the resource and manufacturing capability to develop and manufacture the product.

The supplier's cross-functional team shall assess the feasibility of the product design and the customer's requirements. This shall include a review of all contractual requirements, the scope of work and the information provided by Sellafield Ltd. The supplier shall have included within its assessment the elements sub-contracted to sub-suppliers.

The team shall also assess whether the proposed product can be manufactured, assembled, tested, packaged, and stored in the required quantities, and be delivered at an acceptable cost to Sellafield Ltd, as per the agreed schedule and delivery rate.

The team shall reach a consensus, and then record and sign the team feasibility document. The document shall contain all reports, calculations on process steps, weekly/annual volumes, the resources required, training, skills, equipment, testing and measuring equipment, floor-plan availability, the investment required, capacity

limitations, and constraints. The supplier shall document issues and manage them through to resolution.

The Team Feasibility Form (MPO\_MAN\_005) to be completed by the supplier is shown in Appendix F.

Once the design has been completed and released for production, the supplier shall conduct a further Team feasibility review.

### 3.1.2 Supplier Advanced Product Quality Planning (APQP) Kick-Off

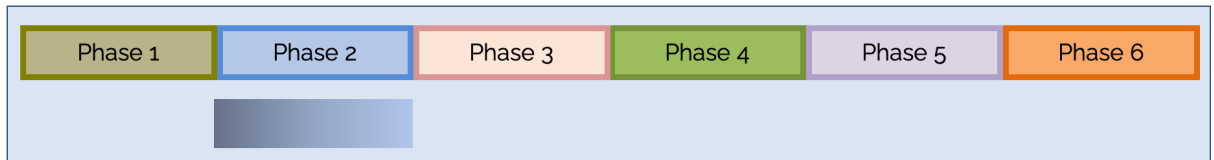


Figure 6: How the APQP links to the NPI process for supplier advanced product quality planning (APQP) kick-off (opening meeting)

The supplier APQP meeting is held as part of the Opening Up meetings to ensure that the supplier understands all the requirements of the APQP process, PPAP and PSW.

The supplier's senior management team shall confirm it understands the APQP requirements for the project and can meet them. It shall also put in place the resources to meet the Sellafield Ltd requirements and shall define roles and responsibilities. The SL IPT shall confirm the PPAP requirements and the PSW level required at NPI phase 5 which is detailed later in the manual. This shall be a contractual requirement which will be level 3 (full submission) by default.

Key contacts within the IPT are identified, as well as the supplier's key contacts for managing its sub-suppliers. At this meeting the supplier shall agree with the IPT the level of APQP that will be applied to the sub-suppliers. The supplier shall then cascade these APQP requirements to its sub-suppliers.

The supplier and IPT shall agree on the structure of regular reviews and documentation, including activities for specification familiarisation and awareness briefings.

The supplier's team shall include senior representatives, including from the following functional areas:

- quality
- manufacturing
- design
- procurement
- project management.

The supplier shall identify the names of the SQEPs representing each function and shall provide a responsible, accountable, consulted, and informed (RACI) matrix to identify the stakeholder roles and responsibilities related to all contract deliverables. A process to inform Sellafield Limited of future changes relating to personnel and training requirements is required.

The RACI document shall be maintained and updated, including documenting the relevant qualifications, training, and experience of all personnel. Where further training is required, this also should be identified.

The supplier shall confirm their understanding of the APQP requirements and present to Sellafield Ltd the proposed quality strategy supporting implementation of the contract. This includes providing confirmation of their understanding of Sellafield Ltd Quality requirements and elements that require further development/gap analysis studies / activities.

Sellafield Limited shall identify the planned Standard / Specification / LFE and regulatory presentations to be delivered by Sellafield Limited Quality representatives and the associated scheduling arrangements and required attendance lists.

**3.1.3 Supplier Product Quality Planning**

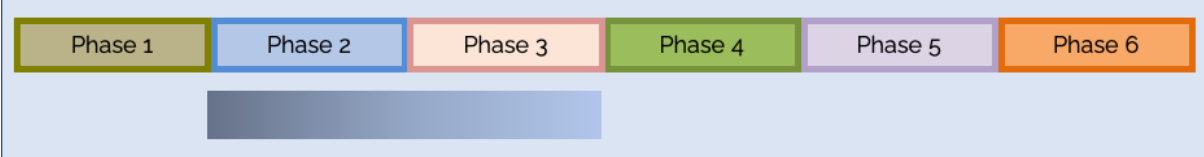


Figure 7: How the APQP links to the NPI process for supplier product quality planning

The purpose of the quality plan (QP) is to ensure that the supplier has the necessary quality arrangements in place, enabling all identified Sellafield Ltd product quality requirements to be achieved. At contract award the supplier as part of the opening up meetings will supply both a contract Quality plan and an APQP quality plan.

The Contract Quality Plan is to ensure the supplier’s Quality Management System can maintain continually improving Quality Management system processes underpinned by the appropriate technical and behavioural competences throughout both their workforce and supply chain partners.

The Supplier shall also develop an APQP Quality Plan defining Product and Process assurance arrangements for controlling the deployment of the APQP process throughout specified stages of the development.

The supplier shall provide an initial Quality Product Planning document hierarchy structure diagram, which defines supplier Product Quality Planning intentions / proposals including areas of the Product / Process subject to sub-contracting operations.

The detail and requirements of both the Contract and APQP quality plans is shown in section 4.2.

**3.1.4 Supplier Drawing and Specification Review**

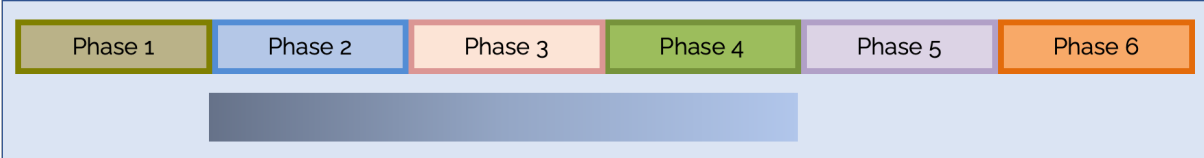




Figure 8: How the APQP links to the NPI process for supplier drawing and specification review

The supplier shall conduct cross-functional reviews of drawings and specifications and support the SL design process to optimise the design solution for manufacture.

As two-dimensional (2D) drawings and three-dimensional (3D) models are released, the ability of the proposed manufacturing processes to meet all specifications shall be reviewed. Regular reviews shall take place with the IPT during the design phase to provide Design for Manufacturing input and feasibility.

All Critical (CCs) and Significant (SC) Characteristics shall be identified and clearly denoted on drawings.

Feedback shall be provided to the design team to support the detailed design.

Quality control (QC) features can be extrapolated and understood to ensure that suppliers can supply an assured product through the proposed manufacturing process.

Any change requests are defined and submitted through the Engineering Change Management (ECM) process (see section 3.2.9).

### 3.1.5 Manufacturing Process Flow Diagram and Floor Plan

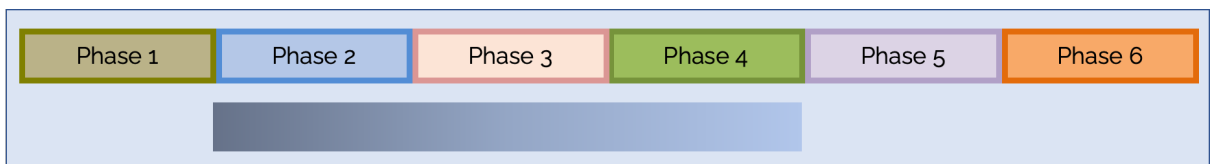


Figure 9: How the APQP links to the NPI process for manufacturing MoM, process flow and floor plan

The supplier will determine a manufacturing Process flow for the product which will define the method of manufacture on the supplier's own format documents.

The process flow diagram and floor plan shall show that all aspects of the manufacturing operations have been considered, and there is a physical plan for achieving all manufacturing, quality and logistics processes involved in the manufacture of the product.

The supplier shall generate the process flow for the product which shows the sequence of all operations. The process flow shall reflect the quality requirements and the product and process assumptions. The process flow shall include all manufacturing processes, sub-assemblies and processes, material delivery, material storage, transportation, inspection, quality steps and rework.

The process flow shall provide input into the floor plan, illustrating the process flow and manufacturing layout, including auxiliary areas such as inspection, work in progress (WIP) and storage.

The document(s) used to record the process flow shall state the following:

- Company name
- A unique identity and revision status

- Reference numbers (including the Sellafield Ltd contract number; the supplier reference number and sub-supplier number, if applicable; and the plant item number or material master number)
- Scope of work
- Sequence of production and manufacturing operations
- Identify any external subcontract operations
- Method & equipment and identification of workstations
- Reference any sub supplier incoming material and parts

The supplier shall submit the process flow diagram to Sellafield Ltd for acceptance and manage any changes through its Engineering Change Management (ECM) process.

### 3.1.6 Design Failure Mode and Effect Analysis (DFMEA)

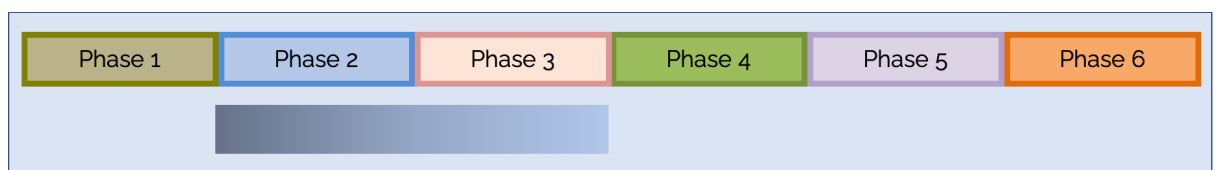


Figure 10: How the APQP links to the NPI process for design failure mode and effect analysis (DFMEA)

The DFMEA is an analytical technique led by Sellafield Ltd.'s engineers responsible for the design. Where appropriate, this shall include input from the suppliers to ensure the potential failure modes and their associated causes and mechanisms have been considered and addressed in the design.

The DFMEA gives the IPT and the supplier an understanding of the strengths and weaknesses of the design, and it assists with defining the manufacturing and quality constraints.

The boundary diagrams related to the product and its systems, interfaces, functions, sub-assemblies, and components should be made available for evaluation.

The supplier, where appropriate, shall provide input to the DFMEA to enable its understanding of the CCs, SCs, any high-ranking Risk Priority Numbers (RPNs) and how its manufacturing expertise may reduce RPNs through changes in the product's design.

### 3.1.7 Design Verification Plan and Report (DVP&R)

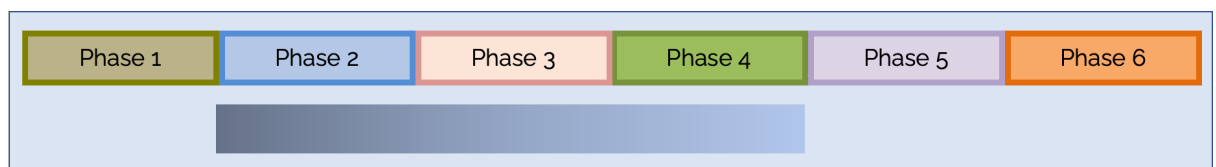


Figure 11: How the APQP links to the NPI process for Design Verification Plan and Report (DVP&R)

The SL Design Responsible Engineer shall create a test validation plan to ensure the product meets the design and performance requirements at all stages of the development. The supplier with the design engineer will determine the support and testing required from the supplier as part of the DVP&R. The DVP&R shall be

used for all prototype builds (phase 3), trial builds (phases 4 and 5) to establish the design is fit for use in its intended environment.

### 3.1.8 New and Existing Equipment Requirements

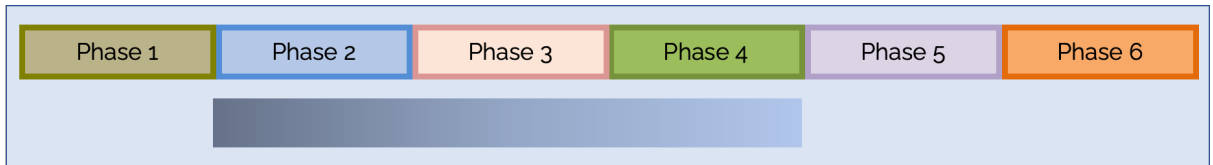


Figure 12: How the APQP links to the NPI process for new and existing equipment requirements

During the team feasibility review, the supplier shall have identified the potential manufacturing route(s), along with any shortfalls in the existing manufacturing and inspection facilities. New equipment needs to be understood and monitored to ensure that all manufacturing facilities are available for volume manufacture.

The supplier should understand all equipment requirements, costs, and timings so that these can be fed into the project timing plan and monitored. The supplier shall demonstrate the available capacity for each piece of equipment, whether new or existing. If shared with other customers' manufactured products, the supplier shall conduct a capacity analysis to verify the intended and free capacity available. Volume increases and capacity commitments on Sellafield Ltd or other customer products should also be considered in calculations.

The supplier shall identify the equipment required to manufacture the product, including but not limited to the following:

- Tooling
- Machines
- Gauges
- Jigs and fixtures
- Capital equipment
- Facilities
- Inspection equipment
- Test equipment

The project schedule shall incorporate the procurement and commissioning of all new equipment. If commissioned production equipment is not available for prototype or trial builds, then contingency plans are required.

The new requirements shall be based on the following:

- Design reviews
- Team feasibility analysis
- SCs and CCs
- DFMEA and PFMEA
- Volume requirements

The supplier shall ensure and demonstrate that all new and existing equipment has the capacity and capability to achieve the product requirements.

The supplier shall ensure that all tooling or equipment requiring storage is stored appropriately to protect against damage and corrosion when not in use.

The supplier shall have a tool wear, monitoring and a maintenance plan based upon OEM recommendations.

All jigs, fixtures and tooling owned by Sellafield Ltd shall be clearly marked and identified as such, and it shall only be used on Sellafield Ltd work.

Bespoke jigs, fixtures and tooling associated with the product's manufacture shall not be modified, repaired, or replaced without gaining prior acceptance from Sellafield Ltd.

**3.1.9 Bill of Materials (BOM) Management**

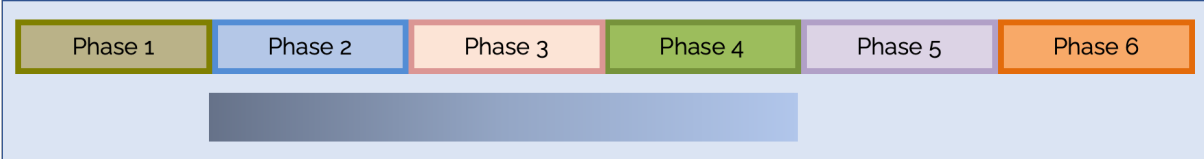


Figure 13: How the APQP links to the NPI process for bill of materials (BOM) management

The production bill of materials (PBOM) is required to identify all the component parts and sub-assemblies needed to build the product

The IPT shall create the engineering bill of materials (EBOM) and review this with the supplier. Using the EBOM, the supplier shall create a PBOM and verify it is complete. The PBOM shall include all consumable materials required for the manufacture of the product.

There may be different versions of the PBOM to support prototype and trial builds.

The supplier shall need to demonstrate a sourcing plan for each component whose manufacture is planned to be outsourced.

**3.1.10 Sub-supplier Advanced Product Quality Planning (APQP) Status**

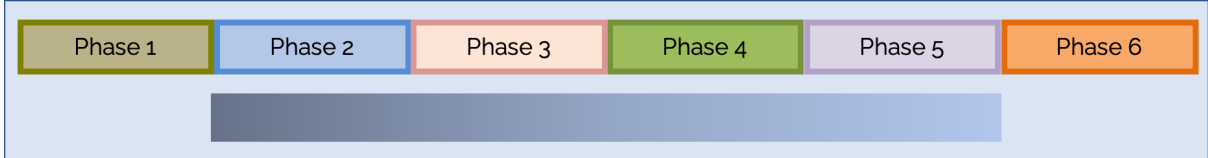


Figure 14: How the APQP links to the NPI process for sub-supplier Advanced Product Quality Planning (APQP) status

The supplier shall manage all sub-suppliers, including tracking and reporting on their APQP status throughout the project.

The supplier shall ensure all sub-suppliers meet APQP requirements. The supplier will assess each sub-supplier to determine the level of APQP. The level of management will depend on the development risk level of the part to be supplied (i.e. cots, new part, new supplier, complexity) and is agreed between the supplier and the IPT.

The supplier shall cascade the product specifications and Sellafield Ltd.'s requirements to the sub-suppliers. It is the responsibility of the supplier to conduct

regular assessments and audits to ensure the sub-suppliers are on track and conform to the requirements.

The supplier shall monitor the sub-suppliers' progress against the project schedule, and the supplier shall provide detailed schedules to the IPT to demonstrate the sub-suppliers' plans and progress. In addition, the supplier shall keep the IPT informed of the progress of its sub-suppliers against the APQP and project requirements.

The sub-suppliers shall make PPAP and PSW submissions to the first-tier supplier for approval, which shall be included in the final PPAP and PSW submission made by the first-tier supplier. The sub supplier PSW levels shall be agreed with the SL IPT.

Members of the IPT can visit suppliers and sub-suppliers at any time with the supplier present and with adequate notice, to assess their manufacturing capability and APQP readiness.

The supplier shall ensure that the supply chain oversight described in section 4.5 of this manual is followed in managing its sub-suppliers.

## 3.2 Detailed Product Design

### 3.2.1 Launch Readiness Review (LRR)

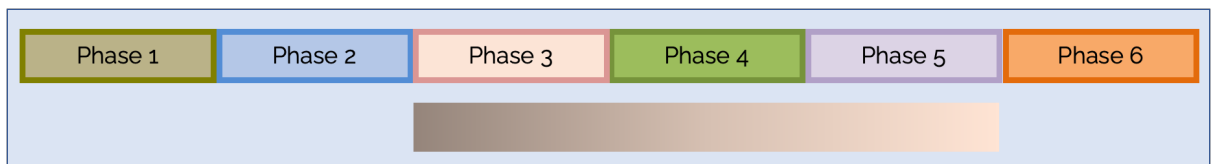


Figure 15: How the APQP links to the NPI process for launch readiness review (LRR)

In addition to the APQP status checklist, the LRR is the process by which the supplier's capability to manufacture the product is assessed by answering a series of questions. Where APQP concentrates on the product, the LRR is designed to review the supplier's overall capability. LRR reviews the following functional capabilities:

- Operational readiness
- Human resources (HR)
- Maintenance
- Procurement and supply chain
- Change control

The IPT APQP coordinator shall lead the LRR with the supplier during each NPI phase. The supplier shall prepare for this. Any gaps in requirements shall be recorded, and the supplier shall commit to close those gaps within a timescale agreed with the IPT.

The LRR checklist shall define the questions to be asked during the NPI phases from phase 3 onwards. The supplier shall provide evidence or demonstrate its compliance to the IPT.

Where topics are covered by both APQP and the LRR, the LRR is seeking deeper levels of compliance than the APQP. These checklists should be reviewed on a

regular basis to be agreed between the supplier and the IPT with a final readiness as the end of each phase to be performed.

### 3.2.2 Supplier Process Failure Mode and Effect Analysis (PFMEA)

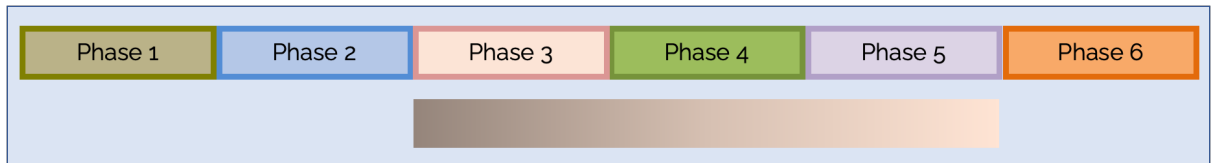


Figure 16: How the APQP links to the NPI process for supplier process failure mode and effect analysis (PFMEA)

The PFMEA is a tool for identifying potential failure modes and mechanisms throughout the manufacturing processes, and their causes and effects. It supports the development of the manufacturing process to ensure that these potential failure modes and mechanisms are managed, and the risks mitigated.

The PFMEA ensures the minimisation of the potential risk of non-conforming products being passed through to the next operation at every process step.

The supplier's cross-functional team shall create a PFMEA for every operation and sub-operation, to identify the process risk, and shall address the risks identified in the DFMEA.

The outputs of the DFMEA, the CCs and the SCs shall be used as the inputs to the PFMEA. The inputs should also include ITNS items.

As a result of the PFMEA process, risks will be reduced through the following:

- Identifying potential process-related failure modes
- Assessing the effects of the potential failures on the product
- Identifying the potential causes of manufacturing or assembly-process failure
- Identifying the process variables on which to focus process controls
- Developing a ranked list of potential failure modes, thus establishing a priority system for preventative- and corrective-action considerations

The supplier team performing the PFMEA shall analyse each operation of the manufacturing process from goods-in to goods-out and for product movement / transportation from one operation to another; score each risk for "severity", "occurrence" and "detection"; and calculate the RPN.

The supplier shall complete the PFMEA, and the IPT shall agree to the risks identified, scoring, and proposed corrective activities to reduce risk.

The PFMEA is a live document and shall be maintained throughout the production lifecycle.

### 3.2.3 Metrology, Inspection and Validation Plan

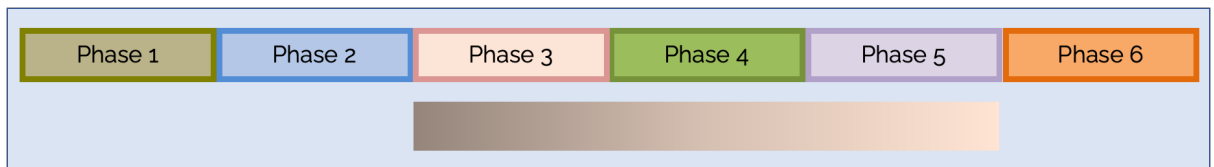


Figure 17: How the APQP links to the NPI process for metrology, inspection, and validation plan

The metrology, inspection and validation plan shall contain details of all the test and validation equipment to be used in the product's manufacture. The equipment selected shall be appropriate for the attribute and variable points being measured. This plan shall also identify the calibration and testing requirements that feed into the supplier's QMS.

The metrology, inspection and validation plan shall identify each piece of equipment and how it meets the requirements. The plan shall cover the following:

- Gauges
- Fixtures
- Measuring equipment
- Testing equipment

The plan shall identify and verify that the metrology equipment is fit for purpose, based on the following:

- Design reviews
- Feasibility analysis
- CCs and SCs (critical to quality), including the supplier's own identified characteristics
- The DFMEA and PFMEA
- Training of the appropriate employees
- Employee sign-off criteria, and the training and capability matrix

#### Calibration

The supplier shall do the following with respect to calibration:

- Ensure that the monitoring and measuring equipment used to perform the product verification activities is calibrated and traceable to international or national measurement standards
- Ensure that the measurement and calibration systems applied are in accordance with BS EN ISO 10012 (see section 6.1) measurement management systems
- Maintain permanent records of the calibration activities
- Have a "drop gauge" policy that is understood across the manufacturing site

Any failure of the measurement and test equipment and/or associated (re)calibration shall be treated as a non-conforming product.

Calibration records shall be included within the manufacturing records.

### 3.2.4 Packaging, Transportation and Environmental Specifications, and Evaluation

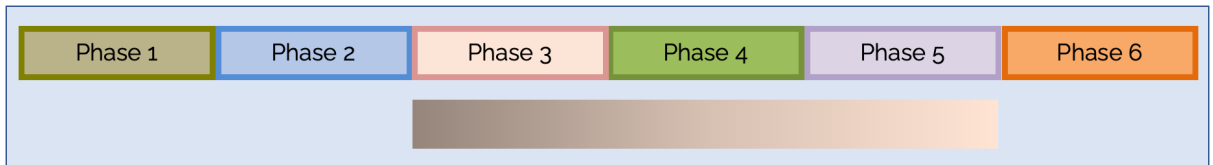


Figure 18: How the APQP links to the NPI process for packaging, transportation and environmental specifications, and their evaluation

This activity ensures that the product is protected during handling, storage (before and after use) and transportation (before and after use), and that the environmental factors, including the carbon footprint, are understood and considered. The packaging shall support all Sellafield Ltd requirements. Multiple delivery locations may be specified.

The IPT provides the supplier with the requirements. The supplier and IPT shall evaluate and agree on the packaging, storage, transportation methods and environmental impacts, based on both Sellafield Ltd.'s and the supplier-specific packaging and storage specifications. The results of the evaluation shall be documented. If the supply of products depends on multiple modes of transport, then testing, storage and evaluation shall consider all the scenarios and be recorded in the PPAP.

In the development and approval of the packaging and transportation solution, the supplier shall do the following:

- Document each packaging and transportation option
- Ensure the loading and off-loading requirements can be met
- Consider dunnage, and ensure the environmental impact is minimised
- Hold a review with the IPT at which all options shall be presented

All product packaging products shall comply with the requirements of Sellafield Ltd.'s engineering standard ES\_0\_5363\_1 (see section 6.2.2).

Products shall be packaged and transported in such a way as to ensure the following have been considered:

- Prevention, detection, and removal of foreign objects and materials
- Prevention of transit damage
- Prevention of distortion
- Prevention of water ingress
- Maintaining integrity for transit and the subsequent storage period defined in the technical product specification (TPS)
- Use of non-reusable packaging shall be minimised
- How any nuclear security requirements identified by Sellafield Ltd shall be met
- Whether the product is or contains any items that are ITNS

The supplier shall store the materials in accordance with ES\_0\_5360\_2 (see section 6.2.2) and do the following:

- Provide secure storage facilities for the product in accordance with the component definition security classification



- Ensure the conditions of storage prevent the deterioration and damage of the stored product
- Assess the condition of products in stock at appropriate planned intervals to detect any deterioration
- Ensure that access to storage facilities is restricted to authorised personnel

With the delivery of each product, the supplier shall provide a Certificate of Conformity (CofC) that contains the following:

- Description of the product
- Drawing number
- Material master number
- Purchase order number
- QP number/reference
- Production inspection and test plan number/reference
- Supplier address and telephone number
- Supplier works order number
- Number of items covered under the CofC
- Package gross weight and any special requirements (lifting instructions, etc.)
- First Article Inspection Report (FAIR) / measurement inspection reference number
- Date of completion
- Sellafield Ltd.'s unique identification numbers of all concessions, production permits and non-conformance report (NCRs)
- Signature, name and position within the company of the supplier's SQEP

The CofC shall be signed by a SQEP (as identified on the RACI), with the signature against the following statement:

*"I certify that the material(s), dimensions and all other aspects of the supplied component(s) comply with the specification(s), drawing(s) and/or other technical requirements in the contract."*

### 3.2.5 Prototype Control Plan

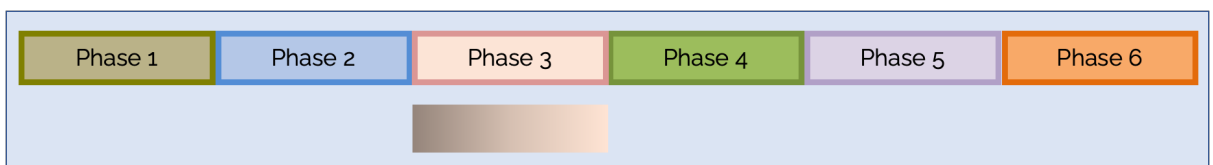


Figure 19: How the APQP links to the NPI process for prototype control plan

The supplier shall develop a control plan(s) defining actions (measurements, inspections, quality checks or monitoring of process parameters) required at each phase of a process to assure the process outputs conform to pre-determined requirements.

The Control Plan(s) shall be used in conjunction with the Inspection and Test plan documents / arrangements (section 4.7) and Sellafield Limited accepted procedures, schedules, and standards. Information contained within the control plan can originate from several sources, including but not limited to the following:

- Process Flow Diagram(s)
- Design Failure Mode and Effects Analysis (DFMEA)

- Process Failure Mode and Effects Analysis (PFMEA)
- Special Characteristics Matrix
- Lessons Learned from similar products/components
- Design Reviews
- Subject Matter Expert (SME) knowledge supporting the process
- Customer compliance issues (Non-Conforming product process)

The Control Plan development shall determine the level of control appropriate for the process being controlled, supporting component, feature, assembly phases, sub-assembly phases within the following designations: (dependent upon which phase of the NPI process the product/process is in).

The Prototype Level Control Plan should include descriptions of the dimensions to be measured and the material and performance tests to be completed during the prototype build.

The supplier shall develop Control Plan arrangements consisting of however not limited to the following:

- Cover Sheet:
  - Company name
  - Control plan and title
  - The scope/phase of work the control plan covers
  - Control plan Acceptance status
  - Reference numbers (Sellafield Limited contract number, sub-supplier reference numbers (if applicable))
  - Plant item and material master numbers
  - Contracted number of items to be produced
  - SQEP nominated roles including signatory list relating to controlling plan activity sign off
  
- Document Sheet (Control Plan):
  - Operation/process/activity number
  - PFMEA outputs
  - Process description/identification
  - Machine, device, jigs & fixtures and associated tooling for manufacture
  - Product/process Characteristic
  - Controlling methods/procedures
  - Reaction Plans

Control Plan(s) shall be submitted to the SL IPT for review and comment, subsequent changes shall require further SL review.

The supplier shall develop a prototype control plan using the format in Appendix J or equivalent.

### 3.2.6 Prototype Build

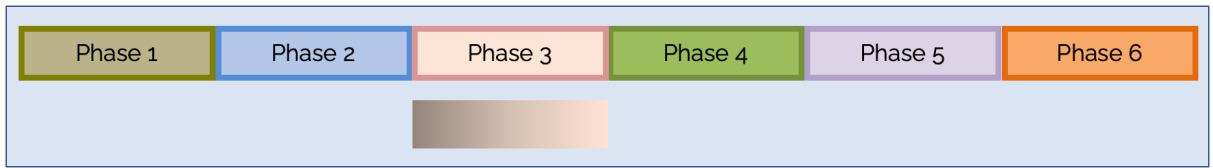


Figure 20: How the APQP links to the NPI process for prototype build

A manufactured prototype is an early sample of the product, concepts and processes. This shall replicate the final product intent as much as possible.

The prototype build (or builds) will confirm the product can be manufactured, conforms with specifications and meets the customer's requirements.

The prototype build allows the supplier to understand the manufacturing process and equipment development needs. Data and learning from the prototype build shall feed into the design before the design is released for production.

The product created in the prototype build may be used for Sellafield Ltd.'s facility commissioning and trials.

### 3.2.7 First Article Inspection Report (FAIR)

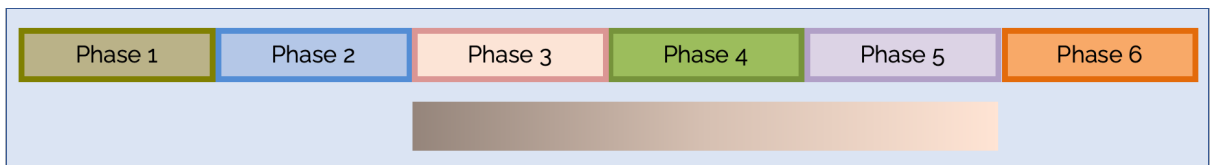


Figure 21: How the APQP links to the NPI process for First Article Inspection Report (FAIR)

The FAIR records all dimensions and other specification items, highlights all deviations, and gives the actions required to correct the product if deviations are found.

The FAIR also records the test and measurement results from the prototype build, "off-tool" products, "off-tool and off-process" products and Run@Rate parts, as follows:

- The report shall list all specifications from the product drawings
- The supplier shall show which data were used to create the measurement report.
- Any measurement reports submitted within the FAIR shall use Sellafield template (MPIC\_Man\_003\_DIP) unless otherwise agreed with the IPT.
- The report shall illustrate geometrical tolerance and how the feature was measured
- The report shall reference the revision levels and issue date for the product drawing and other specification documents

The SL IPT shall review all deviations, non-conforming dimensions and features, and an action plan shall be created that identifies the owners (both supplier and IPT) of each action and agreed timescales.

### 3.2.8 Records and Compliance

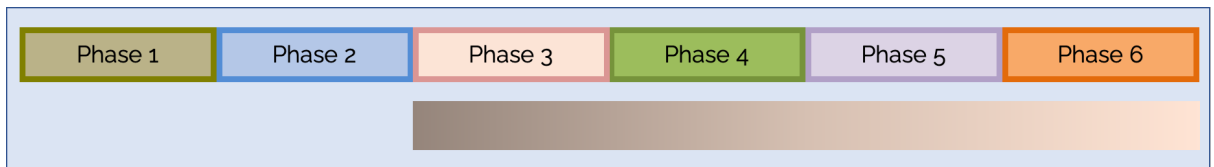


Figure 22: How the APQP links to the NPI process for records and compliance

The supplier shall establish a system for keeping records for a minimum of thirty years.

The supplier shall ensure that all LTRs including those generated by sub-suppliers are compiled in accordance with SLP 2.15.05 and its subsets concurrently with the activity to which they relate.

Correction Fluid (Tippex) is not to be used. Mistakes should be crossed out by a single line so the previous information can still be read, signed, stamped and dated at the side of the change.

The agreed number of sets of the LTRs shall be, unless stated otherwise in the Contracts, be sent to the applicable Quality Manager for the Contract as identified at Opening Up meeting.

Where Radiography is specified within the Purchase Order / Contract, the supplier shall conform to ES\_0\_5260\_2 General Procedure & Guidance specification for Radiographic Examination.

The requirements for records and compliance are defined in Section 4.8. These shall define the production lifecycle records required.

The supplier shall demonstrate a system for the identification, lot traceability and control of the products and materials used to manufacture and deliver the product. In addition, it shall control and demonstrate compliance with materials and processes by keeping and maintaining accurate records and data for all project phases.

The supplier shall, where required, ensure sub-suppliers maintain a system that provides item traceability in accordance with the relevant specified requirements. The supplier shall maintain a traceable-reference-and-stamping system for the person(s) responsible for approving documentation. The responsible person(s) shall be identified in the RACI (see section 3.1.2).

Materials certification shall follow the requirements defined in Section 4.9.

### 3.2.9 Engineering Change Management (ECM)

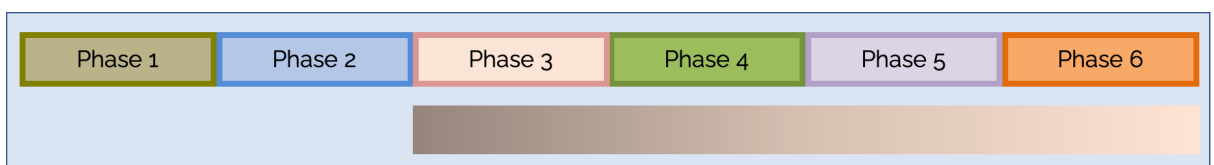


Figure 23: How the APQP links to the NPI process for engineering change management (ECM)

An ECM system is fundamental to any manufacturing business, and it controls:

- changes to specifications,
- any change to the product design or drawings
- any change to manufacturing processes, flow, or the manufacturing methods, at the supplier or sub suppliers
- any change to sub suppliers

This includes the assessment and subsequent approval/rejection of a proposed change. It communicates changes to the IPT through drawing and specification changes, and the up issue of the same, and shall be fully traceable to the manufactured part.

The supplier engineering change process shall comprise the following steps:

- Change request
- Assessment, information gathering and feasibility study
- Approval to proceed and planning
- Implementation
- Post-change evaluation

The supplier shall comply with the IPT's change management process when requesting any changes and in communicating the implemented changes throughout the supply chain.

The supplier shall comply with SLP 1.02.18 and use SLF 1.02.18.01V (see section 6.2.1) to submit the concessions, permits and changes requests.

### 3.2.10 Measurement System Analysis (MSA) Plan

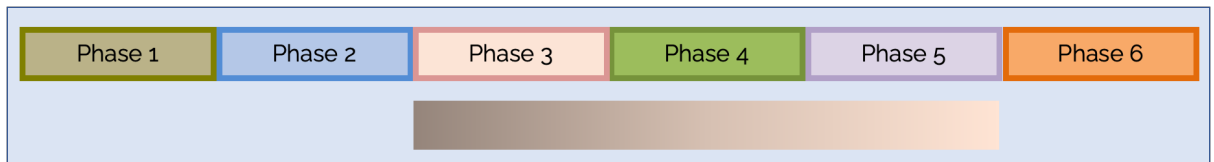


Figure 24: How the APQP links to the NPI process for measurement system analysis (MSA) plan

The MSA validates that the measurement system is fit for analysing a product. It assesses the variation of the measurement system, including both manual and automated processes. It also evaluates the individuals using the equipment, and it determines whether the measurement system is capable and acceptable.

Almost every process produces variation in the manufacture, assembly and checking of a product.

A study can be used to recognise the terminology and concepts, which include bias, variation, normal distribution, linearity, stability, repeatability and reproducibility, operator variation, and total variation. A study shall also determine if the measurement equipment is suitable for the assigned application.

The supplier shall prepare and conduct MSA studies. The studies should include all aspects of the measurement process including all measurement systems, jigs & fixtures and people required for the measurement activity. The studies ensures that the measurement process is repeatable and capable of confirming that the

product is within the desired specification and tolerance, enabling a decision about the product conformity.

All non-measurement related jigs & fixtures require proven capability via means such as statistical analysis. It is advised that all manufacturing jigs and fixtures are verified and calibrated to the 1:10 ratio.

The supplier shall create documentation for the method employed in the use of equipment. Personnel shall be trained and audited regularly in the correct use of the documented processes.

All attribute features shall be agreed with the SL IPT. Employees shall be signed off against the agreed standards, and boundary samples shall be retained. Suppliers shall demonstrate that operators have been trained and tested against these visual standards.

The analysis can be done manually; however, many off-the-shelf software packages available will perform this analysis and are more efficient (e.g. Minitab).

New studies shall be performed if any of the following are identified:

- Tolerances, personnel, or environmental conditions have changed from the original studies
- Equipment has been taken away from the working area for calibration, servicing, or repair
- Unusual results are being collected for no apparent reason

### 3.2.11 Qualified Laboratory Documentation

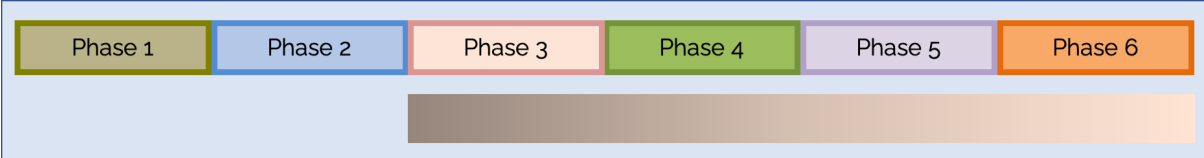


Figure 25: How the APQP links to the NPI process for qualified laboratory documentation

Qualified laboratories shall only be required to be used if the supplier conducts or sub-contracts testing and validation work to verify products or subsystems of the product.

As a minimum requirement, the supplier shall ensure that the laboratory (internal or external) has ISO / IEC 17025 accreditation (see section 6.1). In addition, the supplier shall certify its compliance to the material specified by the design record.

Qualified laboratory documentation consists of the industry certifications for any laboratory involved in completing the validation testing. This could be for an in-house test lab or any off-site contracted test facilities that were used for validation or material certification testing.

### 3.2.12 Operator Work Instructions

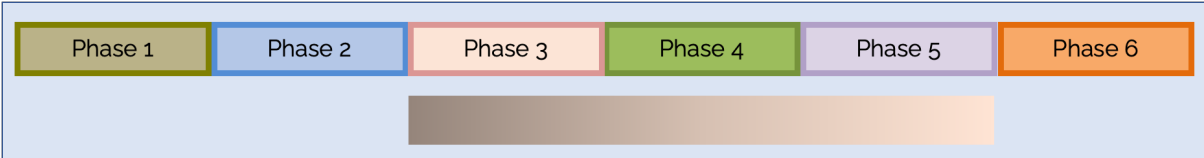


Figure 27: How the APQP links to the NPI process for work instructions

The Operator Work instructions define the method for each operation required for the completion of a manufacturing process with step-by-step operator instructions. This includes but not limited to the following:

- Manufacturing and production process steps
- Handling, transportation, and storage
- Testing, inspection, and measurement
- Quarantine of suspect non-conforming and defective material
- Rework and requalification
- Machine-setting parameters, controls, and programmes, including but not limited to electronic data such as computer numerical control (CNC) programs, automated welding machine settings, coordinate measuring machine (CMM) programs

The work instructions are derived from the shop floor, process flow, PFMEA and control plan.

The operator work instructions shall be used with visual aids where possible per operation, to assist personnel throughout their training and the deployment of the operator work instructions. The instructions shall be explicit and show each step for completing the manufacturing process to ensure a standard repeatable procedure, removing ambiguity from the operation. In addition, the operator work instructions and visual aids shall reference the control plan features.

Any Critical or Significant Characteristics (CCs and SCs) should be identified in the operator work instructions.

The training matrix for each operation should be displayed, and it should show the SQEP level of all shop-floor personnel. Only SQEP operators shall conduct a process without direct supervision.

Key personnel shall be highlighted, and contingency plans shall be put in place for the event that these personnel are not available.

The Operator Work instructions form part of the QMS and shall be subject to regular audits to ensure compliance.

Any processes relating to Special processes (defined in section 4.4) must be submitted by the supplier and accepted by Sellafield Ltd.

### 3.3 Manufacturing Process Development

#### 3.3.1 Pre-production Control Plan

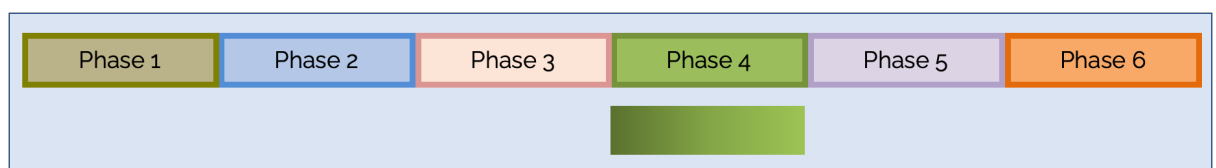


Figure 26: How the APQP links to the NPI process for pre-production control plan

As defined in the Prototype Control Plan (3.2.5), the pre-production control plan will be a development of the prototype control plan. As with the prototype control plan, the pre-production control plan is required for each of the components, features, sub-assemblies, and the final assembly or product.

The Pre-Production Control Plan should contain descriptions of the dimensions to be measured and the material and performance tests to be completed after prototype but prior to product launch and regular production.

**3.3.2 Product Validation Testing**

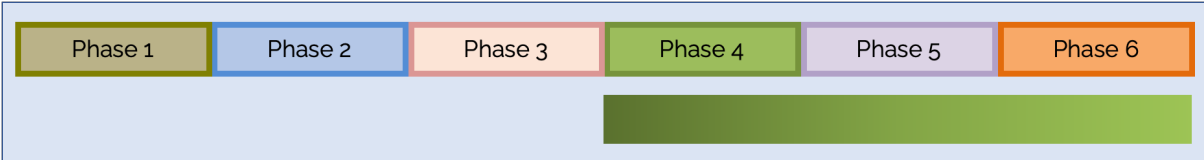


Figure 28: How the APQP links to the NPI process for product validation testing

Product validation testing refers to the tests and validation conducted by the supplier to test the fit, form and function of the finished product. The IPT shall specify the product validation testing at the start of the project.

To provide product confidence, validation testing may be completed on products during phase 4. However, only tests conducted on products manufactured from the full production process at the correct Run@Rate will be deemed acceptable for full validation.

Should any process require a change (e.g. new equipment, fixtures or machines), then the test and validation plan need to be reviewed to determine which tests shall need to be revalidated.

Once product validation testing has been completed, the supplier and IPT shall agree on the product testing requirements and the frequency for phase 6.

**3.3.3 Material Planning and Logistics (MP&L) Plan**

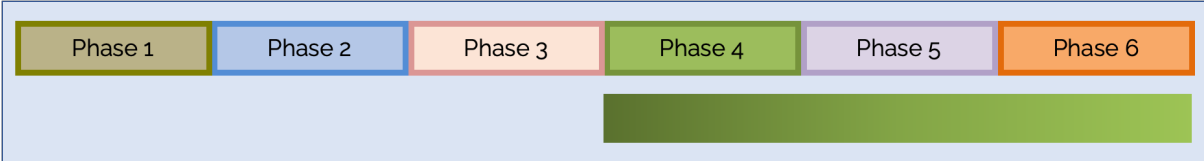


Figure 29: How the APQP links to the NPI process for Material Planning and Logistics (MP&L) plan

The supplier materials planning, and inventory function is required to provide the following:

- Ensure an understanding of the customer schedule for delivery and plan the manufacturing functions to enable the product to be manufactured and available in time for delivery.
- Ensure that all outsourced components, materials, sub-assemblies and consumables are available in the correct quantities and at the correct revision level to support the manufacturing throughout all phases of the NPI process. The reordering of these items is based on supplier lead times and inventory-holding requirements.



- Generate production plans and schedules, and then monitor performance against these production plans.
- Ensure all materials, components, sub-assemblies, consumables and finished products are stored appropriately, and ensure the inventory is accurate and true.

The supplier shall demonstrate it can receive schedules from Sellafield Ltd and shall show how these trigger purchase orders within its supply base, based on the lead times for its suppliers and the existing inventory holding.

Ideally, the supplier shall use an enterprise resource planning (ERP) or manufacturing resource planning (MRP) system to schedule and replenish materials and to perform inventory control.

The supplier shall demonstrate the business continuity planning and risk management of all its sub-suppliers.

The supplier must ensure it fully understands the delivery requirements and provide full contact information including out of hours emergency contacts to the Sellafield Ltd procurement team. In addition, it shall hold all sub-suppliers' contact details for its sub-suppliers and retain a schedule with volume requirements for each sub-supplier.

### 3.4 Manufacturing Process Validation

#### 3.4.1 Production Control Plan

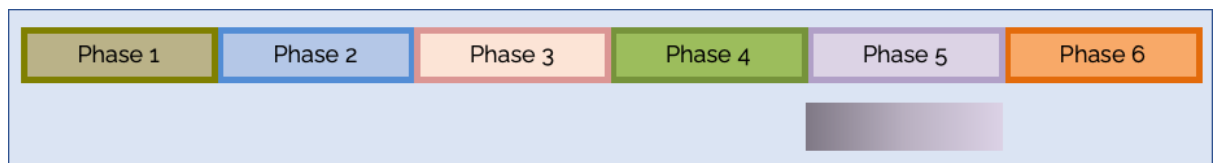


Figure 30: How the APQP links to the NPI process for the Production Control Plan

The Pre Production Control Plan developed during phases 4 is refined and progressed during phase 5 of the NPI process into the final Production Control Plan. It will remain a live document throughout the production lifecycle. It maps out for each process where control is required exactly who, when, how and what product features are controlled.

This level of Control Plan should contain a comprehensive listing of the product and process special characteristics, the process controls, measurement methods and tests that will be performed during regular production.

The supplier shall develop a production control plan using the format in Appendix J or equivalent.

The supplier shall develop, implement, and maintain an audit process to measure the effectiveness of the Production control plan elements.

### 3.4.2 Process Capability (Cp) Study

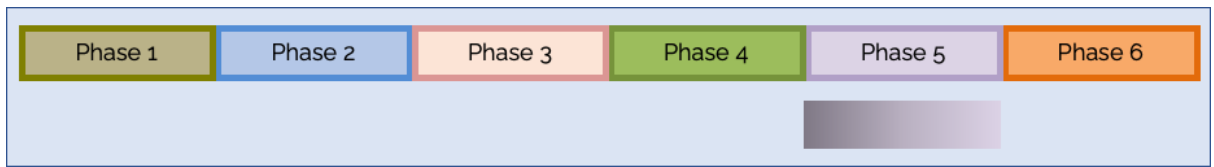


Figure 31: How the APQP links to the NPI process for process capability (Cp) study

Cp studies assess the ability of the process to meet the specifications and seek to understand the inherent process variability for any given characteristic. This covers the following:

- Dimensional Cp and process capability index (Cpk)
- Planned against actual for both throughput and lead time
- OEE

The supplier shall determine the type of discrete / attribute data collection for the product features.

The supplier shall demonstrate its Cp through studies that have been undertaken to prove and ensure that the manufacturing facility can produce products repeatably in a manner that meets all safety and cost requirements. In addition, a comparison between the actual process capacity and the planned process capacity shall be conducted to ensure the manufacturing line is capable of meeting volume requirements.

A Run@Rate trial shall be conducted to confirm the capacity and OEE. This shall include unplanned downtime, planned downtime and scrap. In addition, capability measurement studies shall use the products manufactured in the Run@Rate trial.

During the Run@Rate trial:

- Rework shall be tracked, and data recorded as prescribed in the Quality plans
- Any scrap produced shall be recorded
- Any equipment breakdowns or equipment issues shall be recorded, detailing what the issues were and how long they took to resolve
- The supplier shall record all breaks taken by operators (both planned and unplanned lost time)
- Any material rejected at the point of use is to be recorded
- The supplier shall provide an OEE calculation to demonstrate efficiency

When a capability study shows the process is not capable, the supplier shall investigate and identify solutions, raising an engineering change request if necessary, and shall then implement the change and repeat the study.

The supplier and the IPT shall agree on the volume requirements and the targets for the capability indices (Cp and Cpk) at the beginning of the project.

### 3.4.3 Production Part Approval Process (PPAP) Submission and Part Submission Warrant (PSW)

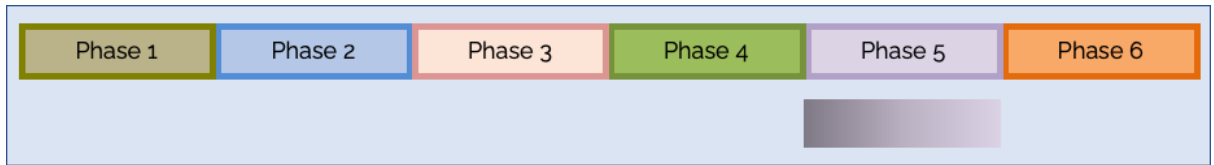


Figure 32: How the APQP links to the NPI process for Production Part Approval Process (PPAP) submission and Part Submission Warrant (PSW)

The PPAP submission is the conclusion of the APQP process. The Sellafield PPAP submission is based upon industry standard PPAP processes. It is an evidence pack against the eighteen points in the matrix, which demonstrates the supplier has followed a structured approach and progression through all elements of the APQP process.

The supplier shall submit the PSW (MPO\_Qual\_001). Upon acceptance by Sellafield Ltd, the supplier shall be permitted to commence volume production and ship products into Sellafield Ltd, accompanied by an SLF 2.15.02.05 "Final Certificate of Inspection Form 5059" (see section 6.2.1). Products supplied to Sellafield before PSW completion will require a production permit to be submitted using the Engineering Query process.

Any intermediate product not dispatched to Sellafield Ltd site, (i.e. into storage) shall require an interim release, with authorisation being obtained through the issue of a signed SLF 2.15.02.04 "Intermediate Certificate of Inspection Form 5199".

There are five levels of PPAP submission, Sellafield Ltd default level is 3. At the start of the project, the supplier will have been informed which level of PPAP it shall be required to submit to.

Any discrepancies shall be actioned and resolved by the supplier and accepted by the SL IPT.

PPAP Documentation Matrix		Submission Level				
		5	4	3	2	1
		Submit/ Retain	Submit/ Retain	Submit/ Retain	Submit/ Retain	Submit/ Retain
1	Design Records - Latest Drawing Levels & Specs	R	*	S	S	R
2	Authorised Engineering Change Documents / Part History	R	*	S	S	R
3	Customer Engineering Approval	R	*	S	R	R
4	Design Failure Mode & Effect Analysis (DFMEA)	R	*	S	R	R
5	Process Flow Diagram	R	*	S	R	R
6	Process Failure Mode & Effect Analysis (PFMEA)	R	*	S	R	R
7	Control Plan	R	*	S	R	R
8	Measurement System Analysis (MSA)	R	*	S	R	R
9	Dimensional Results including First Article Inspection Reports (FAIR)	R	*	S	S	R
10	Performance & Material Test Reports	R	*	S	S	R
11	Initial Process Capability Studies	R	*	S	R	R
12	Qualified Laboratory Documentation	R	*	S	S	R
13	Packaging, Documentation & Labelling Standards	R	*	S	S	R
14	Sample Product	R	*	S	S	R
15	Master Sample / Boundry Samples	R	*	R	R	R
16	Checking Aids / Fixtures	R	*	R	R	R
17	Record of Compliance with Customer Requirements	R	*	S	R	R
18	Part Submission Warrant (PSW)	R	S	S	S	S

**Key:**

- S = The supplier shall submit the documentation to the customer
- R = The supplier shall retain the document and make it available to the customer upon request
- \* = Submit or Retain, to be agreed with PPAP scope agreement

Table 4: PPAP submission documentation table

**PPAP Submission Levels**

- Level 1: PSW with limited supporting documents
- Level 2: PSW with sample products and limited supporting documents
- Level 3: PSW with sample products and complete supporting documents (standard submission level)
- Level 4: PSW and requirements as defined by the IPT
- Level 5: PSW with sample products and full supporting documents available for review at the supplier location; this level will require the IPT to witness production runs, inspection, testing, gauging and goods-in to goods-out

Upon receipt of the PPAP submission, the IPT shall review and approve the PSW, permitting the supplier to start volume production and product shipment to Sellafield Ltd.

**3.4.4 Sample Product**

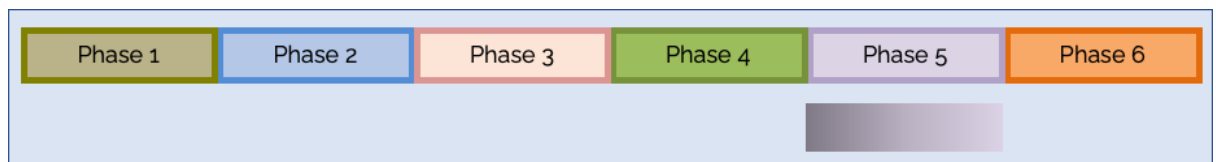


Figure 33: How the APQP links to the NPI process for sample product

As part of the PPAP submission sample products may be required for approval assessment by Sellafield ltd. The parts shall be from the full production tooling

and process route. The samples once approved should be held by either Sellafield Ltd or Supplier.

**3.4.5 Master Samples (including Boundary Samples)**

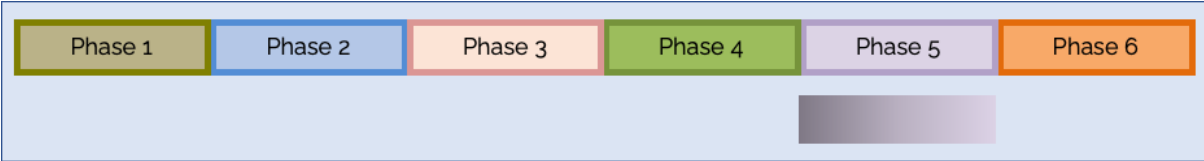


Figure 34: How the APQP links to the NPI process for master samples (boundary samples)

If required, the master samples shall be produced, marked as master samples, dated and accepted by the SL IPT. These are used as the ultimate reference for manufactured products retained by the supplier.

Where it is impossible to retain an entire product, individual sub-assemblies may be deemed acceptable as master samples.

There may also be a need for Boundary samples to be agreed which remove ambiguity between Sellafield Ltd and the supplier with respect to discrete/attribute features (welding, surface finish, etc.). They also support employees' training.

The supplier shall prepare or select samples for processes requiring discrete / attribute testing and analysis, and then agree on boundary samples with the SL IPT.

These samples shall be chosen from those that have achieved the minimum and / or maximum manufacturing tolerances or acceptance levels. All samples shall be marked as boundary samples, dated, and accepted by the SL IPT.

Employees shall be retrained / qualified over an agreed period (e.g. every three to six months) to maintain the standards.

**3.4.6 Supplier and Key Performance Indicator (KPI) Performance Management**

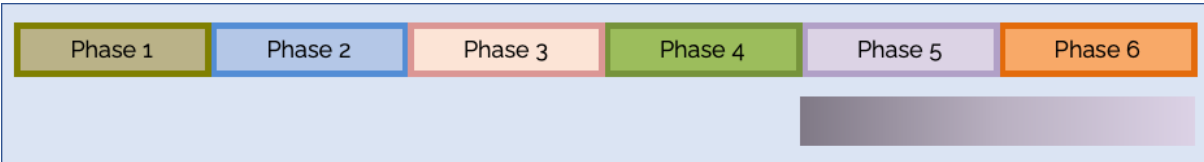


Figure 35: How the APQP links to the NPI process for supplier and key performance indicator (KPI) performance management

Sellafield Ltd shall communicate to the supplier the performance criteria and KPIs it will use to track the performance throughout the contract for volume manufacture. These shall be reviewed at agreed regular intervals.

The supplier shall develop a data gathering and analysis system for the KPIs.

Sellafield Ltd shall advise the supplier of the supply chain oversight arrangements applicable throughout the production lifecycle (e.g. the type or extent), based on several factors. These may include but are not limited to the following:

- Risk associated with technical product-specific features/requirements
- Control plan and PVL for specific items and features
- Special-process type and control arrangements
- Qualification of SQEPs
- Supplier performance against contract deliverables
- NCMs / problem resolution (for products delivered from sub-suppliers)
- NCMs / problem resolution (for products delivered to Sellafield Ltd)
- Concessions raised / accepted / declined
- Process audit results and adherence to the process

The arrangements shall extend to all tiers of the supply chain, and it is the supplier's responsibility to manage its sub-suppliers.

**3.5 Volume Production Supplier Activities**

**3.5.1 Lessons Learnt**

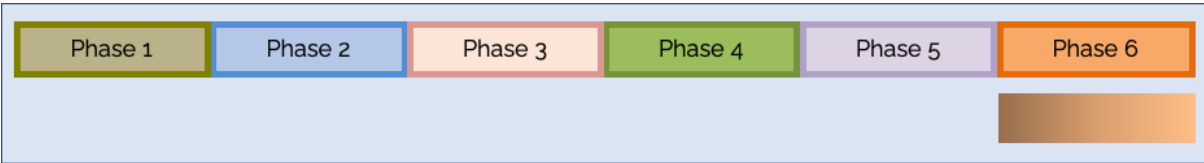


Figure 36: How the APQP links to the NPI process for lessons learnt

Lessons learnt is an invaluable tool for ensuring the information on "things gone right" (TGR), "things gone wrong" (TGW) and areas of improvement are captured to provide learning for the next project.

The IPT shall hold a Lessons Learnt review and document the TGR and TGW. In addition, the supplier shall be responsible for maintaining a TGR / TGW log throughout the duration of the project.

**3.5.2 Process Improvement and Cost-down Activities**

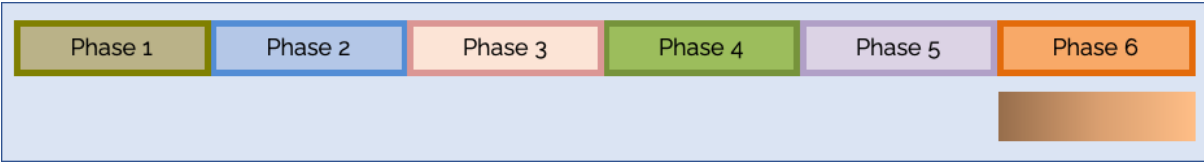


Figure 37: How the APQP links to the NPI process for process improvement and cost-down activities

Once in production with a stable process, process improvement and cost-saving initiatives shall be commenced to improve the product's (or products') quality, cost, and delivery. Process improvement tools include the following:

- Lean Six Sigma
- Kaizen
- 5S
- Fault tree analysis
- Value-stream mapping

### **3.6 Advanced Product Quality Planning (APQP) and the Production Product Approval Process (PPAP)**

While APQP and the PPAP are related, it is vital to understand the different role of each. APQP is a set of activities that determines the quality of the manufactured products. The PPAP is the evidence pack used to demonstrate the existence of a capable, stable, repeatable manufacturing process.

The PPAP is an integral part of APQP. It confirms whether the supplier has met the requirements of APQP. In addition, it evidences whether the supplier has matured the product through the design and production process to meet Sellafield Ltd.'s requirements.

The PPAP submission levels reflect the supplier relationship, capability and confidence established over a period of time, and they are determined by Sellafield Ltd (see Table 4 in section 3.4.3).

A level 3 full submission is required until acceptable capability has been demonstrated through the introduction and manufacturing of products launched through the Sellafield Ltd NPI process.

The PPAP is an evidence file. The PSW is a request to start volume manufacture, which Sellafield Ltd shall accept when the supplier demonstrates the product meets all of Sellafield Ltd.'s requirements and specifications. The PPAP forms a part of the manufacturing record.

The supplier shall update the PPAP with every change in the design or manufacturing process, and it shall be reviewed every twelve months. Changes include but are not limited to the following:

- Design changes
- Product reintroduction (legacy components)
- Source changes (including change of supplier or supplier's facility)
- Changes to the method of manufacture, including changes of machine
- Volume increases that require changes to the manufacturing process or the introduction of new processes
- Tooling changes or refurbishment

## 4 Contract Quality Arrangements

The following section details the Sellafield Ltd specific manufacturing and quality requirements in addition to APQP. These requirements reflect the requirements of the Sellafield Contract Requirements that are applicable to volume manufacture.

### 4.1 Suitably Qualified & Experienced Persons (SQEP)

As highlighted in section 1.3 the supplier shall provide a multifunctional project team of suitably qualified experienced persons (SQEPs).

To be considered an SQEP, an individual's professional competence shall be demonstrated and traceable to a competency profile linked to their role. Professional competence is deemed to be having the demonstrable knowledge, skills, and experience appropriate to the task or activity undertaken, and it shall be supported by formal training and qualification(s).

The supplier shall develop, implement and maintain a skills matrix that identifies each employee's training, competency and qualification requirements.

The process shall include but not be limited to the following actions:

- Defining the knowledge, skill and experience requirements for each process or manufacturing activity
- Developing knowledge of all the national, international, and customer-specific specifications, standards, and accepted procedures applicable to the assigned task and product
- Developing methods for conforming the training effectiveness and qualification(s) before commencing the assigned task and product
- Developing a system for the ongoing confirmation and validation of training effectiveness, including any updates to national, international, and customer-specific specifications, standards, and accepted procedures
- Identifying evidence of the aforementioned items through qualification(s)

The supplier shall notify Sellafield Ltd of any deficiencies identified with personnel competency that may affect the product or service provided and take corrective actions to eliminate personnel competency deficiencies.

The supplier shall define and implement appropriate arrangements to control any changes to its organisational structure or resources that may affect environmental, health and safety, security, and quality performance. Any such changes shall be formally reported to Sellafield Ltd.

All Inspection and test Quality Control plus special processes (Welding, NDE, Heat treatment, Painting & Coating etc.) personnel deployed on the works are suitably experienced and shall be in possession of nationally recognised and current qualifications in mechanical and electrical disciplines.

All testing and inspection practitioners shall be experienced in the application of the technique to the specific material.

The supplier organisation shall operate a formal process to ensure the achievement of quality requirements, and it shall develop and embed a culture of continuous improvement (CI).



## 4.2 Quality Plans

The format of the contract and APQP quality plans required by Sellafield Ltd are shown below.

Both the Contract and APQP Quality Plans shall be submitted to the Sellafield Ltd for review and Acceptance prior to the commencement of activities. Subsequent changes shall require further SL review and acceptance.

### **Contract Quality Plan: (Contract Requirement Quality Management)**

The purpose of the Contract Quality Plan is to ensure the suppliers Quality Management System is capable of maintaining continually improving Quality Management system processes underpinned by the appropriate technical and behavioural competences throughout both their workforce and supply chain partners.

The Contract Quality Plan shall consist of:

- Cover Sheet
- Documentation Sheet
- Activity Sheet

#### **Cover Sheet:**

- Quality Plan title and revision status
- The Scope/Organization of work the Product Quality Plan covers
- Reference Numbers (Sellafield Limited Contract Number, Supplier Reference Number and Sub-Supplier Number(s) (if applicable))
- Plant Item Number or Material Master Number
- Contracted Number of Items to be produced
- Quality Product Planning document hierarchy structure diagram sign off (supplier & customer)
- Quality Plan acceptance (supplier & customer)

#### **Documentation Sheet:**

- APQP/PPAP arrangements process (APQP Stage/Phase planning)
- Contract Accreditation's (e.g. ISO 3834-1-4)
- Contract gap analysis studies (Where applicable)
- Approved Signatory List

#### **Activity Sheet:**

- Quality Management System Requirements
- Gap Analysis Studies
- Nuclear Safety Policy
- Contract Review Process
- Contract Performance Measurement Process(s)
- Change Control Process(s)
- Learning from Experience Process
- Supply Chain Map Process
- Selection of Sub-Supplier Process
- Control of Sub-Supplier Process
- Schedule of Sub-Supplier (CMFT 121)

- Performance of Key Supply Chain Partners Performance Process
- Management of Counterfeit, Fraudulent and Suspect items of services (CFSI) Process
- Foreign Matter Exclusion Policy (FME) Process
- Control of Non-Conforming Product Process
- Quality Assurance/Inspection strategy
- Contract RACI
- Suitable Qualified & Experienced Person (SQEP) nominated roles, including signatory list relating to Quality Plan sign-off activities (Including PPAP Coordination personnel)
- Non-Conforming Product Reporting Process
- Lifetime Quality Records Process
- Manufacturing Quality Records Process
- APQP/PPAP Records Process
- Final Contract sign-off Process (including completion of APQP stages)

### **Advanced Product Quality Planning (APQP) Quality Plan:**

The Supplier shall also develop a Quality Plan defining Product and Process assurance arrangements for controlling the deployment of the APQP process throughout specified stages.

The Quality Plan shall confirm the "Advanced Product Quality Planning" document hierarchy structure required to confirm process assurance arrangements.

The Quality Plan shall control the submission and subsequent review, acceptance and change control of all Quality Documentation, Special Process Documentation, Testing Procedures, Traceability documentation, Process Auditing Scheduling arrangements, and associated Manufacturing and Lifetime Quality Records. This will include document contract retention requirements applicable to all stages of the Advanced Product Quality Planning process, including all associated Sub-Suppliers and Supply Chain Partners.

The APQP Quality Plan shall ensure all Sellafield Limited organisational, Contractual, National & International standards assurance expectations are being suitably controlled and are capable of constantly meeting customer expectations. This is supporting a risk-based approach to the application of appropriate Quality arrangements and objectives to enable the successful delivery of our operations.

The Advanced Product Quality Plan shall consist of:

- Cover Sheet
- Documentation Sheet
- Activity Sheet

### **Cover Sheet: (Including but not limited to): -**

- Advanced Product Quality Plan title and revision status
- The Scope/Phases the Advanced Product Quality Plan covers
- Reference Numbers (Sellafield Limited Contract Number, supplier Reference Number and Sub-Supplier Number(s) (if applicable))
- Plant Item Number or Material Master Number
- Contracted Number of Items to be produced

- Quality Plan Acceptance sign off (supplier & customer)

**Documentation Sheet: (Including but not limited to)**

- APQP documentation requirements
- PPAP documentation requirements
- National/International Standards
- Contract Build Drawings

**Activity Sheet: (Including as a minimum requirement): -**

- Process Management Arrangement Acceptance:
- Management of Welding Activities
- Management of NDE Activities
- Management Material arrangements
- Management of Dimensional Requirements
- Management of Lifetime/Manufacturing records
- Management of APQP/PPAP arrangements
- Management of Jigs & Fixtures
- Product/Process release process (Intermediate/Final/APQP phases)
- Document Acceptance:
- Quality Plan(s)
- Process Flow Diagrams
- Method of Manufacture Procedures
- Dimensional Testing Procedures
- MSA Studies
- DFMEA(s)
- PFMEA(s)
- Control Plans
- Inspection & Test Plans
- Material Certification
- Qualified laboratory Requirements
- Standard Operating Procedures
- Work Instructions
- ISO 3834 1-4 deliverable (technical reviews, product planning reviews, maintenance procedures)
- Special Process Procedures
- Weld Procedures
- Reference/Binary Sample Documentation/Reports
- NDE Procedures
- Traceability Formats
- Reporting Templates
- Process Capability Study Formats
- Certificate of Conformity Formats
- Part Submission Warrant Formats
- Lifetime Quality/Manufacturing Records Index
- PPAP Records Index
- Concurrency of Documentation agreements (including document submission requirements)

### 4.3 Inspection, Oversight and Assurance

The Sellafield Ltd NPI process and associated APQP activities ensure growing maturity levels in manufacturing volume products throughout phases 3–6 of the NPI process. The NPI process and APQP activities enable suppliers to mature their manufacturing capability (through the PDCA cycle). Sellafield Ltd.'s aim is to reduce inspection and oversight and to move towards a model of QA and a self-certified product.

The level of inspection and oversight required by Sellafield Ltd is determined by the Product Validation Level (PVL). The PVL of each operation is determined by the RPN (calculated in the PFMEA) and the capability of the supplier to manage the process. As the manufacturing process matures through phases 3–6 of the NPI process, and the supplier collects and analyses data to demonstrate Cp, the PFMEA and control plans shall be reviewed, and the PVL may change.

Operations and features with inherently high risk to product quality or nuclear safety may remain at a low level of maturity to ensure the appropriate control during manufacturing.

However, oversight shall remain when product risk (as defined by the PFMEA) is high.

In general, Sellafield Ltd shall monitor supplier capability and repeatability during each phase of manufacture and shall agree to changes when the supplier demonstrates sufficient levels of discrete/attribute capability (Cp / Cpk).

Each control plan shall record the PVL of each operation.

#### Product Verification Levels (PVLs)

Every component, feature, sub-assembly and full product – that is, every control plan line item (hereinafter referred to as “items”), shall have a PVL assigned to it. The PVL indicates the type of oversight required by Sellafield Ltd, and are defined as follows:

- PVL 1 – inspection (the sampling rate is to be agreed with the NPI IPT)
- PVL 2 – oversight
- PVL 3 – assurance

As the supplier provides evidence that it has achieved a repeatable, stable process (Cp/Cpk), the PVL is increased.

Many factors inform the PVL of each item, including the following:

- RPN determined through the PFMEA and DFMEA
- process selection
- process repeatability
- reject rates
- criticality (to safety and nuclear safety).

As a result, some items shall always be subjected to inspection by Sellafield Ltd or its suppliers and remain at PVL 1.

### **PVL 1**

This level covers the initial manufacturing, where prototype systems / concept manufacturing routes are yet to be proven or where items on the control plans have proven to have high RPNs or criticality (to safety and nuclear safety).

PVL 1 requires Sellafield Ltd.'s inspection and oversight; greater initial oversight of inspection activities shall be required (as documented on the control plan) to gain confidence that the quality arrangements implemented by the supplier are sufficient and correct. The inspection and oversight required are as follows:

- A 100% supplier QC inspection
- Manufacturing hold points shall be agreed before continuing
- Sellafield Ltd has performed an inspection

### **PVL 2**

The supplier can repeatedly demonstrate compliance to the TPS requirements and is recording the proposed KPV / KPI data to underpin process assurance.

PVL 2 allows for Sellafield Ltd.'s oversight surveillance inspection. The surveillance inspection involves maintaining oversight.

Sellafield Ltd.'s surveillance validates the KPV / KPI and any proposed SPC parameters gained by the supplier through a compliance audit of the process flow and special-process procedures.

PVL 2 still requires a 100% supplier QC inspection. Sellafield Ltd.'s oversight involves checking and acceptance of the supplier's performance data, as follows:

- KPV/KPI data
- RFT data
- Capability and SPCs
- Continued compliance with manufacturing documentation (process flow, special-process procedures, process control plans, etc.)

Once a supplier can demonstrate its capability and repeatability through the acquisition and analysis of the data, and it can meet the requirements of the TPS, it can move to PVL 3.

### **PVL 3**

The supplier has validated its capability and repeatability necessary to ensure the items on the control plan are within the agreed product quality requirements.

PVL 3 provides Sellafield Ltd with assurance and allows a reduced supplier QC inspection. This assurance shall be gained through checking the supplier's performance through auditing the following:

- KPV/KPI data
- RFT data
- Capability and SPCs

- Continued compliance with manufacturing documentation (process flow, special-process procedures, control plans, etc.)

This shall typically apply to the features and items that are not defined as CCs and SCs.

The following table shows how the PVL levels may apply to the NPI phases. As the manufacturing processes mature, the review of the PFMEA, control plans, analysis of statistical data and the results of the capability indices will allow the PVL level to be increased.

PVL	1	2	3
NPI Phase	3,4,5,6	3,4,5,6	4,5,6
<b>Overview</b>	Produce New Product/ Process	Process Established - Proven Capability	Volume Production
<b>Applies to..</b>	...new processes for verification of the quality arrangements proposed by the supplier	... validated processes with repeatability demonstrated compliance to the TPS recording KPV/KPI data	...validated and capable processes that ensure items on the control plan meet the agreed quality requirements
<b>Supplier QC</b>	100% QC	100%QC	reduced QC inspection
<b>SL Quality</b>	inspection & oversight	oversight	Assurance
<b>Progression Criteria</b>	once new processes verified and stable	Once the formal readiness review is passed the supplier is no longer at PVL2, move to PVL3	

Table 5: PVL and NPI phase table

#### 4.4 Special Process Procedures

Special processes are defined as Manufacturing activities, which changes the shape, form, structure, or final appearance of the original product.

The Supplier shall:

- Establish a documented procedure supporting the control of Special Processes for both Supplier and nominated Sub-Suppliers. This shall define controlling measures for:
  - Assessment
  - Review
  - Submission
  - Change Control
- Maintain a traceable reference to authorised personnel required to accept Special Process procedures defining qualification requirements to support document acceptance process (where required).

Special Process procedures shall be specific to the Process and Product requirements (ranges are unacceptable however variance is permitted). Where Special Process procedures are defined as:

- Engineering Control (EC), as per table 6 below, these shall be submitted to the responsible SL IPT member for acceptance prior to commencement of manufacture.
- Manufacturing Engineering Control (MEC), as per table these shall be approved by the Supplier and shall be submitted to Sellafield Ltd for audit. per table 6 , these shall be approved by the Supplier and shall be submitted to Sellafield Ltd for audit.

For any component part controlled by Special process procedures, the documents shall be submitted to the for acceptance before commencement of manufacture of any part, subsequent changes shall require further SL review and acceptance.

Through the design process and DFMEA/PFMEA the level of risk will be identified against each manufacturing process categorised as low/medium/high as below. Processes that are deemed special processes but are assigned a lower risk classification have the ability to remove Sellafield Ltd. upfront approval.

High Risk		Medium Risk		Low Risk	
SL Engineering Control	Manufacturing Engineering Control	SL Engineering Control	Manufacturing Engineering Control	SL Engineering Control	Manufacturing Engineering Control
SL Up Front Approval	In House SQEP Approval	SL Up Front Approval	In House SQEP Approval	SL Up Front Approval	In House SQEP Approval
Visual	Storage and Handling	Visual	Dimensional Inspection	Visual	Dimensional Inspection
DPI	PMI	UT	Brazing	UT	Fusion Welding
MPI	Ferroxyl Testing	DPI	Forming	DPI	Resistance Welding
UT	Salt Testing	MPI	Bending	MPI	Brazing
Eddy Current	Passivity Testing	Eddy Current	Forging	Eddy Current	Buttering / Cladding
Radiography		Radiography	Packing	Leak Testing	Heat Treatment
Dimensional Inspection		Fusion Welding	Storage and Handling	Pressure Testing	Cleaning
Fusion Welding		Resistance Welding	PMI	FAT	Forming
Resistance Welding		Weld Repair	Ferroxyl Testing	Load Testing	Bending
Brazing		Buttering / Cladding	Salt Testing	Weld Repair	Forging
Weld Repair		Heat Treatment	Passivity Testing		Painting
Buttering / Cladding		Cleaning			Metallic Coatings
Heat Treatment		Painting			Grouting / Concrete
Cleaning		Metallic Coatings			PMI
Forming		Grouting / Concrete			Ferroxyl Testing
Bending		Leak Testing			Salt Testing
Forging		Pressure Testing			Passivity Testing
Painting		FAT			Packing
Metallic Coatings		Load Testing			Storage and Handling
Grouting / Concrete					
Leak Testing					
Pressure Testing					
FAT					
Load Testing					
Packing					

Table 6: Special Process Chart

#### 4.5 Supply Chain Oversight

The supplier shall be able to demonstrate a process for the selection, assessment, and ongoing monitoring of its supply chain; this is to ensure that each supplier has the capability to provide products or services in line with the flow-down requirements within this manual.

The supply chain oversight shall include but is not limited to the following:

- Assessing the QMS arrangements of each supplier
- Ensuring that each supplier has the competencies, facilities and equipment to conform to the contractual requirements

- Demonstrating that the supplier has a clear understanding of the specific flow-down requirements, and it understands and can support the APQP requirements for the project
- Establishing supplier KPIs against the contract deliverables
- Maintaining a supplier assessment schedule based on risk and report progress, including any deficiencies identified that affect compliance against the contractual requirements

The supplier shall produce and agree on a supply chain map, including materials, components, assemblies, sub-assemblies, items and agreed special processes. The map shall identify the type and level of assurance to be applied by the supplier to each sub-supplier as part of the scope of contracted work.

The supply chain map shall include the following:

- Organisational hierarchy that exists between the contracting parties
- Names of the contracting parties
- QA arrangements applied to each sub-supplier
- Risk and the appropriate risk mitigation associated with the sub-contracted work

The supply chain map shall be based on SLF 1.10.315.13 (see section 6.2.1) and submitted to Sellafield Ltd for the acceptance of changes as a result of maintenance throughout the contract's lifetime.

The supplier shall ensure that the contract requirements, Sellafield Ltd.'s Volume Products Supplier Manual arrangements, the appropriate standards and specifications, and the necessary requirements are flowed down, understood and complied with by all tiers of the supplier's supply chain.

The supplier shall do the following:

- Maintain a goods inwards process confirming that all purchased raw material(s), product(s) and/or service(s) are in accordance with the TPS requirements
- Where required, perform relevant inspection and test activities to verify the purchased product(s) conform with the TPS requirements
- Ensure that the required supporting documentation has been provided with the incoming product and is SQEP reviewed to confirm that the purchased product(s) or service(s) meets the TPS requirements
- Ensure all supplied supporting documentation that is required within the production lifecycle / manufacturing records is processed accordingly

The supplier shall ensure the purchasing information accurately specifies the requirements for the acceptance of products and services, which is to include the following, as applicable:

- Reference to this quality manual
- Product risk level
- Specification(s) and works information
- Drawing(s)
- Material(s) type(s)
- Quantity
- Certification requirements
- Inspection requirements – at the vendor, on delivery or both



- Functional testing requirements – at the vendor, on delivery or both
- Any special requirements, such as packing or extra testing

The supplier shall be able to demonstrate the health of its sub-suppliers through ongoing monitoring. Evidence of this shall include but not be limited to the following:

- Goods inward NCR process
- Inspection results
- Surveillance reports (expedited)
- Product quality-related issues
- Whether delivery is to schedule
- CFSI issues

The supplier shall establish a set of metrics / KPIs to enable the performance of sub-suppliers to be measured. These metrics / KPIs shall, as a minimum, measure the sub-suppliers' safety, schedule, quality and cost performance. The supplier shall ensure action that is specific, measurable, achievable, realistic and time-bound (SMART) is taken if sub-supplier performance is not achieving the required standard(s) or upon identifying a deteriorating and / or adverse trend.

The supplier shall report to Sellafield Ltd any deficiencies identified from its assurance programme that will affect compliance with contractual requirements. Corrective actions shall identify remedial measures and preventative actions to avoid recurrence of the issue.

#### **4.6 Control of Non-conforming Products and Processes**

To maintain the integrity of Sellafield Ltd.'s products and manage costs, suppliers shall manage and control non-conforming products and processes. Non-conforming parts shall be quarantined, and both parts and processes shall immediately be contained, reviewed and improved to prevent reoccurrence of issues.

The supplier shall immediately (within twenty-four hours) report the non-conformity to the appropriate management level and inform Sellafield Ltd.

#### **Quarantine and Control of Non-conforming Products**

The supplier shall establish and maintain a procedure for addressing the control of non-conforming products and processes; production of the NCR shall be in accordance with CT1.03.124 "Sellafield Ltd Defect / Non-conformance Report" (see section 6.2.1).

Upon identification of a non-conforming product by the supplier, the supplier shall do the following:

- Immediately notify the Sellafield Ltd contract officer, category manager, procurement lead and IPT contact of any delivered non-conforming product(s) and confirm acknowledgement of receipt of notice.
- Contain non-conformances by segregating, identifying, and controlling the product(s) or process(es) to prevent unintended use or delivery. The supplier shall identify the following:

- Affected part number(s), process(es) and name(s)
- Description of the non-conforming condition and the affected requirement
- Quantities, dates, purchase orders and destination of delivered shipments
- Lots, batch numbers, serial numbers, or date codes (as applicable) of the affected lot
- Work with Sellafield Ltd to understand the location and situation of all potentially NCM to enable recovery or corrective action by Sellafield Ltd.
- Clearly and permanent mark the non-conforming product(s) to ensure that defective items shall not be used. Non-conforming products that are subject to scrapping shall be recorded.
- Take necessary actions (within twenty-four hours) to contain the effect(s) of the non-conformance on other products or processes, (i.e. WIP, stores stock, shipping areas, in transit, sub-tier/sub-supplier activities, similar products, and products already dispatched and delivered to Sellafield Ltd).

The shipment of product can only commence once the supplier has demonstrated containment.

A non-conforming product shall not be shipped until the following has been completed:

- the supplier confirms all NCMs have been quarantined; and
- Sellafield Ltd has accepted the product, which in certain instances requires a concession application in accordance with SLF 1.02.18.01V "Technical Query / Concession / Production Permit" (see section 6.2.1).

If Sellafield Ltd identifies NCM after delivery, the supplier shall do the following:

- Contain all potentially NCM still in the supply chain
- Identify all potentially NCM delivered to Sellafield Ltd or its nominated suppliers and locations
- Support Sellafield Ltd in its identification, inspection and retrieval of potentially NCMs
- Propose rework that can be completed *in situ* and gain acceptance from Sellafield Ltd
- Comply with the other actions detailed previously in this section

Records relating to the control of NCMs and the subsequent corrective actions, including where a product was either reprocessed or remanufactured to meet Sellafield Ltd.'s requirements and specifications, shall be maintained and form part of the manufacturing records.

#### **4.6.1 Non-conforming Product Corrective and Preventative Actions**

The supplier shall do the following:

- Implement a structured approach to problem-solving and to establish the root cause(s) of non-conformances, containment, corrective actions and preventative actions. The supplier shall conduct this process in accordance with CT1.03.124 "Sellafield Ltd Defect / Non-conformance Report" (see section 6.2.1).
- Flow down corrective and preventative actions to sub-suppliers (as applicable).

- Investigate similar processes and products where similar failures could occur and carry across all lessons learnt.
- Review and update as necessary the process flow, PFMEA, control plans and operator process / work instructions. The supplier shall resubmit the PPAP / PSW if any processes are changed.

#### **4.7 Inspection and Test Plans**

The Inspection and Test Plan (ITP) defines the scope and frequency of required inspection & testing activities based on the assessment of associated risks and Sellafield Ltd contractually mandated Quality arrangements.

The Supplier shall:

- Submit the ITP to Sellafield Ltd for acceptance prior to the commencement of manufacture
- Ensure the ITP consists of:
  - Cover sheet:
    - Company name
    - ITP title and revision status
    - Quality Plan(s), Method of Manufacture (MoM)/Process Flow documents (PFD) and Control plans which the ITP is supporting
    - Reference numbers (Sellafield Ltd contract number, supplier reference number (including sub-suppliers)
    - Plant item number/material master numbers
    - Contracted number of items
    - Abbreviations / inspection / testing codes
  - Inspection activity sheet:
    - Description of operation / activity
    - Associated Procedures
    - Inspection code and frequency
    - Acceptance Criteria
    - Verifying Documentation
    - Accept/Reject
    - Date of Inspection
    - Provision for supplier sign & stamp off
    - Provision for Sellafield Ltd sign & stamp off

All queries related to ITP contents, frequencies and submission / acceptance conditions shall be discussed within the contract Quality Opening Up meeting.

The Supplier shall maintain a review, revision and change control system for all ITP documents.

#### **Inspection Activity Codes**

The control plans shall facilitate the signing off of activities against the agreed inspection activity codes to monitor the work completed. The selection of an

appropriate inspection activity code shall consider the specification, the difficulty of the activity and the criticality resulting from the PFMEA.

The following inspection activity codes shall be used to identify the action required and shall be included in the prototype control plan:

Action	Activity Code
100% Inspection	A1
Sample Inspection	A2(#)
100% Witness	W1
Sample Witness	W2(#)
100% Review	R1
Sample Review	R2(#)
Hold Point	H
Approval	AP
Surveillance	S

Table 7: Inspection activity codes

## 4.8 Records and Compliance

The supplier shall demonstrate it has a register of documents by type that also details what media has been used to store the documents.

The records the supplier shall keep the following:

- Customer requirements, drawings, engineering specifications, testing and validation requirements
- Completed team feasibility document
- QP(s)
- Floor plan and manufacturing process flow diagrams
- DFMEA and PFMEA
- Control plans – all three types
- Operator process / work instructions, including operator identification
- Lot traceability, including mixed batches
- Metrology, inspection and validation reports
- Customer complaints and NCM problem-resolution documents
- Cp studies, trends and results
- Process surveillance audit studies
- MSA studies and reports
- Packaging and transport evaluation reports
- FAIR/ISIR report(s)
- External material laboratory reports
- CofCs (for OEM and sub-suppliers)
- External validation and testing reports
- Authorised ECM history
- Sub-supplier APQP/PPAP document submission
- Plant maintenance records, including downtime
- SQEP trained employees (training and capability matrix)

- Lessons learnt documentation and signed PSW
- REACH
- BS ISO 14001 environmental regulations
- COSHH
- Nuclear safety regulations
- Production records, including which operators and inspectors conducted each production process
- Change control documentation, history and introduction dates
- Ongoing measurement results and trends
- Lot traceability original mill certificates (or equivalents)
- Process records, as defined by special processes
- Heat treatments and surface treatments
- Product identification

The following summary points should be considered:

- The effective management of records requires senior management support and commitment
- An effective records management system must be resourced adequately with clearly identified responsibilities
- The records system must comply with appropriate legislation
- When more than one organisation is involved in record-keeping during the various lifecycle phases of a facility, the responsibilities and interfaces should be clearly defined
- The records management system should be designed to enable managers to easily sort and sentence records
- The ownership of records during storage should be identified
- Due consideration should be given to the storage location
- Human factors should be considered carefully when designing a records management system for effectiveness and ease of use
- The records management system should identify what records should be kept and for how long
- Consideration should be given to storing records on a project/facility basis to facilitate easier retrieval and provide an adequate description of what they are
- The design of the record-keeping arrangements should be able to cope with technological and organisational changes
- Consideration should be given to the management of records generated electronically as part of an operational activity (e.g. data logger)
- The records management system should cover the full lifecycle of the facility from design through to de-licensing

#### **4.9 Management of Materials**

The Supplier shall establish a lifecycle material management system which covers as a minimum the following subject areas:

- Material certification
- Receipt Inspection
- Management of Counterfeit, Fraudulent and Suspect Items
- Foreign Material Exclusion

- Product Traceability

Where required as part of the product specification this information shall also form part of a quality Plan submission for acceptance by Sellafield Ltd.

### **Material Certification**

A procedure shall be submitted detailing the methodology within the supplier for material certification review and acceptance. This shall be submitted to Sellafield Ltd for agreement prior to the commencement of material procurement.

All required certificates provided shall comply with BS EN 10204 3.1 or Sellafield Ltd contract specific purchase documentation. The supplier shall supply to Sellafield Ltd original material mill certificates listing the mechanical and chemical properties as required by the contract specification.

Where a supplier is not in receipt of the true verified copy of the original certificate, the supplier shall validate (name, position & signature) the certificate in accordance with BS EN 10204 as a "TRUE COPY OF THE CERTIFICATE IN OUR POSSESSION".

Where a product has been manufactured from a previously certified material, the supplier shall provide the certificates of both material products produced by one supplier and reworked by another supplier, e.g., fittings made from pipe or plate, flanges made from a forging or plate.

The supplier shall review and accept the original material mill certificates or certified copies to verify conformance with the contract specification prior to the commencement of work. The supplier's authorised representative shall validate the certificate to confirm the mechanical and chemical properties comply with the requirements of the order.

Stockist certificates are not acceptable when original material mill certificates or certified copies are specified within the contract specification.

No information shall be deleted or otherwise obscured from the certificate, including purchaser details. Any evidence of alteration to a certificate, or an illegible certificate, shall be rejected.

Where Material has been subjected to a heat treatment for a specified mechanical property requirement Heat treatment furnace charts shall be provided.

Where Materials have been subject to a heat treatment which alters the mechanical properties listed on the 3.1 certificate items mechanical properties shall be revalidated by a UKAS accredited laboratory.

### **Management of Counterfeit, Fraudulent and Suspect Items**

The supplier shall ensure that processes are in place to mitigate the risk of Counterfeit, Fraudulent and Suspect Items (CFSI) being deployed to Sellafield Ltd. The processes shall include identification of CFSI, assurance of product and service source, selection of sub-suppliers and verification that purchased products or services meet the specified requirements.

In the event of CFSI being found, the supplier shall immediately quarantine the item, notify Sellafield Ltd in case a similar item is in use and initiate the nonconformity process as described in control of nonconforming products or processes (Section 4.6). Such product shall not be returned to the supplier to prevent their re-introduction into the supply chain. The information should be treated as Learning from Experience and disseminated to Sellafield Ltd.

The supplier shall ensure that processes are in place to control and document the disposition of items identified as suspect. Sellafield Ltd shall be provided records of the dispositions of suspect Items, as agreed at the opening up meetings.

### **Foreign Material Exclusion**

The supplier shall have a Foreign Material Exclusion (FME) process which should include but is not limited to the following:

- Identification as to whether FME principles apply to the scope of work and if so, when, i.e. final vessel closures, works testing, dismantling, packing and dispatch
- Identification, segregation and management of FME areas
- Identification and use of materials, equipment, processes and systems demonstrating their status, i.e. 5S, shadow boards, lanyards, work management, materials control including items to be removed or added such as bolts, washers, items in or items out and management of waste arising such as swarf
- Training and awareness information including good housekeeping for personnel involved in such activities

### **Product Traceability**

The supplier shall have a documented process for identification and traceability of materials and products during storage, manufacturing and delivery in accordance with specified requirements. The supplier shall, where required, ensure stockists maintain a system that provides item traceability in accordance with the relevant specified requirements.

## 5 Abbreviations

The following table not only includes the abbreviations used in this document but also additional abbreviations that may be used in any conversations relating to the subject matter covered by this manual.

2D	Two dimensional
3D	Three dimensional
APQP	Advanced product quality planning
BCP	Business continuity plan
BOM	Bill of materials
CC	Critical characteristic
CFSI	Counterfeit, fraudulent and suspect items
CI	Continuous improvement
CMM	Coordinate measuring machine
CNC	Computer numerical control
CofC	Certificate of Conformity
COSHH	Control of Substances Hazardous to Health
Cp	Process capability
Cpk	Process capability index
DFMEA	Design failure mode and effect analysis
DVP&R	Design Verification Plan and Report
EBOM	Engineering bill of materials
ERP	Enterprise resource planning
EC	Engineering control
FAI	First Article Inspection
FAIR	First Article Inspection Report
FAT	Factory acceptance testing
FME	Foreign material exclusion
FMEA	Failure mode and effect analysis
GDF	Geological disposal facility
HR	Human resources
IAF	International Accreditation Forum
IAEA	International Atomic Energy Agency
IC	Intelligent customer
ICG	Inspection and Certification Group
IPT	Integrated product team
IT	Information technology
ITNS	Important to nuclear safety
ITP	Inspection and test plan
KPC	Key product characteristic
KPI	Key performance indicator
KPV	Key process variable
LFE	Learning from experience
LRR	Launch readiness review
MEC	Manufacturing engineering control
MoM	Method of manufacture
MRP	Manufacturing resource planning
MML	Manufacturing maturity level
MP&L	Material Planning and Logistics
MSA	Measurement system analysis



NCM	Non-conforming material
NCR	Non-conformance report
NDE	Non-destructive examination
NOI	Notification of Inspection
NPI	New Product Introduction
OEE	Overall equipment effectiveness
OEM	Original equipment manufacturer
ONR	Office for Nuclear Regulation
OTIF	On-time, in-full delivery
PBOM	Production bill of materials
PCD	Process control document
PDCA	Plan Do Check Act
PFMEA	Process failure mode and effect analysis
PFD	Process flow diagram
PPAC	Production Product Approval Checklist
PPAP	Production Part Approval Process
PSW	Part Submission Warrant
PVL	Product verification level
QA	Quality assurance
QC	Quality control
QMS	Quality management system
QP	Quality plan
RACI	Responsible, accountable, consulted and informed
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RFT	Right first time
RPN	Risk Priority Number
R&R	Repeatability and reproducibility
SC	Significant characteristic
SLF	Sellafield Ltd form
SLP	Sellafield Ltd practice
SLSP	Sellafield Ltd supporting practice
SME	Subject matter expert
SPC	Statistical process control
SQEP	Suitably qualified and experienced person
TGR	Things gone right
TGW	Things gone wrong
TPS	Technical product specification
UKAS	United Kingdom Accreditation Service
WIP	Work in progress

## 6 References

### 6.1 Regulatory Standards

Reference	Title
BS EN 10204	Metallic Product Types of Inspection Documents
BS EN ISO 10012	Measurement Management Systems – Requirements for Measurement Processes and Measuring Equipment
IAEA SF-1	IAEA [International Atomic Energy Agency] Safety Standards, Fundamental Safety Principles, Safety Fundamentals No. SF-1 (2006)
ISO 9001	Quality Management Systems – Quality Management System (QMS) Requirements
ISO 19443	<b>Nuclear requirements for application of ISO 9001 in Civil Nuclear Industry</b>
ISO 14001	Environmental Management System
ISO/IEC 17025	Requirements for the competence of testing & calibration laboratories
ONR LCH	Office for Nuclear Regulation (ONR) Licence Condition Handbook
ONR TAG 077	Office for Nuclear Regulation (ONR) Technical Assessment Guide (TAG 077)

### 6.2 Management of Suppliers

The following documents are available from the Management of Suppliers' website. To gain access to the Management of Suppliers' website please get in touch with your Sellafield Ltd contact.

#### 6.2.1 Sellafield Ltd Processes and Forms

Reference	Title
SLP 1.02.18	How Do I Resolve Technical Queries, Concessions and Production Permits?
SLF 1.02.18.01V	Technical Query / Concession / Production Permit
CT 1.03.124	Sellafield Ltd Defect / Non-conformance Report
SLF 1.10.315.13	Sellafield Ltd Supply Chain Management Model
SLF 2.15.02.05	Final Certificate of Inspection (Form 5059)
SLF 2.15.05.01	Lifetime Records (LTR) Requirements and Certification Record

#### 6.2.2 Tender and Contract Specifics

Reference	Title
CFMT 121	Main Suppliers Identification and Proposed Control of Sub-suppliers and Suppliers
ES_0_5360_2	The Storage and Handling of Stainless Steel Components and Fabrications
ES_0_5363_1	The Evaluation of Materials for Contact with Stainless Steel
IRF99	The Intelligent Customer Capability Framework

**6.3 Amendment Record**

<b>Date</b>	<b>Version</b>	<b>Comments</b>
03/03/2023	1.0	1 <sup>st</sup> release
12/07/2023	1.1	General update following Supply Chain reviews. Changes include Phase 4 & 6 renamed, text & templates updated & text/references corrected/amended.
19/12/2023	1.1	Cover page title bar modified – no upissue

## Appendix A: Phase 2 – Product Concept Deliverables

The following subsections describe the expected deliverables at the end of the NPI phase 2, for all APQP elements undertaken within phase 2 (product concept).

All deliverables listed shall be the responsibility of the supplier to provide unless stated otherwise for the deliverable in question.

For each deliverable, it is indicated whether that has “commenced”, “continued” or “completed” as part of this phase (see Figure 2).

### A 3.2.1 Supplier Team Feasibility Review and Commitment – Commenced

- A Sellafield Ltd product requirements document that has been reviewed by the supplier, with any considerations or comments added, and a signed feasibility form. This signifies the following:
  - All contract requirements are understood
  - All quality requirements are understood
  - All functions have been involved in the review
  - All considerations and assumptions have been identified
  - New equipment, facility and personnel requirements are understood, including potential capital investment
  - The required volume and the associated capacity are understood and achievable

### A 3.2.2 Supplier Advanced Product Quality Planning (APQP) Kick-Off – Completed

- A reviewed APQP process that has been kicked off with a meeting between the IPT and the supplier
- Set and agreed key dates for the programme's APQP elements and NPI
- Reviewed APQP, PPAP and PSW requirements, and confirmation of the supplier's agreement of these
- Any requests raised for clarification of the APQP elements and deliverables by the supplier
- Defined responsibility and accountability for each of the supplier's departments/functions involved in the project
- Defined and populated RACI matrix
- Agreement between the IPT and the supplier regarding the frequency of regular reviews to track and monitor project progress
- Evidence of the meeting cadence and governance for the project
- Details of and planning for any supplier training necessary to meet training requirements

### A 3.2.3 Supplier Product Quality Planning – Commenced

- Draft QPs produced and provided by the supplier and its associated supply base, which need to be reviewed by the responsible SL IPT member
- Evidence that the responsible SL IPT member has successfully conducted a review to ensure the supplier has comprehensively reviewed and fully understands all Sellafield Ltd's contractual, regulatory, international and national standards and specifications

- Evidence that the supplier's manufacturing processes have the capability to meet Sellafield Ltd.'s quality expectations with reference to the relevant standards
- Evidence that the supplier has reviewed all sub-supplier QPs
- Completed a gap analysis conducted by the supplier where any deficiencies/ absences of capability exist, and a subsequent action plan developed
- Details of any special processes that have been identified by the supplier as being required

#### **A 3.2.4 Supplier Drawing and Specification Review – Commenced**

- Evidence that the supplier has conducted a specification review, including the following:
  - An evaluation of the specifications and standards that have been applied to the product
  - Evidence that the design's specifications and standards can be met
  - Details of any additional equipment required to meet the specification
  - Where required, feedback that has been provided to the IPT, which has been tracked and for which responses have been received

#### **A 3.2.5 Manufacturing Process Flow and Floor Plan – Commenced**

- A draft process flow and floor plan demonstrating the space/footprint required to manufacture the product, the process flow and any new facilities required to accommodate the manufacturing process; this shall include the following:
  - Process steps and a brief description
  - Goods-in raw material(s)
  - Goods-out finished goods
  - Potential quality inspection points
  - Storage, including for WIP
  - Method of movement between operations
  - Off-line handling
  - Rework areas, including reinspection areas
  - Material quarantine / suspect area

#### **A 3.2.6 Design Failure Mode and Effect Analysis (DFMEA) – Commenced**

- Evidence that the supplier has contributed to and reviewed the DFMEA
- Evidence and confirmation that the supplier fully understands the CCs and SCs
- Evidence that the supplier can control all high-scoring RPN items

#### **A 3.2.7 Design Verification and Validation Plan and Report (DVP&R) – Commenced**

- A DVP&R plan based on the DFMEA outputs
- Evidence and confirmation that the supplier understands the test specifications and volumes
- Confirmation that the supplier has the capability and capacity to meet the plan
- Acceptance of the DVP&R plan by the responsible SL IPT member

### **A 3.2.8 New and Existing Equipment Requirements – Commenced**

- A plan for the tooling and equipment required to manufacture and test the product, to ensure the following:
  - The equipment, gauge/test and facilities' requirements have been identified
  - Lead times are understood by all parties
  - The capacity of the equipment needed to meet project requirements is understood and can be met
  - The plan aligns with the NPI phase dates
  - Allowances have been made in the plan for procurement, installation, commissioning, training, etc.
- Evidence from the supplier of actuals or plans for the following:
  - Suitable storage facilities for tooling and equipment when not in use
  - A tool wear, monitoring and maintenance system

### **A 3.2.9 Bill of Material Management – Commenced**

- The first issue of the PBOM based on the EBOM (provided by the IPT)
- A plan for each outsourced component on the PBOM

### **A 3.2.10 Sub-supplier Advanced Product Quality Planning (APQP) Status – Commenced**

- A list of all sub-suppliers, including details of the products and processes they will deliver
- Evidence of how the supplier will manage the deployment of APQP into its sub-suppliers; this shall overlay the product timing plan
- For each sub-supplier, a status document agreed by the supplier that demonstrates the performance of the sub-supplier against the APQP deliverables, and that identifies risks to the project and the route of escalation for such risks
- Evidence that the IPT has regularly monitored the aforementioned status document

## **Appendix B: Phase 3 – Detailed Product Design Deliverables**

The following subsections describe the expected deliverables at the end of the NPI phase 3, for all APQP elements undertaken within phase 3 (detailed product design).

All deliverables listed shall be the responsibility of the supplier unless stated otherwise for the deliverable in question.

For each deliverable, it is indicated whether that has “commenced”, “continued” or “completed” as part of this phase (see Figure 2). Any deliverables that were completed in the previous phase will not be carried forwards to this phase.

### **B 3.2.1 Supplier Team Feasibility Review and Commitment – Completed**

- A team feasibility document that has been reviewed, updated considering the released design and signed off, which also records any considerations/comments (see Appendix F)

### **B 3.2.3 Supplier Product Quality Planning – Completed**

- The completed QP, including sub-suppliers, which shall be submitted to Sellafield Ltd for review and Acceptance by the responsible SL IPT member

### **B 3.2.4 Supplier Drawing and Specification Review – Continued**

- All released 3D models and 2D drawings, which shall have been sent to the supplier by the IPT
- Evidence that a drawing and specification review has been conducted by the supplier, during which the following has occurred:
  - Features have been reviewed
  - Tolerances have been discussed and agreed upon
  - CCs and SCs have been reviewed and understood, and it has been confirmed they can be achieved
  - Data points have been reviewed and understood
  - QC features have been reviewed
- Feedback regarding concerns or changes that would improve the manufacturability of the product, which is to be provided to the supplier
- Evidence that the supplier’s ECM process has been put in place and reviewed by the IPT

### **B 3.2.5 Manufacturing Process Flow and Floor Plan – Continued**

- The floor-plan footprint that is required to manufacture the product, showing the material process flow through volume manufacturing
- An updated manufacturing process flow and floor plan that is in line with the latest drawing release and results from prototype builds, including the following:
  - Detailed floor plan
  - Process steps and description
  - Goods-in raw material(s)

- Goods-out finished goods
- Quality inspection points
- Storage, including WIP
- Method of movement between operations
- Off-line handling
- Rework area, including reinspection areas
- Material quarantine/suspect area

### **B 3.2.6 Design Failure Mode and Effect Analysis (DFMEA) – Completed**

- A completed DFMEA and evidence the supplier has provided input to it
- Evidence the DFMEA has been reviewed during the project and also if engineering changes have impacted the customer's requirements
- Evidence the supplier has addressed all CCs, SCs and high RPNs; for any issues that cannot be addressed, and the risk cannot be reduced, evidence of this being communicated to the IPT and agreement to control these through the manufacturing processes

### **B 3.2.7 Design Verification and Validation Plan and Report (DVP&R) – Continued**

- A documented DVP&R
- A constructed CC and SC matrix
- A test plan that meets the DVP&R requirements
- A measurement and inspection plan
- Feedback from the prototype build that has been incorporated into the DVP&R

### **B 3.2.8 New and Existing Equipment Requirements – Continued**

- Details of the final tooling and equipment required to manufacture the product, as agreed with the IPT
- Evidence of the timely procurement of the tooling, gauges / test equipment, and facilities required, with evidence of purchase orders and sub-supplier confirmations
- Evidence that the procurement aligns with the NPI product timing plan and livery schedule
- A new equipment plan that includes procurement, delivery lead time, installation, commissioning, training etc.
- Evidence that the tooling and gauges / test equipment can meet Sellafield Ltd.'s volumes and quality requirements, and within the cost budgets agreed
- Evidence from the supplier of actuals or plans for the following:
  - Suitable storage facilities for tooling and equipment when not in use
  - A tool wear, monitoring and maintenance system

### **B 3.2.9 Bill of Material (BOM) Management – Continued**

- A PBOM that has been developed based on the released design and EBOM; this shall include the following details for all items and materials, including consumables, to be used in the manufacturing process:
  - Part number (including issue level), name and description
  - Quantity required
  - Packaging



- Supplier(s)
- Minimum order quantity
- Minimum and maximum stock levels
- Storage location
- Leadtime for supply
- Evidence from the supplier regarding the following:
  - EBOM (correct issue level)
  - Sub-supplier selection and approval status
  - How suppliers have been selected
  - Approvals for the supplier
  - CofCs
  - Computer-aided design (CAD) and drawing issue level
  - Revision levels
  - Material and weight
  - Quantity for assembly
  - Consumables
  - Planning and scheduling
- Evidence that the PBOM has formally been released through the engineering change process

#### **B 3.2.10 Sub-supplier Advanced Product Quality Planning (APQP) Status – Continued**

- Sub-supplier APQP status report for review by the IPT
- APQP requirements completed by the sub-suppliers, including but not limited to the following:
  - PFMEA, control plans and work instructions
  - Inspection and testing results
  - MSA studies
  - BOMs
  - Equivalents to all that the IPT shall require from the supplier

#### **B 3.3.1 Launch Readiness Review (LRR) – Commenced**

- Evidence the LRR conducted on the supplier by the IPT has been completed
- An action plan for remedying any issues identified in the LRR

#### **B 3.3.2 Supplier Process Failure Modes and Effects Analysis (PFMEA) – Commenced**

- Evidence from the supplier regarding the following:
  - A multifunctional team across several disciplines has been used to create the PFMEA
  - The DFMEA has been used to extrapolate SCs and CCs, including high RPNs as inputs
  - The PFMEA identifies each operation within the manufacturing process from goods-in to goods-out
  - The PFMEA shall conform to the manufacturing process flow and floor plan (see section 3.2.5)
  - The 3D models, 2D drawings and technical specifications have been used in generating the PFMEA

- Historical concerns identified by the customer have been applied to the PFMEA
- The supplier's historical knowledge and lessons learnt have been applied to the PFMEA; ideally, the supplier shall have a historical catalogue of problems, failure modes and resolutions
- The supplier understands the interfaces of the product
- Any high RPNs have been identified and actions taken
- Data gathered from the prototype builds have been fed into the PFMEA

### **B 3.3.3 Metrology, Inspection and Validation Plan – Commenced**

- Evidence of the supplier's inspection capability
- A definition of what gauge/test/validation equipment will ensure the product meets the specifications and requirements, and how it will be used; this includes the following:
  - A procurement plan for all necessary equipment that meets manufacture delivery expectations and is actively managed
  - Evidence of the maturity and delivery of each piece of equipment
  - Evidence of the storage of equipment when in use and not in use
  - Evidence that the equipment and its performance have been safeguarded (through maintenance and protection) from adjustments, damage and deterioration
  - Clear identification of the gauge/test/validation equipment owned by Sellafield Ltd, and a maintained log of all equipment throughout the supplier's facility to demonstrate legal ownership
  - Confirmation that the measuring equipment is fit for its intended purpose
  - Equipment calibration records demonstrating the calibration regime and status for all equipment

### **B 3.3.4 Packaging, Transportation and Environmental Specifications and Evaluation – Commenced**

- Evidence that the supplier has evaluated the packaging and transportation proposals against both Sellafield Ltd.'s and the supplier's specific packaging specifications, including ES\_0\_5363\_1; this includes evidence of the following:
  - Consideration has been shown to all environmental aspects (including carbon footprint) to minimise impact, dunnage and waste disposal
  - Packaging, shipping and transportation options have been evaluated, and feedback on considerations and recommendations (including on adverse weather conditions, loading and off-loading) has been provided to the IPT
  - Sellafield Ltd.'s requirements have been evaluated, including standards, and feedback has been provided to the IPT
  - Plans for transport trials of the product have been presented
- Evidence that the storage of products shall comply with ES\_05360\_2 and that it will fulfil the following:
  - Be secure, in line with Sellafield Ltd.'s stated requirements
  - Prevent damage to or deterioration of the product
  - Be accessible only to authorised personnel

- Evidence that the delivery documentation and CofC(s) comply with Sellafield Ltd.'s requirements; the responsible SL IPT member shall have accepted a sample of all documentation before the shipment of any product

### **B 3.3.5 Prototype Control Plan – Completed**

- A prototype control plan that identifies/includes each of the following:
  - All checks, measurements and inspections required to manufacture the prototype product
  - All controls for each operation detailed in the PFMEA, including SCs and CCs
  - All high RPNs from the PFMEA
  - For each item in the plan, the following is included:
    - Feature to be controlled
    - Frequency of control
    - Equipment to be used
    - Standards applied
    - Actions to be taken in the event of an adverse result
  - The PVL levels for each item and feature, and evidence (external to the control plan) that these have been agreed with the responsible SL IPT member
  - Clear control on all materials used from goods-in to goods-out, with obvious material identification throughout the process.
- Evidence that the control plan has been reviewed and accepted by the responsible SL IPT member before the commencement of the prototype build

### **B 3.3.6 Prototype Build – Completed**

- The prototype builds; if the prototype manufacturer is not the serial manufacturer, a full set of APQP documents shall be provided
- Evidence whether the prototype build has confirmed the capability of the design to meet Sellafield Ltd.'s facility requirements
- Evidence whether there is a clear understanding of the route to volume manufacture of the product with repeatable, capable manufacturing processes
- Evidence that a review and assessment of the prototypes with the IPT has taken place, and actions to resolve issues have been agreed and undertaken
- A list of open points to document any manufacturing issues, including specification and tolerance control methods throughout manufacture, assembly and storage; this should include action owners and timescales
- The future use of the prototype shall have been agreed upon, e.g., facility commissioning, DVP&R or agree its safe disposal

### **B 3.3.7 First Article Inspection Report (FAIR) – Commenced**

- Evidence of completion of a full FAIR of any prototype parts delivered to SL showing variances
- Evidence that all variances from the specification have been reviewed and actioned, an action plan detailing action owners and timescales

### **B 3.3.8 Records and Compliance– Commenced**

- A documented system for the control of materials and processes including the following:
  - Lot traceability original mill certificates (or equivalents)
  - Mixed-material batch traceability
  - Heat treatments and surface treatments
  - Process records, as defined by special processes
  - Operator and quality inspector records
  - CofCs
  - Product identification

### **B 3.3.9 Engineering Change Management (ECM) – Commenced**

- A process for the control of engineering changes, including the following:
  - Evidence that a feasibility review has been conducted when the supplier is in receipt of an updated drawing or specification
  - A stepped process for the management of engineering changes
  - Evidence of communication with the IPT, including a detailed plan to implement the change
  - A formal documented system that references the revision level, introduction date and a full description of changes made to the product
  - A documented process to update APQP records, including but not limited to the PFMEA, control plans and operator work instructions
  - A part history document that notes all changes by providing a full detailed explanation of each change and at which point in time it was implemented
  - Methods of controlling changes in manufacturing to ensure each build complies with the correct version of the process and product specification
  - Evidence that the pedigree (which is the revision level of each component and sub-assembly) of each finished product is understood and documented
  - Details of how obsolete components and sub-assemblies are quarantined and either reworked or disposed of

### **B 3.3.10 Measurement System Analysis (MSA) Plan – Commenced**

- A draft proposal for MSA studies on equipment that shall be used to confirm product specifications
- Where equipment is available, evidence that an MSA has been completed and the result made available to the IPT for review
- Evidence that the supplier has SQEP capability in the MSA core tools

### **B 3.3.11 Qualified Laboratory Documentation – Commenced**

Evidence that only accredited laboratories are to be used where the test has a certified method, or where the responsible SL IPT member accepts the method and test facilities or supplier

### **B 3.3.12 Operator Process / Work Instructions – Commenced**

- Operator process/work instructions and visual aids that clearly describe the methods and processes, are easily understood, reference control plan features, and the detail has started to be developed.
- Any Prototype build should be used to aid development of Operator Process/Work Instructions.
- A training matrix that provides evidence that all employees have been trained and signed off as SQEP

## **Appendix C: Phase 4 – Manufacturing Process Development Deliverables**

The following subsections describe the expected deliverables at the end of the NPI phase 4, for all APQP elements undertaken within phase 4 (manufacturing process development).

All deliverables listed shall be the responsibility of the supplier unless stated otherwise for the deliverable in question.

For each deliverable, it is indicated whether that has “commenced”, “continued” or “completed” as part of this phase (see Figure 2). Any deliverables that were completed in the previous phase will not be carried forwards to this phase.

### **C 3.2.4 Supplier Drawing and Specification Review – Completed**

- All released CAD and 2D drawings need to concur with latest released drawings from SL
- Evidence that a drawing and specification review has been conducted by the supplier, during which the following has occurred:
  - Features have been reviewed
  - Tolerances have been discussed and agreed upon
  - CCs and SCs have been reviewed and understood, and it has been confirmed they can be achieved
  - Data points have been reviewed and understood
  - QC features have been reviewed
- Any Learning from prototype and pre-production builds will have been included in the drawings and specifications.
- Feedback regarding concerns or changes that would improve the manufacturability of the product, which is to be provided to the supplier
- Evidence that the supplier’s ECM process has been put in place and reviewed by the IPT

### **C 3.2.5 Manufacturing Process Flow and Floor Plan – Completed**

- Installed manufacturing and test equipment (all equipment required)
- An updated floor plan and process flow that concurs with the physical layout
- Evidence that the final floor-plan footprint matches the manufacturing layout and process, including the following:
  - Detailed floor plan
  - Process steps and description
  - Goods-in raw material(s)
  - Goods-out finished goods
  - Quality inspection points
  - Storage, including WIP
  - Method of movement between operations
  - Off-line handling
  - Rework areas, including reinspection areas
  - Material quarantine/suspect area

### **C 3.2.7 Design Verification and Validation Plan and Report (DVP&R) – Completed**

- Execution of the DVP&R plan and a published report
- Evidence the results have been reviewed and accepted by the responsible SL IPT member

### **C 3.2.8 New and Existing Equipment Requirements – Completed**

- All pieces of new equipment, which have been installed and commissioned in their respective production locations that align with the floor plan
- Evidence that the tool trials have been completed and match the initial trial results at the original equipment manufacturer (OEM) of the equipment
- Evidence that all test equipment and facilities have been tested and approved
- Master test samples are in place
- An equipment maintenance plan that is in line with the OEM's recommendations
- Spare parts and consumables that have been purchased, and evidence that stock levels of these are managed
- Evidence that the calibration has been agreed upon and built into the supplier's calibration schedule
- Evidence that training has been completed
- Suitable storage facilities for tooling and equipment when not in use
- A tool wear, monitoring and maintenance system

### **C 3.2.9 Bill of Material (BOM) Management – Completed**

- A PBOM listing the material used for this NPI phase, which has a higher level of detail than previous versions
- A detailed, comprehensive parts list that includes the following:
  - Part numbers and revision
  - Supplier and lead time
  - Delivered dimensions
  - Batch quantity
  - Part price
- Evidence that the planning, scheduling and ordering of all purchased parts, services and consumables has been completed
- Supporting evidence for lead times, batch sizes, and risk items that may need greater control and monitoring
- Evidence that the PBOM has formally been released through the engineering change process

### **C3.2.10 Sub-supplier Advanced Product Quality Planning (APQP) Status – Continued**

- Sub-supplier APQP status being managed by supplier
- APQP requirements completed by the sub-suppliers, including but not limited to the following:
  - PFMEA, control plans and work instructions
  - Inspection and testing results
  - MSA studies
  - BOMs
  - Equivalents to all that the IPT shall require from the supplier

### **C 3.3.1 Launch Readiness Review (LRR) – Continued**

- Evidence the LRR conducted on the supplier by the IPT has been completed
- An action plan for remedying any issues identified in the LRR

### **C 3.3.2 Supplier Process Failure Modes and Effects Analysis (PFMEA) – Continued**

- Evidence from the supplier regarding the following:
  - A multifunctional team across several disciplines has been used to review the PFMEA
  - The correct level of 3D models, 2D drawings and technical specifications have been used in reviewing the PFMEA
  - The PFMEA has been updated to include previously unidentified failures
  - The interfaces of the product are understood by the supplier
  - High RPNs have been identified and actions taken
  - The PFMEA has been reviewed and updated with any additional failures not previously identified during phase 3 (detailed product design) and from the prototype builds
  - The necessary action has been taken to address risks not previously identified
  - The change log on the PFMEA has been updated to identify all changes

### **C 3.3.3 Metrology, Inspection and Validation Plan – Continued**

- All equipment, which shall have been installed, commissioned and made available.
- Evidence from the supplier of the following:
  - The gauge/testing/validation equipment has been confirmed (at the OEM) as being capable of being used off-site, and it has passed the same qualification on-site after installation and commissioning
  - The new and existing gauge/test/validation equipment requiring calibration has been logged on to a calibration system
  - The calibration system is in accordance with BS EN ISO 10012 (see section 8.1)
- A "drop gauge" policy, which includes procedures for technicians and operators if the equipment is dropped accidentally or damaged

### **C 3.3.4 Packaging, Transportation and Environmental Specifications and Evaluation – Continued**

- Evidence that the supplier understands the shipping documentation and the requirements for shipment to and acceptance by Sellafeld Ltd.
- Evidence that all packaging, transportation and storage methods have been evaluated and trialled to ensure the product is protected sufficiently by the packaging in those situations, in that the packaging does the following:
  - Protects the product during transit, storage and all possible environmental situations of any duration



- Does not degrade or damage the product during the transportation phase
- Complies with all Sellafield Ltd.'s standards and specifications
- Evidence that the supplier has investigated the most environmentally friendly materials to contain and protect the product to specification
- Evidence of supplier agreement with the IPT regarding Sellafield Ltd.'s responsibilities for disposal
- Evidence that shipping trials have been completed to the satisfaction of the responsible SL IPT member and Sellafield Ltd
- Evidence that the environmental impacts on dunnage have been agreed with the responsible SL IPT member
- Evidence that all product storage meets the requirements of Sellafield Ltd
- Evidence that all documentation, including CofCs, has been accepted by the responsible SL IPT member

### **C 3.3.7 First Article Inspection Report (FAIR) – Continued**

- Evidence that the full FAIR for both "off-tool" and "off-tool and off-process" parts from the manufacturing process development phase have been submitted to and accepted by the IPT
- Evidence that all variances from the specification have been reviewed and actioned, with agreed owners and timescales identified

### **C 3.3.8 Records and Compliance – Continued**

- A documented system for the control of materials and processes, including the following:
  - Lot traceability original mill certificates (or equivalents)
  - Mixed-material batch traceability
  - Heat treatments and surface treatments
  - Process records as defined by special processes
  - Operator and quality inspector records
  - CofCs
  - Product identification

### **C 3.3.9 Engineering Change Management (ECM) – Continued**

- A process for the control of engineering changes, including the following:
  - Evidence that a feasibility review has been conducted when the supplier has received an updated drawing or specification
  - A stepped process for the management of engineering changes
  - Evidence of communication with the IPT, including a detailed plan to implement the change
  - A formal documented system that references the revision level, introduction date and a full description of changes made to the product
  - A documented process to update APQP records, including but not limited to the PFMEA, control plans and operator work instructions
  - A part history document that notes all changes by providing a full detailed explanation of each change and at which point in time it was implemented

- Methods of controlling changes in manufacturing to ensure each build complies with the correct version of the process and product specification
- Evidence that the pedigree (which is the revision level of each component and sub-assembly) of each finished product is understood and documented
- Details of how obsolete components and sub-assemblies are quarantined and either reworked or disposed of

### **C 3.3.10 Measurement System Analysis (MSA) Plan – Continued**

- An MSA study plan that identifies which instruments, measurements, jigs and fixtures, test equipment and gauges are required
- Evidence of the methods used by the supplier to evaluate the equipment, gauges, measuring, testing, etc. (e.g. manual calculations or software [Minitab])
- Evidence that the operator has followed the prescribed work instruction(s) for the specific piece of equipment
- Evidence that all employees have been trained and signed off against each piece of equipment, including evidence of training for attribute features and boundary samples
- Where the studies have been completed, the following will be provided:
  - Evidence of the responsible SL IPT member's acceptance of the MSA
  - Where a non-capable system has been identified by a study, a recovery plan, including action owners and timescales

### **C 3.3.11 Qualified Laboratory Documentation – Continued**

- Evidence that only accredited laboratories are to be used where the test has a certified method, or where the responsible SL IPT member accepts the method and test facilities or supplier

### **C 3.3.12 Operator Process / Work Instructions – Continued**

- Operator process / work instructions that have been updated as pre-production builds are completed during phase 4 (manufacturing process development) and reflect the current outputs of the of the PFMEA and control plans, including the following:
  - Operator process / work instructions and visual aids that clearly describe the methods and processes, are easily understood, reference control plan features, and detail how to manage non-conforming materials, reject parts and rework methods
  - Within the operator process / work instructions, identification of any CCs and SCs
  - A training matrix that provides evidence that all employees have been trained and signed off as SQEP
  - Evidence that the full operator process / all work instructions are part of the QMS, including their revision status and date, and are signed by the document owner
  - Evidence that electronic machine-setting parameters and programs have back-ups and version release control

### **C 3.4.1 Pre-production Control Plan – Completed**

- A pre-production control plan that identifies/includes each of the following:

- All checks, measurements and inspections required to manufacture the product during phase 4 (manufacturing process development); this shall be an evolution of the prototype control plan (see section 3.3.5)
  - All controls for each operation detailed in the PFMEA, including SCs and CCs
  - All high RPNs from the PFMEA
  - For each item in the plan, the following is included:
    - Feature to be controlled
    - Frequency of control
    - Equipment to be used
    - Standards applied
    - Actions to be taken in the event of an adverse result
  - The PVL levels for each item and feature, and evidence (external to the control plan) that these have been agreed with the responsible SL IPT member
  - Clear control on all materials used from goods-in to goods-out, with obvious material identification throughout the process.
- Evidence that the control plan has been reviewed by the responsible SL IPT member before the commencement of the product builds
  - Evidence that the pre-production control plan has been updated after each pre-production build and the subsequent PFMEA review

#### **C 3.4.2 Product Validation Testing – Commenced**

- Evidence of the supplier having agreed with the IPT the product validation testing requirements, including any certification requirements
- Evidence that the supplier can complete the product validation testing
- Where tests are completed, evidence that their results have been reviewed and accepted by the responsible SL IPT member
- If a test fails, a root-cause analysis to understand the process operation that may be attributable to the failure, and an action plan for resolving the issue, which identifies the action owners and timescales

#### **C 3.4.3 Material Planning and Logistics (MP&L) Plan – Commenced**

- Evidence of the following:
  - The supplier understands the delivery requirements of Sellafield Ltd and confirmation that its product planning can meet these requirements
  - The ERP or MRP system contains all lead times and delivery information
  - The sub-suppliers have acknowledged and can meet the delivery requirements
  - All consumables and lead times required for the manufacturing process are known, and the supplier has a robust replenishment and reordering process (e.g. a Min-Max system)
  - The MP&L plan includes all materials for equipment trials and validation
  - The supplier has conducted an internal audit of all materials to ensure that the PBOM and ERP/MRP have equivalent data
  - The inventory management system is accurate for all materials, components, sub-assemblies and consumables, and there is a method for verifying this (e.g. perpetual inventory or visual management)

- There is a process for managing reject and scrap products to ensure that the inventory is adjusted correctly
  - The supplier's storage facilities are acceptable for the storage of materials.
- Evidence that the supplier has reviewed with the IPT its supply chain business continuity planning, the high-risk suppliers and the associated mitigation plans, and that any comments have been addressed
- Evidence of how the supplier shall manage the performance of its suppliers through KPIs

## **Appendix D: Phase 5 – Manufacturing Process Validation Deliverables**

The following subsections describe the expected deliverables at the end of the NPI phase 5, for all APQP elements undertaken within phase 5 (manufacturing process validation).

All deliverables listed shall be the responsibility of the supplier unless stated otherwise for the deliverable in question.

For each deliverable, it is indicated whether that has “commenced”, “continued” or “completed” as part of this phase (see Figure 2). Any deliverables that were completed in the previous phase will not be carried forwards to this phase.

### **D 3.2.10 Sub-supplier Advanced Product Quality Planning (APQP) Status– Completed**

- Ongoing monitoring and adherence to the sub-supplier's APQP plan
- Sign off of PPAP and sub-supplier PSW

### **D 3.3.1 Launch Readiness Review (LRR) – Completed**

- Evidence the supplier has completed the LRR assessments and accepted by the responsible SL IPT member

### **D 3.3.2 Supplier Process Failure Modes and Effects Analysis (PFMEA) – Completed**

- Evidence from the supplier regarding the following:
  - A multifunctional team across several disciplines has been used to review the PFMEA
  - The correct level of 3D models, 2D drawings and technical specifications have been used in reviewing the PFMEA
  - Data from the prototype builds and pre-production builds has been fed into the PFMEA, and the RPNs have been reviewed
  - The PFMEA has been reviewed and updated to include any additional failures not previously identified during phase 4 (manufacturing process development)
  - The necessary action has been taken to address risks not previously identified
  - The entire process has been analysed while being run at full production rate (Run@Rate) to highlight issues never envisaged at conception and at lower volumes
  - The production control plan has been reviewed after making changes to the PFMEA and updated accordingly
  - The change log on the PFMEA has been updated to identify all changes

### **D 3.3.3 Metrology, Inspection and Validation Plan – Completed**

- Evidence that the gauge/testing/validation equipment has met the requirements and produced the same results after being installed and commissioned
- Evidence that all gauge/test/validation equipment has been calibrated and logged on to a calibration record within the supplier QMS

### **D 3.3.4 Packaging, Transportation and Environmental Specifications and Evaluation – Completed**

- Evidence that the supplier has agreed the intended packaging, storage, shipping and transportation requirements with the responsible SL IPT member
- Evidence that trials have been completed by the supplier and accepted by the responsible SL IPT member

### **D 3.3.7 First Article Inspection Report – Completed**

- A full FAIR of Run@Rate parts, showing variances
- Evidence showing all variances away from the specification have been reviewed and actioned

### **D 3.3.8 Records and Compliance – Continued**

- A documented system for the control of materials and processes, including the following:
  - Lot traceability original mill certificates (or equivalent)
  - Mixed-material batch traceability
  - Heat treatments and surface treatments
  - Process records as defined by special processes
  - Operator and quality inspector records
  - Operator ID
  - CofCs
  - Product identification

### **D 3.3.9 Engineering Change Management (ECM) – Continued**

- A process for the control of engineering changes, including the following:
  - Evidence that a feasibility review has been conducted when the supplier has received an updated drawing or specification
  - A stepped process for the management of engineering changes
  - Evidence of communication with the IPT, including a detailed plan to implement the change
  - A formal documented system that references the revision level, introduction date and a full description of changes made to the product
  - A documented process to update APQP records, including but not limited to the PFMEA, control plans and operator work instructions
  - A part history document that notes all changes by providing a full detailed explanation of each change and at which point in time it was implemented

- Methods of controlling changes in manufacturing to ensure each build complies with the correct version of the process and product specification
- Evidence that the pedigree (which is the revision level of each component and sub-assembly) of each finished product is understood and documented
- Details of how obsolete components and sub-assemblies are quarantined and either reworked or disposed of

#### **D 3.3.10 Measurement System Analysis (MSA) Plan – Completed**

- Evidence that the supplier has completed all MSA studies as defined in the MSA plan
- Results of the completed studies on all equipment from the plan, confirming whether each piece of equipment is capable or non-capable
- Evidence of the acceptance of the MSA by the responsible SL IPT member
- A recovery plan (presented with the studies) identifying the non-capable equipment, which includes the action owners and timescales
- Evidence that all attribute features have been agreed with the IPT and signed off against the agreed standards and boundary samples
- Evidence that the operators have been trained and tested against visual standards and that boundary samples have been retained
- Evidence that the supplier has an ongoing testing and approval plan for employees; this could include such items as eyesight tests

#### **D 3.3.11 Qualified Laboratory Documentation – Continued**

- Evidence that only accredited laboratories are to be used where the test has a certified method, or where the responsible SL IPT member accepts the method and test facilities or supplier

#### **D 3.3.12 Operator Process / Work Instructions – Completed**

- Operator process / work instructions that have been updated after the completion of phase 4 (manufacturing process development) and reflect the current outputs of the of the PFMEA and control plans, including the following:
  - Operator process / work instructions and visual aids that clearly describe the methods and processes, are easily understood, reference control plan features, and detail how to manage non-conforming materials, reject parts and rework methods
  - Within the operator process / work instructions, identification of any CCs and SCs
  - A training matrix that provides evidence that all employees have been trained and signed off as SQEP
  - Evidence that the full operator process / all work instructions are part of the QMS, including their revision status and date, and are signed by the document owner
  - Evidence that electronic machine-setting parameters and programs have back-ups and version release control

#### **D 3.4.2 Product Validation Testing – Continued**

- Evidence of the completion of the product validation testing on the product produced off the Run@Rate trial
- Evidence that the results have been reviewed and accepted by the responsible SL IPT member
- If a test fails, a root-cause analysis to understand the process operation that may be attributable to the failure, and an action plan for resolving the issue, which identifies the action owners and timescales

#### **D 3.4.3 Material Planning and Logistics (MP&L) Plan – Continued**

- Evidence of the following:
  - The supplier understands the delivery requirements of Sellafield Ltd and confirmation that its product planning can meet these requirements
  - The ERP or MRP system contains all lead times and delivery information
  - The sub-suppliers have acknowledged and can meet the delivery requirements
  - All consumables and lead times required for the manufacturing process are known, and the supplier has a robust replenishment and reordering process (e.g. a Min-Max system)
  - The MP&L plan includes all materials for equipment trials and validation
  - The supplier has conducted an internal audit of all materials to ensure that the PBOM and ERP/MRP have equivalent data
  - The inventory management system is accurate for all materials, components, sub-assemblies and consumables, and there is a method for verifying this (e.g. perpetual inventory or visual management)
  - There is a process for managing reject and scrap products to ensure that the inventory is adjusted correctly
  - The supplier's storage facilities are acceptable for the storage of materials
- Evidence that the supplier has reviewed with the IPT its supply chain business continuity planning, the high-risk suppliers and the associated mitigation plans, and that any comments have been addressed
- Evidence of how the supplier shall manage the performance of its suppliers through KPIs

#### **D 3.5.1 Production Control Plan – Completed**

- All results from a process audit on the Production Control plan, as conducted by the supplier, including the following:
  - Measurement analysis of all drawing features
  - Analysis of all CCs and SCs
  - Analysis of equipment, maintenance and handling required to manufacture the product
  - Evidence of adherence to the measurement plan
  - A documented process for the escalation for non-conforming products



### **D 3.5.2 Process Capability (Cp) Study – Completed**

- A completed Run@Rate trial that provides evidence of the following:
  - The production process is repeatable and capable of meeting Sellafield Ltd.'s peak demand/volumes
  - By using SPC, the Cp and Cpk achieves the agreed value with the IPT
- In the event the process is non-capable, the following shall be delivered:
  - Evidence of an investigation and an action plan that includes action owners and timescales
  - A decision from the IPT whether a further full or partial Run@Rate trial is required

### **D 3.5.3 Production Part Approval Process (PPAP) Submission and Part Submission Warrant (PSW) – Completed**

- A PPAP and PSW that have been submitted to the IPT with evidence that the product complies with the specification
- Evidence that the responsible SL IPT member has reviewed the PPAP submission and accepted the PSW
- Evidence that the supplier has resolved any discrepancies, or that the discrepancies are registered and have been accepted by the responsible SL IPT member

### **D 3.5.4 Sample Product – Completed**

- Any samples required as part of the PPAP submission have been submitted and accepted by the responsible SL IPT member

### **D 3.5.5 Master Samples (Boundary Samples) – Completed**

- Master samples have been produced and accepted by the responsible SL IPT member
- Boundary samples that have been compiled by the supplier
- Evidence that the boundary samples have been accepted by the responsible SL IPT member
- Evidence that the boundary samples shall have been used for training

### **D 3.5.6 Supplier and KPI Performance Management – Commenced**

- Evidence that the agreed KPIs are on track
- Evidence that each metric has an owner, recording and data definitions, and an agreed reporting frequency (e.g. weekly or monthly)
- Evidence that the owner ensures data is recorded and analysed correctly and agrees to improvement plans with the production manager/team leader/supervisor
- Evidence that the sub-supplier KPIs are on track

## Appendix E: Phase 6 – Volume Production Deliverables

The following subsections describe the expected deliverables at the end of the NPI phase 6, for all APQP elements undertaken within phase 6 (volume manufacture).

All deliverables listed shall be the responsibility of the supplier unless stated otherwise for the deliverable in question.

For each deliverable, it is indicated whether that has “commenced”, “continued” or “completed” as part of this phase (see Figure 2). Any deliverables that were completed in the previous phase will not be carried forwards to this phase.

### E 3.3.8 Records and Compliance – Completed

- A documented system for the control of materials and processes (see Appendix J), including the following:
  - Lot traceability original mill certificates (or equivalent)
  - Mixed-material batch traceability
  - Heat treatments and surface treatments
  - Process records as defined by special processes
  - Operator and quality inspector records
  - CofCs
  - Product identification

### E 3.3.9 Engineering Change Management (ECM) – Completed

- A process for the control of engineering changes, including the following:
  - Evidence that a feasibility review has been conducted when the supplier has received an updated drawing or specification
  - A stepped process for the management of engineering changes
  - Evidence of communication with the IPT, including a detailed plan to implement the change
  - A formal documented system that references the revision level, introduction date and a full description of changes made to the product
  - A documented process to update APQP records, including but not limited to the PFMEA, control plans and operator work instructions
  - A part history document that notes all changes by providing a full detailed explanation of each change and at which point in time it was implemented
  - Methods of controlling changes in manufacturing to ensure each build complies with the correct version of the process and product specification
  - Evidence that the pedigree (which is the revision level of each component and sub-assembly) of each finished product is understood and documented
  - Details of how obsolete components and sub-assemblies are quarantined and either reworked or disposed of

### **E 3.3.11 Qualified Laboratory Documentation – Completed**

- Evidence that only accredited laboratories are to be used where the test has a certified method, or where the responsible SL IPT member accepts the method and test facilities or supplier

### **E 3.4.2 Product Validation Testing – Completed**

- Evidence that the supplier and the IPT have agreed to the ongoing production testing requirements
- Evidence that the testing has been completed in line with the agreed specification

### **E 3.4.3 Material Planning and Logistics (MP&L) Plan – Completed**

- Evidence of the following:
  - The supplier understands the delivery requirements of Sellafield Ltd and confirmation that its product planning can meet these requirements
  - The ERP or MRP system contains all lead times and delivery information
  - The sub-suppliers have acknowledged and can meet the delivery requirements
  - All consumables and lead times required for the manufacturing process are known, and the supplier has a robust replenishment and reordering process (e.g. a Min-Max system)
  - The MP&L plan includes all materials for equipment trials and validation
  - The supplier has conducted an internal audit of all materials to ensure that the PBOM and ERP/MRP have equivalent data
  - The inventory management system is accurate for all materials, components, sub-assemblies and consumables, and there is a method for verifying this (e.g. perpetual inventory or visual management)
  - There is a process for managing reject and scrap products to ensure that the inventory is adjusted correctly
  - The supplier's storage facilities are acceptable for the storage of materials
- Evidence that the supplier has reviewed with the IPT its supply chain business continuity planning, the high-risk suppliers and the associated mitigation plans, and that any comments have been addressed
- Evidence of how the supplier shall manage the performance of its suppliers through KPIs

### **E 3.5.6 Supplier and Key Performance Indicator (KPI) Performance Management – Completed**

- Evidence that the agreed KPIs are on track
- Evidence that each metric has an owner, recording and data definitions, and an agreed reporting frequency (e.g. weekly or monthly)
- Evidence that the owner ensures data is recorded correctly and agrees to improvement plans with the production manager/team leader/supervisor


### **E 3.6.1 Lessons Learnt– Completed**

- Evidence that the supplier and IPT have conducted a lessons learnt exercise that includes the following:
  - A discussion and record of Things gone Right (TGR)
  - A discussion and record of Things gone Wrong TGW
  - Identification of the impacts of all TGR and TGW on the project
  - Evidence that the findings shall be used to improve the next project

### **E 3.6.2 Process Improvement and Cost-down Activities – Completed**

- Evidence that, at an agreed point, the supplier and IPT shall identify and agree on process improvement and cost-down activities
- Evidence that these activities shall be ongoing through the production supply life of the product

# Appendix F: Team Feasibility Form

 Sellafield Ltd	<b>SUPPLIER TEAM FEASIBILITY COMMITMENT</b>	<b>PHASE 3</b>	Sheet 1 of 2
--	---	----------------	--------------

Supplier Name: \_\_\_\_\_ SL MPO Part No: \_\_\_\_\_

SL MPO Project Name: \_\_\_\_\_ SL MPO Part Name: \_\_\_\_\_

**Feasibility Considerations:**  
 The multi functional project team have considered the following questions, not intended to be all-inclusive in performing the feasibility evaluation. The production intent design release drawings and specifications have been provided and used as a basis for analysing the ability to meet Sellafield's product requirements.  
 All "NO" answers are supported with further comments, explaining concerns and / or proposed change requirements, necessary to be addressed before the production design release to enable achievement of the product requirements. All comments, requirements and assumptions are detailed on sheet 2.

	CONSIDERATION	YES	NO
1	Is the product design complete and ready to release for the manufacture of production equipment tooling, jigs & fixtures?		
2	Can the engineering performance specifications be met as written; i.e.		
	- Material specification		
	- Testing		
	- Corrosion resistance		
3	Are any special process requirements defined and agreed, including;		
	- Heat treatment		
	- Surface treatment		
	- Welding		
	- Machining		
4	Have Design for Manufacture & Assembly (DFM/ DFA) principles been applied to the design?		
5	Have packaging, dunnage and environmental requirements been agreed?		
6	Can shipping and transportation requirements can be met?		
7	Can the product be manufactured to the tolerances specified on drawing, within agreed costs?		
8	Is there adequate capacity to produce the product?		
9	Does the design allow the use of efficient material handling techniques?		
10	Are special handling requirements needed for product weight?		
11	Can the product be manufactured without incurring any unusual or unbudgeted:		
	- Costs for capital equipment?		
	- Costs for tooling, gauging, jigs & fixtures?		
	- Alternative manufacturing methods?		
	- 100% life time inspection costs?		
12	Can product be manufactured with Cpk's that meet requirements?		
13	Is statistical process control required on the product?		
14	Is statistical process control presently used on similar products?		
15	Where statistical process control is used on similar products:		
	- Are the processes in control and stable?		
	- Are Cpk's greater than 1.33?		

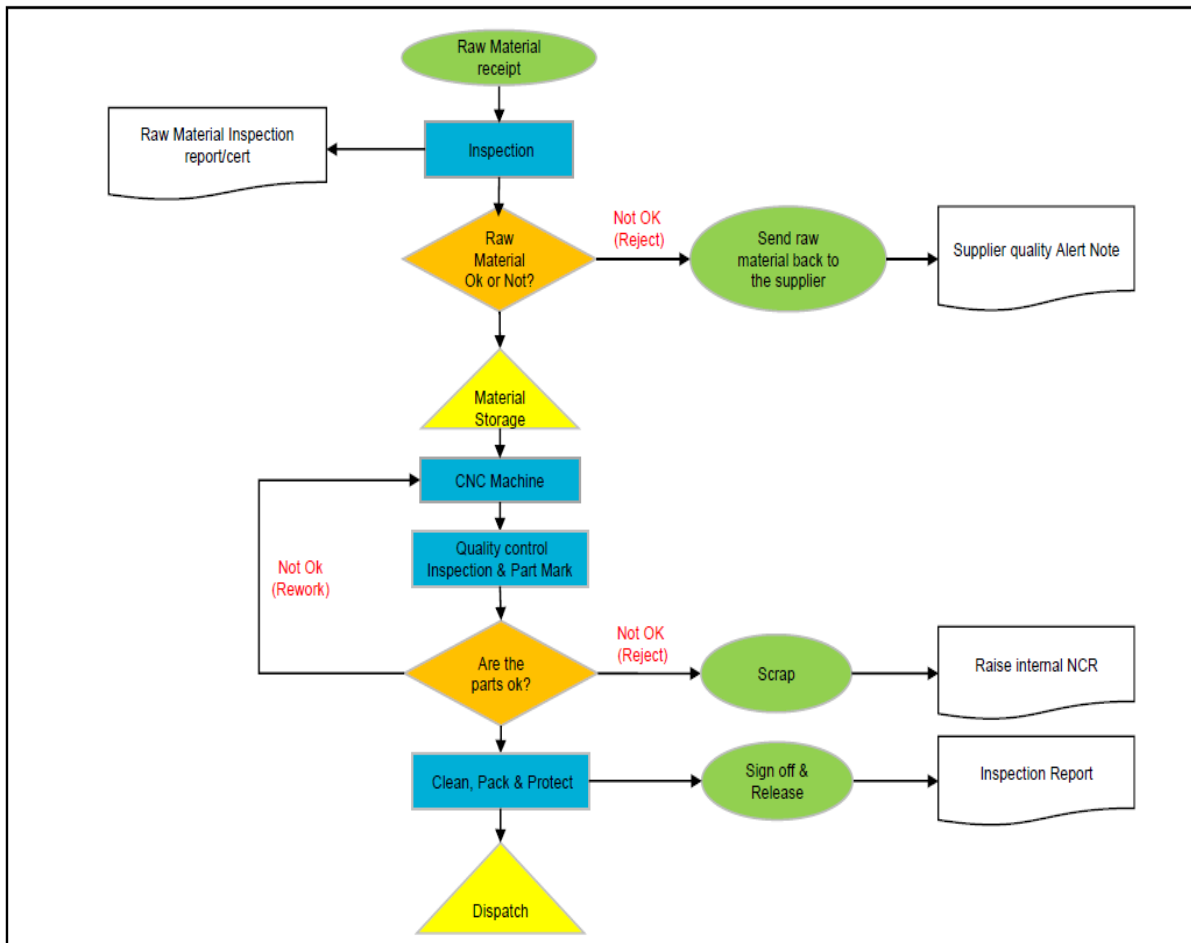
**Conclusion:**

<input type="checkbox"/>	Feasible	Product can be produced as specified with no revisions.
<input type="checkbox"/>	Feasible	Changes recommended (see attached).
<input type="checkbox"/>	Not Feasible	Design revision required to produce product within the specified requirements.

**Sign-Off:**

Supplier Project Manager / Date	Supplier Project Engineer / Date
Supplier Manufacturing Engineer / Date	Supplier Quality Engineer / Date
Supplier Commercial Lead / Date	Supplier Other / Date

## Appendix G: Process Flow Chart Example



Process Flow Chart Symbols		
Meaning	Symbol	Description
Start or End		An elongated circle represents the start or end of a process.
Step/Flowline		Represents direction of flow/process from one step to another.
Process/Operation		Rectangle/square box shows instructions/actions/activity.
Decision		Diamond box represents decision on particular activity.
Storage		Represents storage of material/parts.
Delay/Wait		Indicate delay in operation/process/activity.
Document		Represents supportive documents required.
Start or End		Alternate of elongated circle that also used to represents the start or end of a process.







# Appendix J: Control Plan Example Template

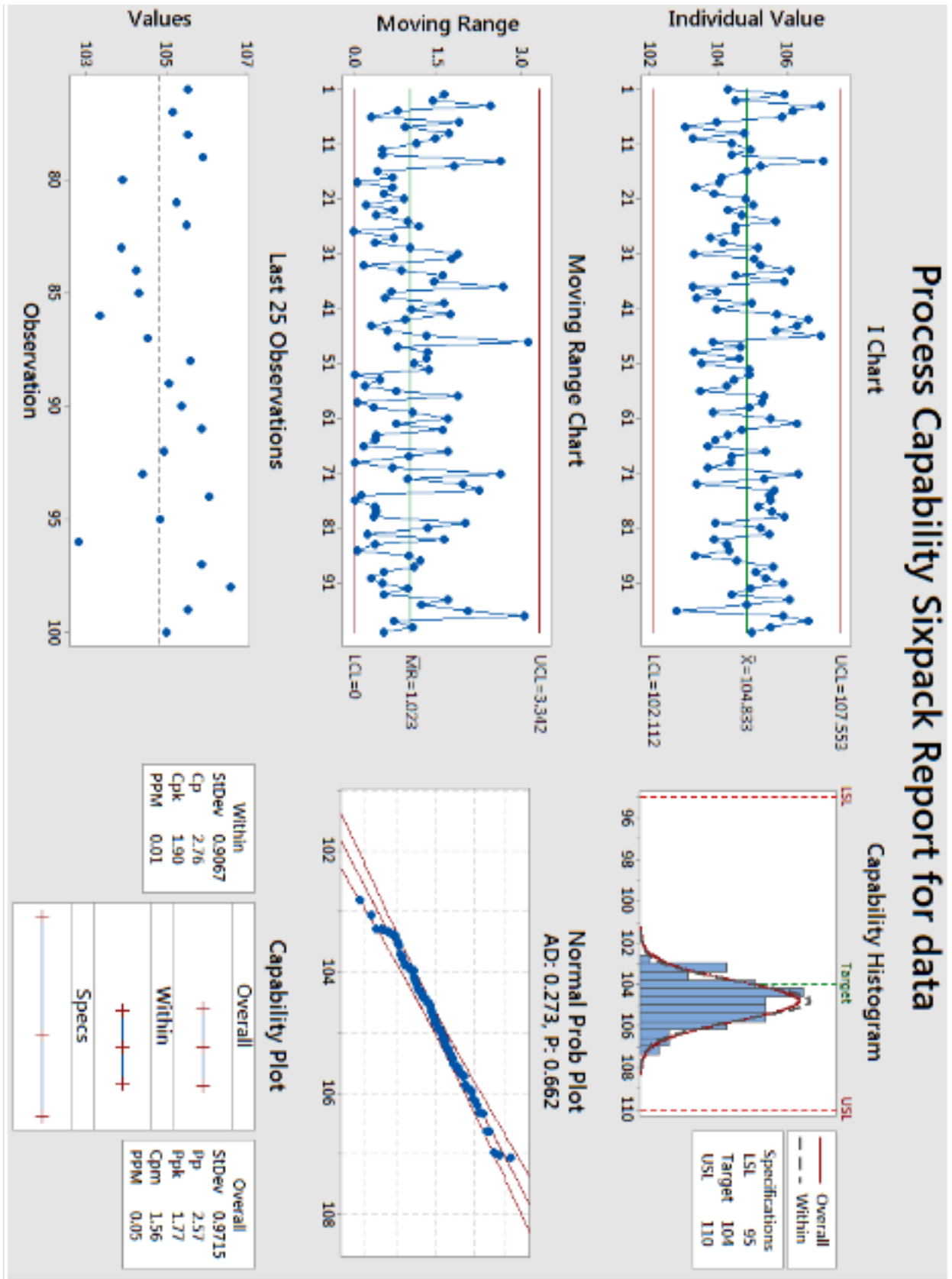
CONTROL PLAN													
<input type="checkbox"/> Prototype <input type="checkbox"/> Pro Prod <input type="checkbox"/> Volume													
Control Plan Number		Key Contact/Phone				Date (Orig.)		Date (Rev.)					
Part Number / Latest Change Level		Integrated Product Team				Customer Engineering Approval/Date (if Req'd.)		Customer Quality Approval/Date (if Req'd.)					
Part Name/Description		Supplier/Plant Approval/Date				Other Approval/Date (if Req'd.)		Other Approval/Date (if Req'd.)					
Supplier/Plant		Supplier Code		Other Approval/Date (if Req'd.)				Other Approval/Date (if Req'd.)					
PART / PROCESS NUMBER	PROCESS NAME/ OPERATION DESCRIPTION	MACHINE DEVICE, JIG, TOOLS, FOR MFG.	CHARACTERISTICS			SPECIAL CHAR. CLASS	PRODUCT/PRO CESS SPECIFICATION / TOLERANCE	METHODS			MML LEVEL	REACTION PLAN	
			NO.	PRODUCT	PROCESS			SAMPLE SIZE	FREQ.	CONTROL METHOD			



## Gage R&R Type 2

Part Name	Part 1		Part Number	12345		USL	0.02	MSA Co-ordinator	John			
Gauge / Equipment Name	Height Gauge #001		Reason For MSA	PPAP Requirement		LSL	-0.02	Date	01-03-2022			
Gage Discrimination	0.025		Characteristics	Ballcon number 010		Tolerance	0.04	MSA Document Number	001			
<b>DATA COLLECTION</b>												
<b>APPRASERS</b> No of Trials / Parts 1 2 3 Avg. Xa Range Ra No of Trials / Parts 1 2 3 Avg. Xb Range Rb No of Trials / Parts 1 2 3 Avg. Xc Range Rc	1	2	3	4	5	6	7	8	9	10	Average	<b>RESULTS / EVALUATION</b>  Repeatability (Equipment Variation) $EV = R \text{ double bar} * K1$ Reproducibility (Appraiser Variation) $AV = O((X \text{ diff} * K2)^2 - (EV^2/nr))$ Repeatability & Reproducibility (R&R) $R \& R = O(EV^2 + AV^2)$ Part Variation (PV) $Pv = Rp * K3$ Total Variation (TV) $TV = O(R\&R^2 + PV^2)$ % Equipment Variation (EV) $\% EV = (EV / TV) * 100$ % Appraiser Variation (AV) $\% AV = (AV / TV) * 100$ % Repeatability & Reproducibility (R&R) $\% R \& R = (R \& R / TV) * 100$ % Part Variation (PV) $\% PV = (PV / TV) * 100$ No. of Distinct Data Categories $ndc = 1.41 (PV / GRR)$ Repeatability & Reproducibility (R&R) $w.r.t \text{ Total Tolerance}$
	38.02	38.03	38.1	38.05	37.98	38.31	38.16	38.07	37.92	38.15	38.0790	
	38.04	38.04	38.11	38.04	38	38.31	38.16	38.08	37.93	38.16	38.0870	
	38.05	38.04	38.1	38.04	37.99	38.3	38.15	38.08	37.92	38.16	38.0830	
	38.04	38.04	38.10	38.04	37.99	38.31	38.16	38.08	37.92	38.16	38.0830	
	0.03	0.01	0.01	0.01	0.02	0.01	0.01	0.01	0.01	0.01	0.0130	
	38.04	38.04	38.1	38.04	37.99	38.32	38.16	38.08	37.93	38.16	38.0860	
	38.07	38.04	38.1	38.04	37.99	38.31	38.16	38.08	37.94	38.16	38.0890	
	38.05	38.04	38.11	38.04	37.98	38.31	38.15	38.07	37.93	38.15	38.0830	
	0.03	0.00	0.01	0.00	0.01	0.01	0.01	0.01	0.01	0.01	0.0100	
38.04	38.04	38.11	38.04	37.98	38.31	38.16	38.08	37.92	38.16	38.0840		
38.04	38.04	38.1	38.04	37.98	38.3	38.16	38.08	37.92	38.16	38.0820		
38.04	38.04	38.1	38.04	38	38.32	38.15	38.07	37.93	38.16	38.0850		
38.04	38.04	38.10	38.04	37.99	38.31	38.16	38.08	37.92	38.16	38.0837		
0.000	0.000	0.010	0.000	0.020	0.020	0.010	0.010	0.010	0.000	0.0090		
Part Average	38.043	38.039	38.103	38.041	37.988	38.310	38.157	38.077	37.927	38.158	X D bar = 38.0842 Rp = 0.3833	
R D bar = $(Ra+Rb+Rc) / 3$	0.0103		UCL = R D bar X D3		0.0267		UCLx = $(X \text{ D bar} + (A2 * R))$				38.095	
X Diff = $(Max X - Min X)$	A2	D3	LCL = R D bar X D3	K1	K2	K3	LCLx = $(X \text{ D bar} - (A2 * R))$				38.074	
Trials / Appraisers	1.023	0	2.58	0.5908	0.5231	0.3146	n = 10	Number of Parts		Number of Trials	f = 3	
3 Trials 3 Appraisers												
<b>Capability Index</b>												
Condition 1 :	$\% GRR < 10$ Acceptable $10 < \% GRR < 30$ Conditionally acceptable $\% GRR > 30$ Not acceptable											
Condition 2 :	The number of distinct data categories (ndc) should be greater than or equal to 5											
Conclusion & Remarks :	Prepared By								Approved By			
	Results											
	5.14											
	Results											
	27.41											

# Appendix L: Process Capability Study Example



# Appendix M: Run@Rate / Capacity Studies Example Template

	Part Number	Run@Rate Date:
	Part Description	Supplier Name:
1	<b>Annual Capacity Planning Volume</b>	Supplier Location:
	piece/year	

## Capacity Planning

2	Process Step							
3	Process Description							
		<i>Units</i>						
I - Supplier Planned Working Standards	4	Shiftlength	hours					
	5	time planned for breaks (lunch etc.)	minutes / shift					
	6	planned downtime for maintenance/repairs/cleaning etc.	minutes / shift					
	7	planned downtime per changover	minutes					
	8	planned changeovers per shift						
	9	<b>Working hours/shift (4-(7*8)-5-6)</b>	<b>hours</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	
	10	Shifts/ day	shifts					
	11	shifts/ week	shifts					
	12	Weeks/ year	weeks					
	13	<b>Total hours/year (9*11*12)</b>	<b>hours</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	
II - Supplier Planned Capacity Data	14	% of line for this part (Allocation %) - See Example	%					
	15	Planned Production Rate (part # item 1)	pcs/hour					
	16	<b>Cycle time (sec/pcs)</b>	<b>sec/pcs</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	
	17	Planned % scrap	%					
	18	Planned % line efficiency	%					
	19	<b>Adjusted production rate (15*(1-16)*17)</b>	<b>pcs/hour</b>					
	20	<b>Available yearly capacity (18*14*(1-16)*17)*13</b>	<b>pcs/year</b>					
	21	<b>Utilization % (1/19)</b>	<b>%</b>					
	<b>Bottleneck operation</b>							
<b>Supplier Capacity Planning result</b>			<b>0.00%</b>	<b>Acceptable</b>				

III - RUN@RATE Results	22	Trial run duration (total time, incl. downtime, setup, setdown)	minutes					
	23	Total parts produced	pcs					
	24	Number of bad parts (first pass failures)	pcs					
	25	downtime/stand-still (see process sheets)	minutes					
	26	<b>netto production time (22-25)</b>	<b>minutes</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
	27	<b>First pass yield % ((23-24)/23)*100</b>	<b>%</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>
	28	<b>Number of good parts (23-24)</b>	<b>pcs</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	
	29	<b>Net production rate (28/22)</b>	<b>pcs/ hour</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>
	30	<b>minimum required production rate (....)</b>	<b>pcs/ hour</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>
		<b>cycle time ((22*60)/28)</b>	<b>sec/ pcs</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>
		<b>netto cycle time ((26*60)/28)</b>	<b>sec/ pcs</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>
	31	<b>Performance % (29/30)</b>	<b>%</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>
	32	<b>Bottleneck operation</b>		<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>
IV - Overall Equipment Efficiency	33	Equipment Availability: (9/4)	%	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	
	34	Performance Efficiency	%	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	
	35	Quality Rate: ((23-24)/23)	%	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	
	36	<b>OEE: (37*38*39)</b>	<b>%</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	
		<b>OEE level</b>		<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	<b>#DIV/0!</b>	


SHADED CELLS ARE CALCULATED and protected

37	The RUN@RATE results are acceptable and meet melec capacity planning volume requirements:	<b>Run@Rate Performance</b>	<b>#DIV/0!</b>	Auditor Information
	The attached capability study results meet melec requirements	Status	<b>#DIV/0!</b>	Name:
	Corrective actions are required:	Date:		Company:
	New production readiness trial run is required:	Date:		Location:

Supplier representative signature: \_\_\_\_\_

customer signature: \_\_\_\_\_

# Appendix N: Part Submission Warrant (PSW) Template

 <b>Sellafield Ltd</b>		<b>Part Submission Warrant</b>	
Part Name _____		SL Part Number _____	Rev. _____ <small>If applicable</small>
Tool PO Number _____		Engineering Drawing Change Level _____	Dated _____
Additional Engineering Changes _____			Dated _____
Shown on Drawing Number _____		Purchase Order No. _____	Weight (kg) _____
Checking Aid Number _____		Engineering Change Level _____	Dated _____
<b>SUPPLIER DETAILS</b>		<b>SUBMISSION INFORMATION</b>	
Supplier name and Code _____		Customer Name/Division _____	
Street Address _____		Customer Contact _____	
City _____	County _____	Post Code _____	
Note: Does this part contain any restricted or reportable substances?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>REASON FOR SUBMISSION (check at least one)</b>			
<input type="checkbox"/> Initial submission	<input type="checkbox"/> Engineering Change(s)	<input type="checkbox"/> Tooling: Transfer, Replacement, Refurbishment, or additional	<input type="checkbox"/> Correction of Discrepancy
<input type="checkbox"/> Tooling inactive > than 1 year	<input type="checkbox"/> Change to Optional Construction or Material	<input type="checkbox"/> Sub-Supplier or Material Source Change	<input type="checkbox"/> Change in Part Processing
	<input type="checkbox"/> Parts produced at Additional Location	<input type="checkbox"/> Other - please specify below _____	
<b>SUBMISSION LEVEL (Check one)</b>			
<input type="checkbox"/> Level 1 - Warrant only (and for designated appearance items, an Appearance Approval Report) submitted to customer.			
<input type="checkbox"/> Level 2 - Warrant with product samples and limited supporting data submitted to customer.			
<input type="checkbox"/> Level 3 - Warrant with product samples and complete supporting data submitted to customer.			
<input type="checkbox"/> Level 4 - Warrant and other requirements as defined by customer.			
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19			
(check) <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>			
<input type="checkbox"/> Level 5 - Warrant with product samples and complete supporting data reviewed at supplier's manufacturing location.			
<b>DECLARATION</b>			
I affirm that the samples represented by this warrant are representative of our parts and have been made to the applicable customer drawings and specifications and are made from specified materials on regular production tooling with no operations other than the regular production process. I also certify that documented evidence of such compliance is on file and available for review.			
<b>EXPLANATION/COMMENTS</b> _____			
List Moulds / Cavities / Production Processes _____			
Authorised Supplier Signature _____		Date _____	
Print Name _____		Phone No. _____	
Title _____		e-mail _____	
<b>FOR SELLAFIELD USE ONLY</b>			
PPAP Warrant Disposition: <input type="checkbox"/> Approved <input type="checkbox"/> Rejected <input type="checkbox"/> Interim Approval		Comment: _____	
Sellafield Signature _____ Date _____		_____	
Print Name _____		_____	

